

Introduction to REACH & CLP

Outline: REACH & CLP in brief

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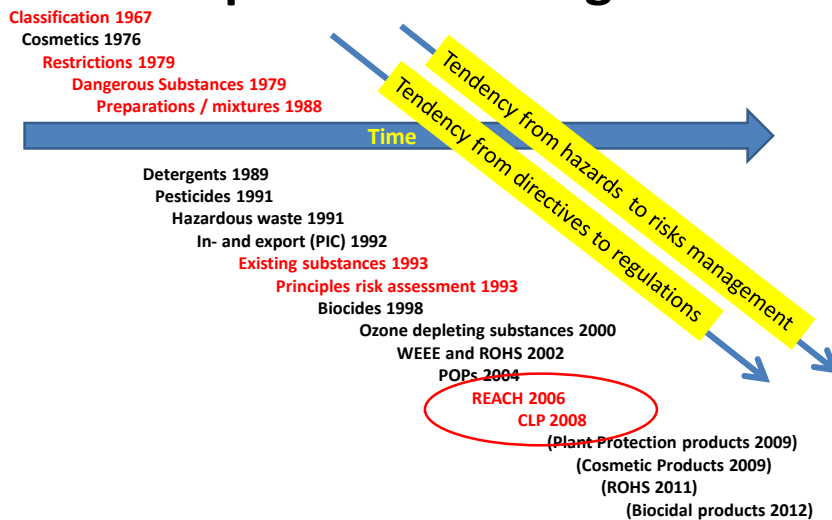


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Development of EU legislation

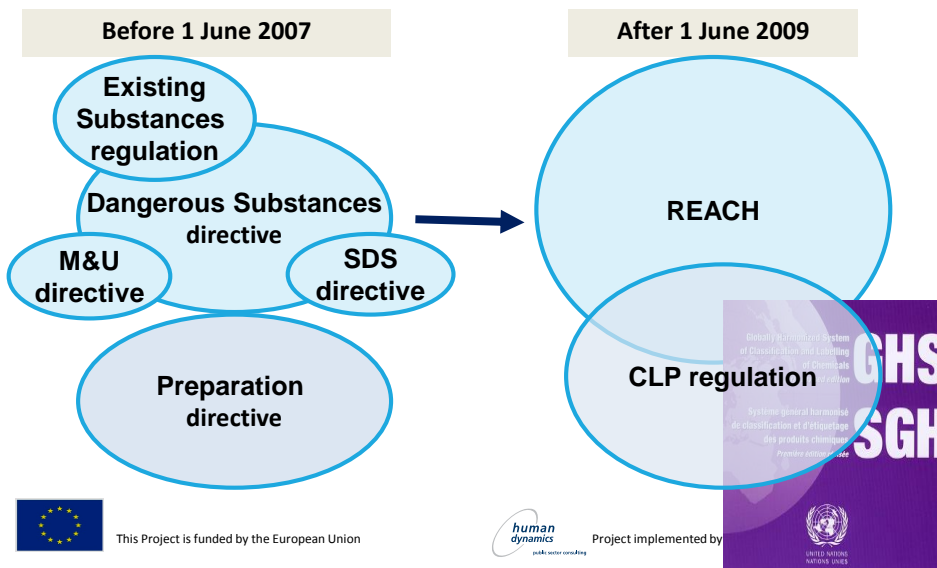


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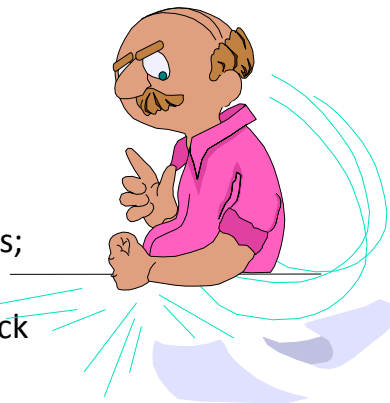
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What has been changed in chemicals management in the EU



Why? The nature of the problem

- Amount of chemicals (60,000 - 70,000 EU market)
- Largely unknown effects (very limited / no data)
- Burden too heavy to authorities; (capacity limited)
- Procedures inadequate (no quick response possible)
- Responsibility unclear
- Public / political confidence low



