



Chemicals in the EU

Directive 67/548/EEC
Regulation (EEC) No. 793/93
REACH

Screening Croatia and Turkey

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➤ **Directive 67/548/EEC**

- Notification of ‘new substances’
- Classification and labelling
- Test methods.

➤ **Regulation (EEC) No. 793/93**

- Data collection
- Risk assessment
- Risk reduction.

➤ **REACH.**



Directive 67/548/EEC

On the approximation of the laws,
regulations and administrative
provisions **relating to the
classification, packaging and
labelling of dangerous substances**



Directive 67/548

➤ Contents

- Notification of ‘new substances’
- Classification and labelling of dangerous substances
- Testing methods.

➤ Amended

- 13 amendments
- 29 adaptations to technical progress.



Notification (1)

- ‘New substances’: those **not** listed in European Inventory of Existing Commercial Substances (EINECS - list of substances marketed in EU before Sept. 1981)
- New substances cannot be placed on the market ≥ 10 kgs per manufacturer per year - on their own or in preparations - unless they have been notified
- 200-300 substances registered per year
- Managed via the New Chemicals Database: ~6500 notifications
- ~4000 new substances listed in the European List of Notified Commercial Substances (ELINCS) - latest edition March 2005: Substances notified until June 2003.



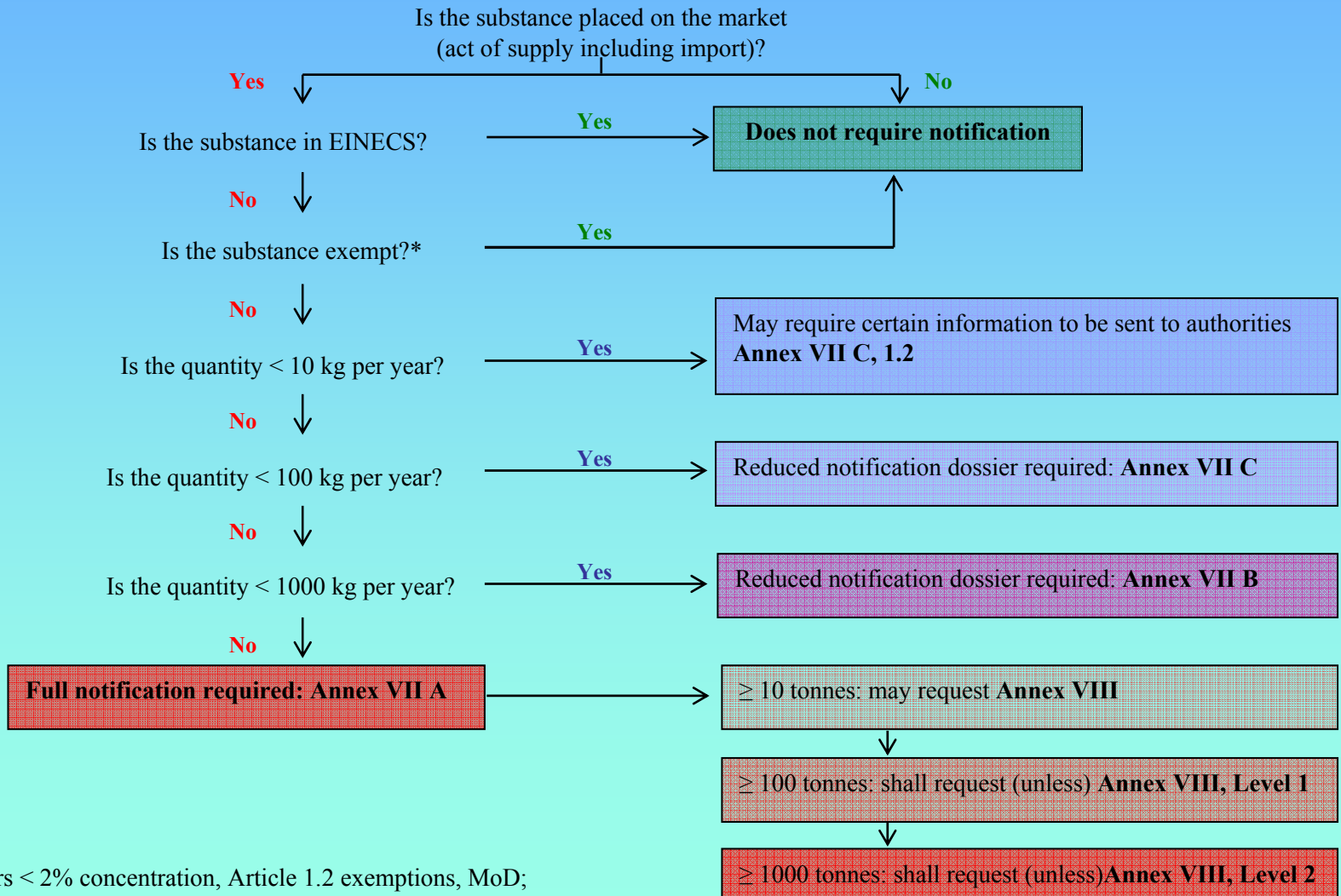
Notification (2)

