

REACH

A brief overview



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1. Why a new EU chemical policy?

Problems:

- No sufficient information
- Identification and assessment of risks proved to be slow
- 'Existing' vs. 'new' chemicals
- Lack of sufficient information publicly available
- Former legislation:
 - Provide information not on downstream users, unless classification and SDS
 - New chemicals: notified and tested = barrier to innovation

1. Why a new EU chemical policy?

Aims:

- Improve protection of human health and the environment (!)
- Enhancing the competitiveness of the EU chemicals industry (!)
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU internat. obligations (WTO)

2. The working of REACH

Introduction

- One single system
- Non-phase-in substances
- Phase-in substances
- Basic elements (part I)
 - All substances - unless explicitly exempted from its scope
 - Manufacturers /importers - relevant information and manage them safely
 - Reduction testing on vertebrate animals, data sharing is required; for other tests data sharing on request by other registrants

2. The working of REACH

Introduction

- Basic elements (part II)
 - Better information on hazards and risks- information and manage them safely down and up the supply chain
 - Downstream users brought into the system
 - Evaluation by Agency for testing proposals; co-ordinates evaluation, prepare proposals for restrictions or authorisation

2. The working of REACH

Introduction

- Basic elements (part III)
 - Substances with properties of very high concern are subject to authorisation:
 - Applicants have to demonstrate that risks associated with uses are adequately controlled or that the socio-economic benefits of their use outweigh the risks.
 - Applicants must analyse whether there are safer suitable alternative and if there are prepare substitution plans
 - Commission may amend or withdraw any authorisation on review if suitable substitutes become available.
 - Restrictions - to regulate that the manufacture (placing on market or using) of certain dangerous substances is subject to conditions or prohibited.

2. The working of REACH

Introduction

- Basic elements (part IV)
 - European Chemical Agency (ECHA) manage technical, scientific and administrative aspects
 - A classification and labelling inventory promote agreement within industry on the classification of a substance. For some: a Community wide harmonisation of classification by the authorities.
 - A system combining: publicly available information over the internet, the current system of requests for access to information and REACH specific rules on the protection of confidential business information.

2. The working of REACH

Scope

All substances:

- Manufactured
- Imported
- Used as intermediates
- Placed on the market, on their own, in preparations or in articles

unless they are:

- Radioactive
- Subject to customs supervision
- Non-isolated intermediates

2. The working of REACH

Registration

- Dossier send to Agency
 - Not receiving indication of incompleteness
1. Substances on their **own** or **in preparation** (part I):
 - Exemptions: Annex IV and V
 - Obtained information: risks assessment
 - Documents:
 - ≥ 1 tonne: technical dossier (information on properties, uses, classification and guidance on safe use)
 - ≥ 10 tonnes: chemical safety report (information on hazards, classification, assessment to PBT or vPvB, exposure scenarios)

2. The working of REACH

Registration

1. Substances on their **own** or **in preparation** (part II):

- GLP required for toxicological and eco-toxicological tests and analysis
- Annex III:
 - substances in quantities of 1 to 10 tonnes
 - non-phase-in and phase-in substances
 - meeting at least one of the two criteria (physicochemical information and (eco)toxicological information)
- Annex VII: Set of substances are prioritised
- Annexes VII and VIII:
 - tonnage 10- 100 tonnes
 - tonnage of \geq 100 tonnes

2. The working of REACH

Registration

1. Substances on their **own** or **in preparation**(part III):

- Annex X:
 - not possess the required information required by Annex IX
 - tonnage \geq 1000 tonnes
- Registrants:
 - are required to jointly submit information on the hazardous properties and classification
 - can jointly submit the CSR: one lead registrant on behalf of the others and the others submit other information individually (such as company details and production volume)

2. The working of REACH

Registration

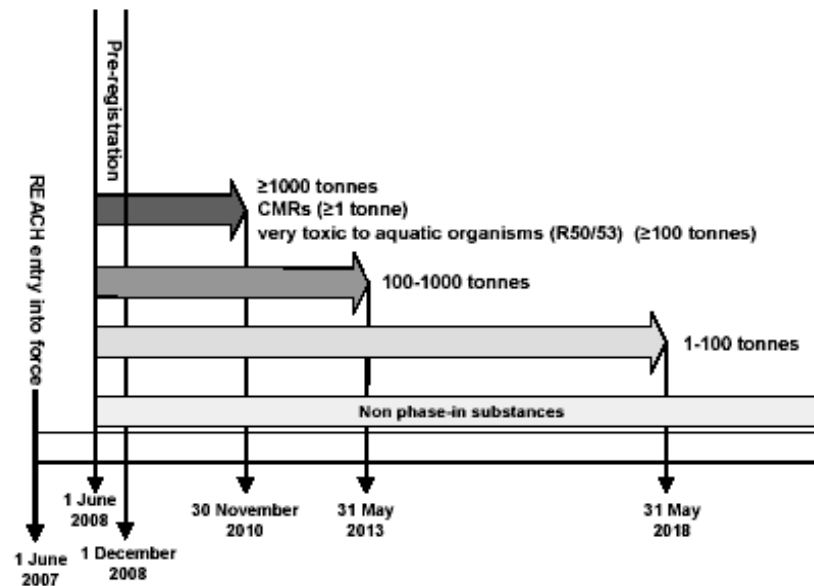
1. Substances on their **own** or **in preparation** (part IV):

- Certain isolated intermediates - 'light' registration
 - manufactured under strictly controlled conditions
 - those that do not leave the site
 - which they are used or transported under controlled conditions)
 - Containing: hazard classification, information on properties and information on risk management measures applied or recommended
- Intermediate > 100 tonnes - information required in Annex VII needs to be included in registration dossier
 - transported under controlled conditions
 - and risk of exposure is potentially higher

2. The working of REACH

Registration

1. Substances on their **own** or **in preparation** (part V):
 - Step-wise fashion registration to phase-in substances at and over 1 tonne/year – substances of high concern (CMR and potential PBT/vPvBs) registered early



2. The working of REACH

Registration

1. Substances on their **own** or **in preparation** (part VI):

- Registration is not rejected within a set deadline
=> the registrant may begin (for non-phase-in substances) or continue (for phase-in substances) to manufacture or import the substance.
- This does not imply any form of approval by the Agency of the assessment or use.