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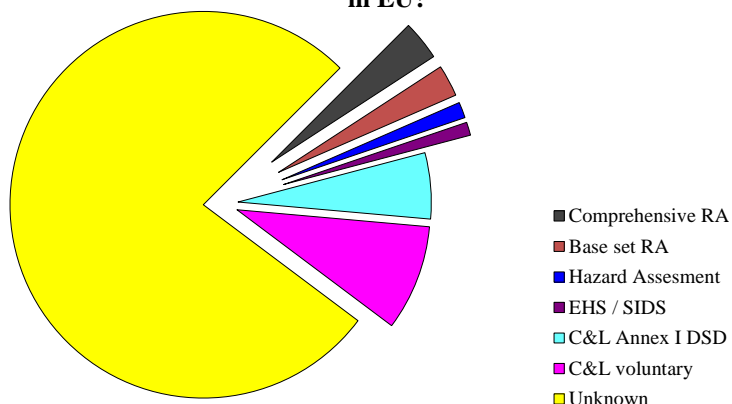


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Why? The size of the problem

Total number on the market about 70.000 substances
in EU?



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Basic principles of REACH

- **Sustainable development**
 - **Industry** is responsible for safe use of substances
 - **Authority** controls compliance of industry
 - **NGO's** must accept marketing of sustainable substances; no phasing-out across the board
- **Priority for data collection**
 - Manufacturing / marketing according to quantity
 - Three categories of priority: 1000 – 100 - 1 tonnes/year
 - Hazardous properties
 - CMR properties > 1 tonne/year (high priority)
 - PBT/vPvB properties > 100 tonnes/year (high priority)



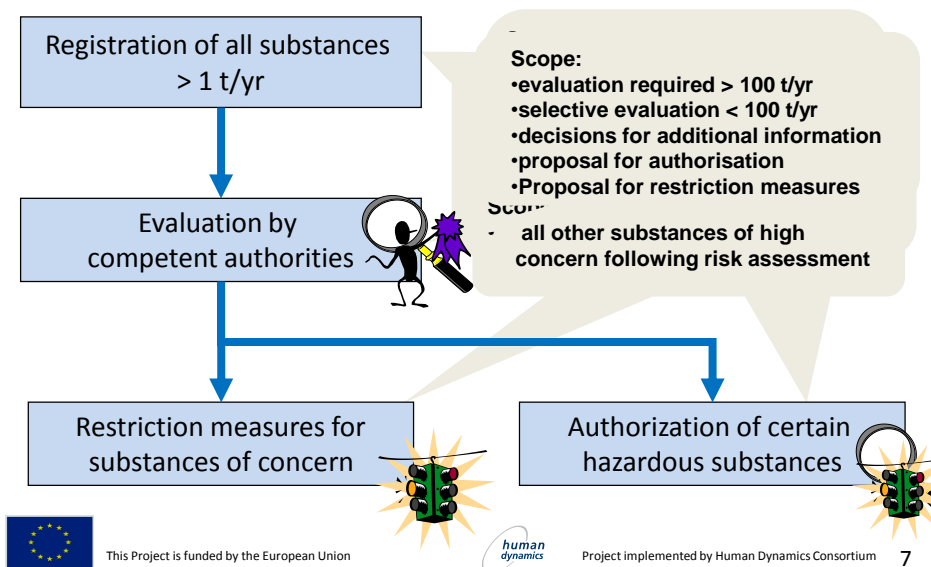
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Main elements of REACH



Scope of REACH

- **Manufactured / imported in Community's territory**
 - Substances as such and in preparation within REACH
 - For intermediates on site/transported separate provisions
 - Cosmetics as end-products excluded from "info into supply chain"
- **Substances / components of preparations / certain articles**
 - Excluded are substances in Annex IV ("no-concern")
 - Excluded are categories of substances in Annex V, e.g. substances in nature
 - Minerals, natural gas, liquefied petroleum gas, natural gas condensate, process gases, crude oil: in nature of not chemically modified
 - Other substances in nature if not chemically modified, unless classified as dangerous