- Notification scheme: *a priori* assessment
- Notification dossier:
 - Notifier (manufacturer/importer)
 - chemical identity
 - production process and proposed uses
 - physical-chemical properties
 - toxicological studies
 - eco-toxicological studies
 - classification and labelling.

Data requirement increases at higher market volume



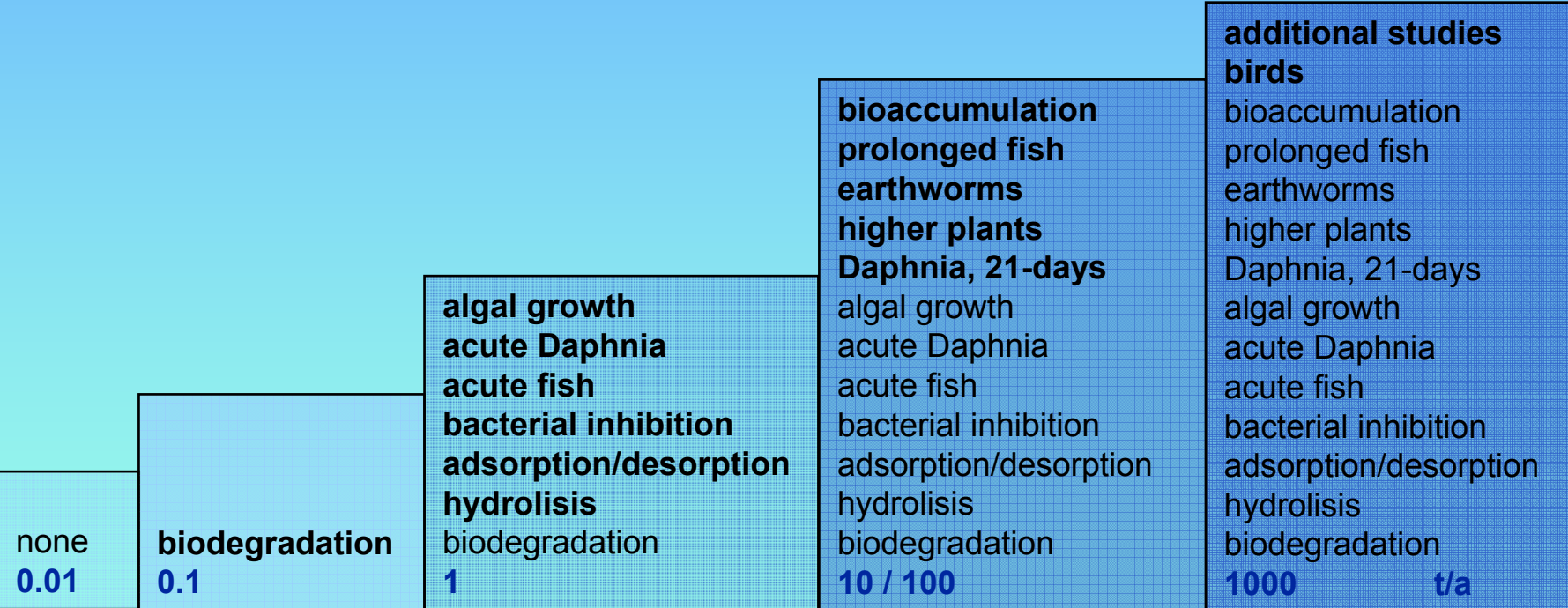
Information requirements



* polymers < 2% concentration, Article 1.2 exemptions, MoD;