2. The working of REACH

Registration

2. Substances in **articles**:

- All substances
 - intended to be released from articles during normal and reasonably foreseeable conditions of use
 - substances are present in the articles above 1 tonne/year
 - registered according to the normal rules
 - including tonnage deadlines and information requirements
- All substances
 - very high concern above a concentration limit of 0.1% w/w
 - present above 1 tonne/year
 - notified to the Agency except where exposure to humans and environment can be excluded during normal conditions

2. The working of REACH

Data sharing

Potential registrants - **phase-in** substances:
pre-register between 1 June 2008 and 1 December 2008.

- To facilitate data sharing
- To reduce testing on vertebrate animals
- Data gained by vertebrate animal testing need to be shared, in exchange for payment (for phase-in and non-phase-in)
- Data not involving tests on vertebrate animals must be shared on request of potential registrant
- To reduce costs to industry

2. The working of REACH

Data sharing

Substance Information Exchange Forum:

for pre-registrants of the same phase-in substance:
share data - get an overview about studies available (pre-registration)

Downstream users of a substance that has not been pre-registered may ask the Agency to extend the pre-registration period by six-months (find a supplier or pre-register themselves)

2. The working of REACH

Information in the supply chain

- Down and up the supply chain: information relating to health, safety, environmental properties, risks and risk management measures
- Not required to be exchanged: commercially sensitive information
- Tool for information transfer: Safety Data Sheet for all dangerous substances
- Passed down: relevant scenarios need to be annexed to SDS
- Passed up: new information on hazardous properties and information that challenges the quality of risk management measure

2. The working of REACH

Downstream users

- Required to consider the safety based primarily on information from their suppliers
- Need to apply appropriate risk management measures
- SDS supplied
- Need to check that use(s) are 'covered' by the SDS
- Have right to make use(s) known to the supplier(s)-supplier can include use(s) in chemical safety assessments as 'identified' uses or pass the request on up the supply chain

2. The working of REACH

Downstream users

- Can choose to keep use confidential or use it outside the conditions described AND use ≥ 1 tonne / year:
 - DU have to perform a Chemical Safety Assessment developing the exposure scenarios for his intended uses – if necessary a refinement of supplier's hazard assessment

2. The working of REACH

Evaluation

- Dossier evaluation: Agency do quality check
 - Compliance check: compliance with the requirements
 - Checking of testing proposals: aim is to prevent unnecessary animal testing- check proposals (in registration dossier) before tests are performed
- Substance evaluation:
 - Agency (and Competent Authorities of Member States) may request further information from the industry to clarify suspicions of risks (human health or environment)
- Agency in co-operation with Member States developed guidance on the prioritisation of substances for further evaluation.

2. The working of REACH

Authorisation

- Authorisation required:
 - CMR category 1 and 2
 - PBT, vPvBs
 - Identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case-by-case basis (such as endocrine disrupters)
- Authorisation procedure:
 - First step: which substances on candidate list will be included in system (Annex XIV), which uses will be exempted from the authorisation requirements (sufficient controls by other legislation) and deadlines.
 - Second step: substances included in Annex XIV- apply for authorisation within deadlines

2. The working of REACH

Authorisation

- Authorisation will be granted:
 - Risk from use adequately controlled
 - Socio-economic benefits outweigh the risks and there are no suitable alternatives

2. The working of REACH

Restrictions

- All activities with a substance which are not restricted are allowed under REACH unless the substance is included in the authorisation system.
- Restrictions provisions act as a safety net and proposals for restrictions will be prepared by Member States or the Agency in the form of a structured Dossier.

2. The working of REACH

European Chemical Agency (ECHA)

Activities:

- Manage the registration process
- Carry out dossier evaluations
- Co-ordinated the substance evaluation process
- Take decisions resulting from evaluations (except by disagreement among MS)
- Provide expert opinions
- Regard confidentiality and access to information
- Handle request for exemptions (for product and process oriented R&D)
- Facilitate the sharing of animal test data at the pre-registration stage (SIEFs)

2. The working of REACH

Classification and labelling inventory

Ensure that hazard classifications (and consequent labelling) of all dangerous substances (EU) are available to all

2. The working of REACH

Access to information

Non-confidential information on chemicals will be made available

The interests of the public's 'right to know' is balanced with the need to keep certain information confidential.

3. Benefits and Costs

Benefits

- Positive occupational impact, public health impact and environmental impact
- Increased information on hazards and controls
- REACH will contribute to reduced pollution of air, water, soil and pressure on biodiversity.

3. Benefits and Costs

Costs

- Direct costs: €2.3 billion over the first 11 years
- Costs to downstream users: additional cost at € 0.5-1.3 billion in a 'normal' expectation and € 1.7-2.9 billion by 'higher costs'
- Total costs: € 2.8-5.2 billion over 11 to 15 years