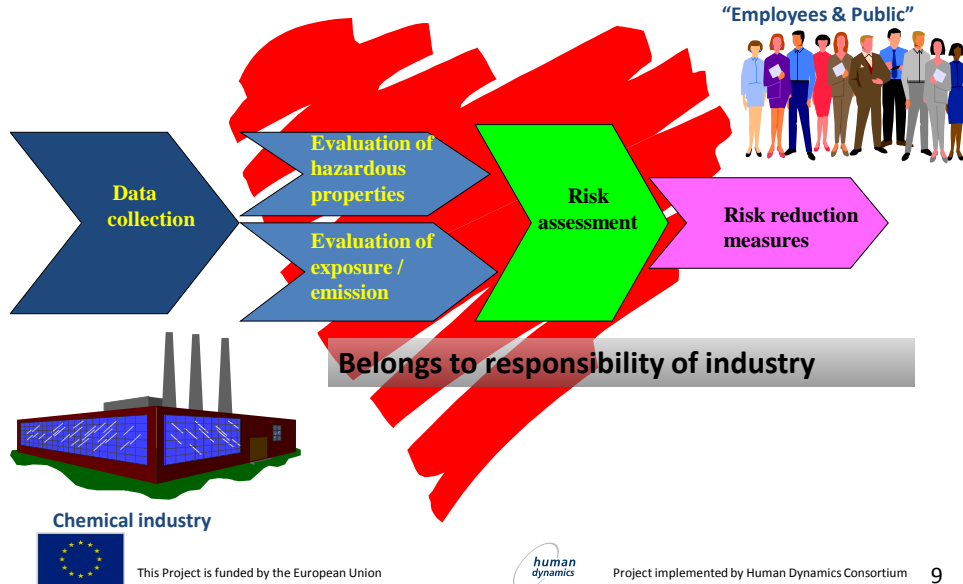
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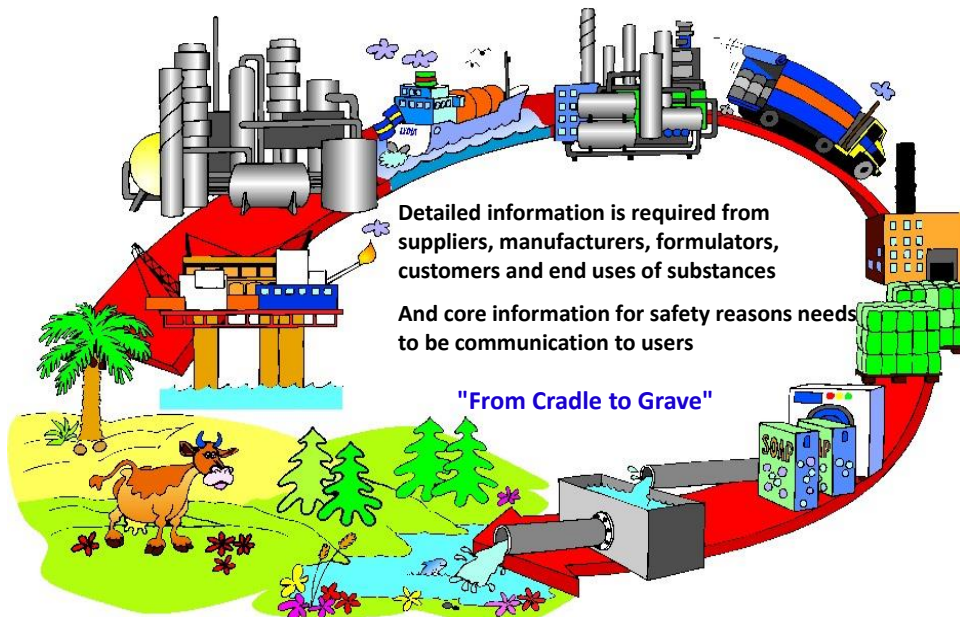
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Core issue is responsible risk management



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Communication up- and down supply chain



Legal structure of REACH

Legal “body text” on scope, registration, data sharing, requirements, evaluation, authorisation, restrictions, Agency, etc. in XV titles,

plus 17 annexes on technical details:

- I. General provisions on chemical safety assessment
- II. Guide to compiling safety data sheets
- III. Criteria for registering substances between 1 – 10 tonnes per annum
- IV. Exemptions from registration according to Article 2(7)a
- V. Exemptions from registration according to Article 2(7)b
- VI. Information requirements referred to in Article 10
- VII. Standard information requirements for substances in 1 tonne or more
- VIII. Standard information requirements for substances in 10 tonnes or more
- IX. Standard information requirements for substances in 100 tonnes or more
- X. Standard information requirements for substances in 1000 tonnes or more
- XI. Rules for adaptation of standard testing regime in annexes VII to X
- XII. General provisions for downstream users to assess substances and prepare chemical safety reports
- XIII. Criteria for PBT and vPvB substances
- XIV. List of substances subject to authorisation
- XV. Dossiers
- XVI. Socio-economic analysis
- XVII. Restrictions on manufacturing, marketing and use of dangerous substances