Eco-toxicological studies



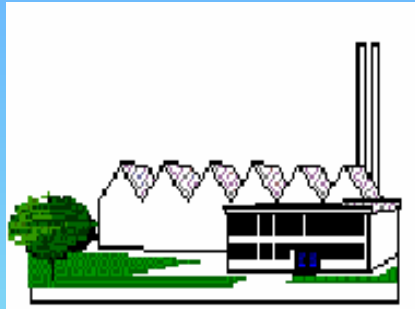


Notification Process (1)

- Manufacturer/importer notifies: full dossier to Competent Authority (CA) in relevant MS (incl. comprehensive test reports)
- Notifier prepares SNIF file (electronic summary):
 - Summary info, including: origin, use, tonnage, ID, physchem., tox., eco-tox., C&L
 - Checked by CA, forwarded to ECB, loaded into New Chemicals Database.
- Risk assessment:
 - Either by notifier or by CA
 - CA checks/performs and sends to ECB to update database.
- CA can request additional tests:
 - Testing proposal circulated to ECB and other MS for comments.
- ECB conformity check (incl. EC number): distributes file to all CAs for information/comments.



Notification Process (2)



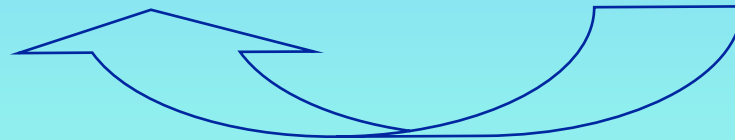
Industry
notification dossier



National
Competent Authority



ECB - Ispra
New Chemical Database



Distribution to
25 Member
States
+ Norway



Classification

- Classification: Substance intrinsic properties (Art. 4)
- Classification criteria (Annex VI):
 - On the basis of physicochemical properties
 - On the basis of toxicological properties
 - On the basis of specific effects on human health
 - On the basis of environmental effects.
- Annex I: List of substances classified with harmonised classification & labelling (4 000 substances)
- If substance not in Annex I: industry's obligation to carry out investigations, package and provisionally label (Art. 6)
- Basis to classify preparations (Dir 1999/45)



Packaging and Labelling (1)

- Packaging *and fastenings* (art. 22):
 - Contents cannot escape
 - Materials cannot be attacked by contents
 - Strong and solid
 - Child resistant fastenings, tactile warnings.
- Labelling (Art. 23): hazard warning
 - Name of substance and responsible of placing substance in EU market
 - Danger symbols
 - Standard phrases (Risk & Safety phrases).



Packaging and Labelling (2)

Example: Hydrazine

Classification: R10-Carc.Cat.2;R45-T;R23/24/25-C;34-R43-N;R50-53



Labelling:



T



N

May cause cancer. Flammable. Toxic by inhalation, in contact with skin and if swallowed. Causes burns. May cause sensitization by skin contact. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Avoid exposure - obtain special instructions before use. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/Safety data sheets.



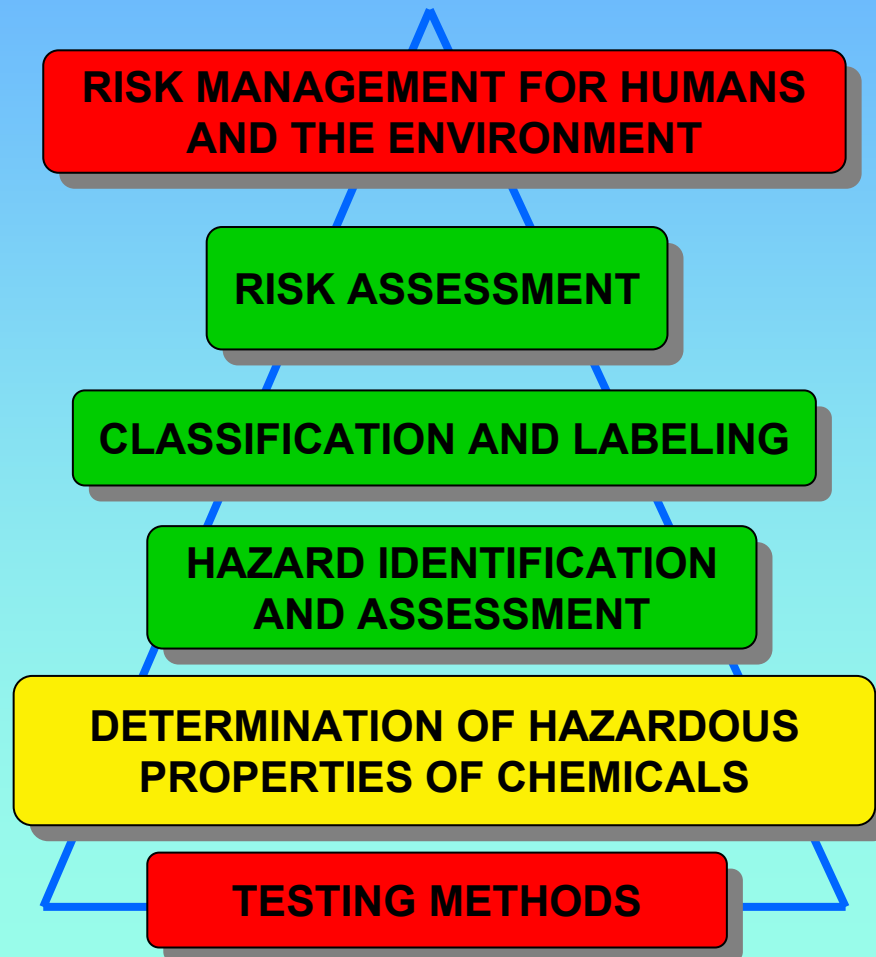
Test Methods (1)

- ~90 standard test methods in legislation
- Subject to progressive development and refinement
- Typically adopted following recommendation of Organisation for Economic Cooperation and Development (OECD)
- EU inputs into OECD Test Guidelines
- OECD accepted Test Guidelines transferred of into **Annex V** of Directive 67/548/EEC
- Promotion, development and adoption of alternative Testing Methods:
 - lead by European Centre for validation of Alternative Methods (ECVAM)
 - to feed into EU legislation and OECD TG programme.



Test Methods (2)

Protecting People and
the Environment
from
Dangerous Chemicals





Test Methods (3)

Single Market and
Free Trade

FREE MOVEMENT OF GOODS

based
on

Both at EU
and global level

MUTUAL ACCEPTANCE OF DATA

relays
on

**HARMONISATION
OF
TESTING METHODS
for
HAZARDOUS OR DANGEROUS CHEMICALS**



Test Methods (4)

Testing Methods
Annex V structure

ANNEX V
Dir. 67/548/EEC*

- 88/302/EEC
- 92/69/EEC
- 93/21/EEC
- 96/54/EC
- 98/73/EC
- 2000/32/EC
- 2000/33/EC
- 2001/59/EC
- 2004/73/EC

Contains standardised Testing Methods to determine the properties of chemicals

Part A.
Methods for the
determination of
**PHYSICO-CHEMICAL
PROPERTIES**

Part B.
Methods for the
determination of
TOXICITY

Part C.
Methods for the
determination of
ECOTOXICITY



Test Methods (5)

Annex V Testing Methods Summary

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Physico-Chemical

Mp, Bp, Density, Surface Tension, Vapour Pressure
Water Solubility, Partition Coefficient
Flash point
Flammability (solids, gases, contact with water)
Pyrophoric properties
Explosive properties
Auto-ignition temperature (solids, liquids or gases)
Oxidizing properties (solids)
Polymers