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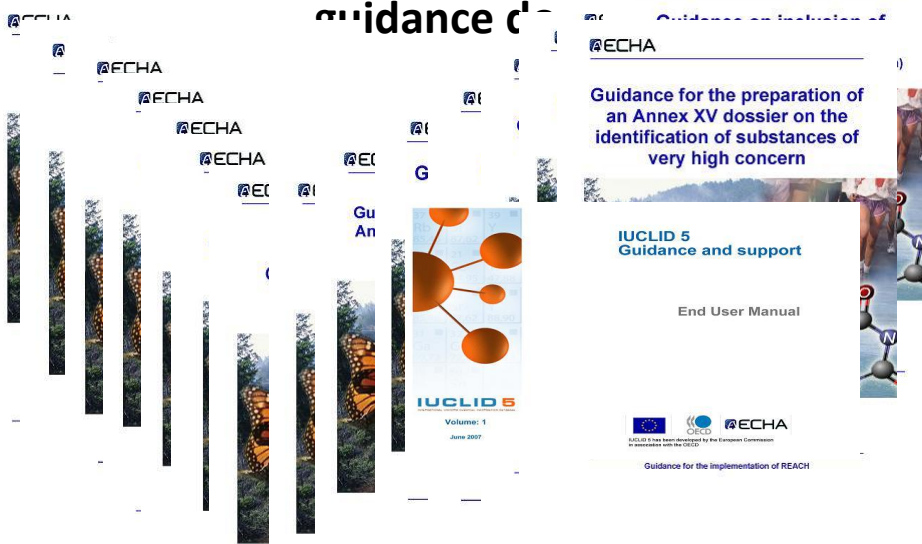


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Helping hand from REACH guidance documents

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Guidance for the implementation of REACH

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General aspects of GHS / CLP

- **GHS – Global Harmonised System**
 - UN-driven worldwide classification system, not mandatory
 - Covers substances and transport classification
 - Merges three main systems: EU - USA – Canada
 - Sets optional building blocks on hazard classes and/or categories from which countries can choose
 - Basis is UN “Purple Book”; living documents, updated each 2 years
- **CLP regulation**
 - EU method for implementing GHS
 - Substances and mixtures classification, packaging, labelling
 - New language of risk communication by symbols and signal words
 - Symbols changed, some completely, others in minor way



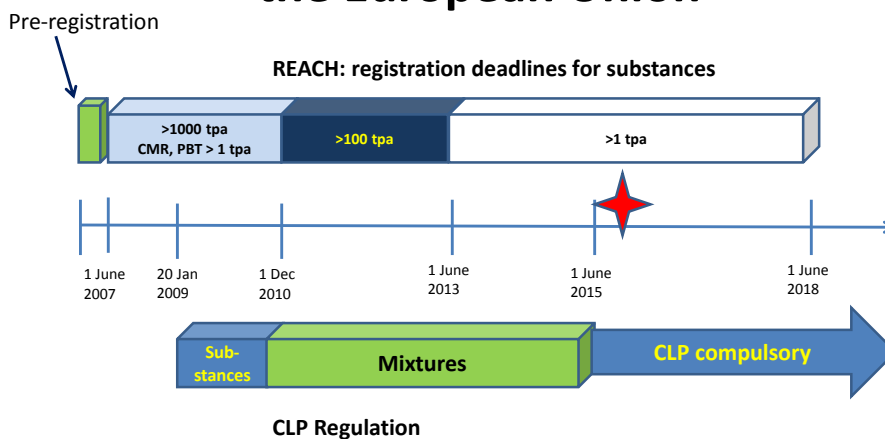
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Critical CLP & REACH timelines within the European Union



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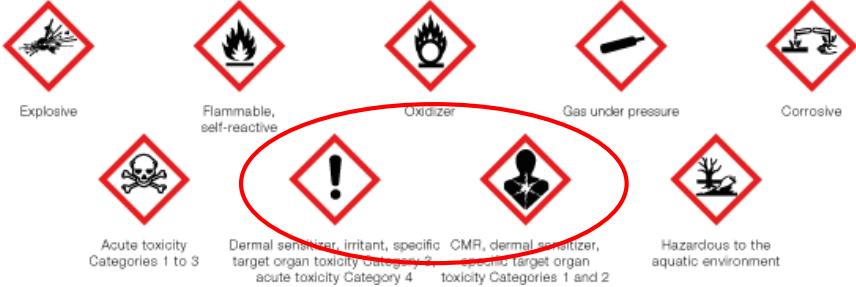
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GHS/CLP pictograms

Old hazardous substance symbols valid until 2015



New hazardous substance symbols valid since 2010



Explosive

Flammable, self-reactive

Oxidizer

Gas under pressure


Corrosive


Acute toxicity Categories 1 to 3

Dermal sensitizer, irritant, specific target organ toxicity Category 2, acute toxicity Category 4