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Toxicity

Acute (oral, dermal, inhalation, skin irritation, eye irritation)
Skin Sensitization
Repeated dose (oral, dermal, inhalation)
Sub-chronic (oral, inhalation, dermal)
Chronic Toxicity
Mutagenicity-Genotoxicity
Carcinogenicity
Reproductive Toxicity
Immunotoxicity
Neurotoxicity
Toxicokinetics

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Ecotoxicity

Acute Toxicity (fish, daphnia, algae)
Bioconcentration
Biodegradation (ready, intrinsic)
BOD, COD
Abiotic degradation
Toxicity to earthworms



Regulation (EEC) no. 793/93

On evaluation and control of the
risks of existing substances



Regulation 793/93

- Aim: to gather information, evaluate and control the risks of ‘existing substances’
- Existing substances: those in EU market before September 1981 (i.e. reported for EINECS inventory)
- Four steps:
 - data collection – of all available information on substances m/i between 10 and 1 000 tpy
 - priority setting – 141 substances selected from amongst all registered chemicals m/i > 1 000 tpy
 - risk assessment – of prioritised substances (finished for ~ 70 substances)
 - risk reduction strategies – if in risk assessment conclusion (for ~ 57 substances, finished for ~ 42).



Data collection

- Industry sends in HEDSET (format) :
 - Available info
 - For substances in priority lists: Annex VII A under Dir 67/548
- Stored in ECB in database called IUCLID 4
- Access restricted for confidential parts
- Industry obligation to update information:
 - New uses which change type, form, magnitude, duration of exposure
 - New data on physicochemical properties, toxicological or ecotoxicological effects
 - Changes in provisional classification (under Dir 67/548).



Risk Assessment

- Priority setting: four lists, 141 HPV substances
- Performed by CAs
- Coordination by ECB
- Risk assessment
 - Covers: environment, human health (consumer, workers, and human health via the environment)
 - Done following Technical Guidance Document
 - Using information provided by industry
- Risk assessment report sent to Scientific Committee (SCHER)
- Conclusion: i) more info ii) no risk iii) risk measures needed
- Adopted by CAs and published in Official Journal.



Risk Reduction

- Risk reduction strategies prepared by CA responsible for RA (rapporteur)
- Risk reduction recommendation proposed by rapporteur and Commission
- Discussed with MS and stakeholders (coordinated by Commission)
- Risk measures:
 - Marketing and use restrictions (Dir 76/769)
 - EU wide occupational exposure levels (Dir 98/24 or Dir 2004/37)
 - Other EU legislation (Water Framework Directive, IPPC, etc).



REACH

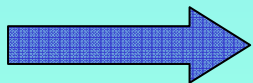
Proposal for a Regulation concerning
the Registration, Evaluation,
Authorisation and Restrictions of
Chemicals (REACH), establishing a
European Chemicals Agency



Why REACH?

Current chemicals management system is inefficient

- Different legislation for ‘new’ (post-1981) and ‘existing’ (pre-1981) substances
- Lack of information about most chemicals on the market
- Burden of proof lies on public authorities
- Identification and management of risks is problematic.



Need to reform the current system



What is REACH?

➤ Proposal for a 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.



Elements of REACH

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



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 \geq 1 tonne/year
- Exemptions: other law, Annex II/III; polymers (review); PPOR
- As registered: biocides, pesticides, notified substances.

➤ Consortia encouraged

Industry's responsibility



Pre-registration

- To facilitate data sharing
- When? By 18 months after entry into force
- What?
 - Substance name
 - Potential registrant details (or 3rd party representative)
 - Deadline for registration.
- Agency publishes list of information on website.



Registration

➤ **1-10 tonnes**

- Physicochemical properties of Annex V + Available information
- Screening by registrant: if screening criteria are met → full Annex V
- New substances provide full Annex V.

➤ **10-100 tonnes:**

- Annex V + Annex VI
- Chemical Safety Report.



Registration

➤ **100-1000 tonnes:**

- Annex V + Annex VI
- Testing proposal for tests required in Annex VII
- Chemical Safety Report
- Early registration of PBTs/vPvBs (R50/53) > 100 tonnes (3 years).

➤ **≥ 1000 tonnes**

- Annex V + Annex VI
- Testing proposal for tests required in Annex VII and Annex VIII
- Chemical Safety Report.



Eco-toxicological studies

<p>algal growth acute Daphnia biodegradation 1-10</p>	<p>acute fish activated sludge inhibition adsorption/desorption hydrolisis algal growth acute Daphnia biodegradation 10-100</p>	<p>Simulation testing on ultimate degradation in surface water Soil simulation testing Sediment simulation testing Identification of degradation products Bioaccumulation in aquatic species, preferably fish Further information on adsorption/desorption Short-term toxicity to invertebrates Effects on soil micro-organisms Short-term toxicity to plants long term fish long term invertebrates acute fish activated sludge inhibition adsorption/desorption Hydrolisis algal growth acute Daphnia biodegradation 100-1000</p>	<p>Further information on the environmental fate and behaviour of the substance and/or degradation products Long-term toxicity testing on invertebrates Long-term toxicity testing on plants Long-term toxicity to sediment organisms Long-term or reproductive toxicity to birds Simulation testing on ultimate degradation in surface water Soil simulation testing Sediment simulation testing Identification of degradation products Bioaccumulation in aquatic species, preferably fish Further information on adsorption/desorption Short-term toxicity to invertebrates Effects on soil micro-organisms Short-term toxicity to plants long term fish long term invertebrates acute fish activated sludge inhibition adsorption/desorption Hydrolisis algal growth acute Daphnia biodegradation 1000 <i>t/a</i></p>
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Evaluation

➤ Dossier evaluation

- By public authorities
- Examination of testing proposals
- Compliance check.

➤ Substance evaluation

- Rolling plans with substance prioritisation
- Follow-up suspicion of risk: request more info.



Authorisation

AIM: Ensure risks from substances of very high concern (SVHC) are properly controlled and eventually substituted.

➤ Applies to

- SVHC (CMR, PBT, vPvB, ‘serious and irreversible effects’)
- Substance, substance in preparation (unless below concentration limit), substance incorporated into an article.

➤ Substance **cannot be used unless authorised**

➤ **Prioritised** - Substances progressively authorised (as resources allow)

➤ **Downstream Users** can use suppliers authorisation.



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 – responsibility to ensure evaluation is carried out; take decisions
 - Authorisation/restrictions - facilitate process; suggest priorities
 - Secretariat for Forum and Committees
 - Deal with appeals - registration, R&D, evaluation, confidentiality



Does REACH start from scratch? (1)

➤ Registration

- Technical Dossier – *as under Reg 793/93 & Dir 67/548*
- Chemical Safety Report – *New(-ish)*

➤ Pre-registration/Inquiry

- Inquiry – *as under Dir 67/548*
- Pre-registration – *New*

➤ Evaluation

- Testing Proposals – *New(-ish)*
- Compliance Check – *as under Dir 67/548*
- Substance Evaluation – *as under Reg 793/93 & Dir 67/548*



Does REACH start from scratch? (2)

➤ Restrictions

- Annex XIV Dossier – *as under Reg 793/93 & Dir 67/548*
- Restriction proposal – *as under Dir 76/769*
- SEA Analysis – *as under Dir 76/769*

➤ Authorisation

- Identification of SVHC – *as under Reg 793/93 & Dir 67/548*
- Setting Priorities and Authorisations – *similar to Reg 793/93*

➤ European Chemicals Agency

- Committee work – *as in ECB*
- Detailed content work – *New (done by MS CAs)*



The Legislative Process: Timetable

- Commission proposal: October 2003
- EP first reading opinion: 17 Nov 2005
- Council political agreement: 13 Dec 2005
- EP second reading: Oct 2006?

REACH in force: 2007?



European Commission, DG Environment
Unit C.3: Chemicals

Information

E U R O P A

Thank you!

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