CMR, dermal sensitizer, specific target organ toxicity Categories 1 and 2

Hazardous to the aquatic environment

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Legal structure of CLP

- Legal „body text“ on general rules and principles plus
- 7 annexes on technical details
 - Annex I: Classification and labelling requirements for hazardous substances and mixtures
 - Annex II: Special rules for labelling and packaging
 - Annex III: List of Hazard Statements
 - Annex IV: List of Precautionary Statements
 - Annex V: Pictograms
 - Annex VI: Harmonised List of Hazardous Substances
 - Annex VII: Table of Equivalence



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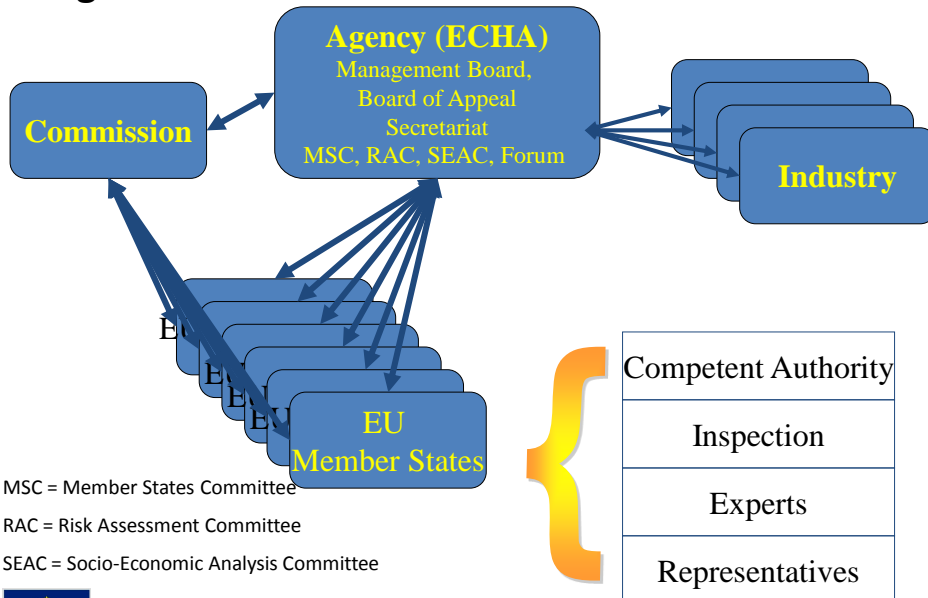


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Organisation of REACH & CLP

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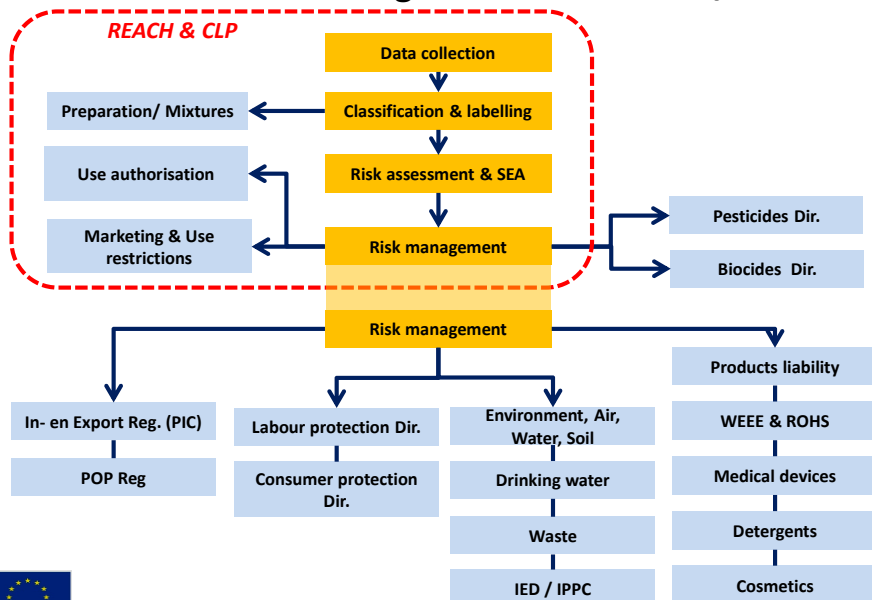


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EU chemicals management with REACH/CLP

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Conclusion on Risk management system

- **Risk assessment = integrated tool**
 - Harmonised methodology
 - Resulting in risk characterisation
 - Allows justified risk control measures
- **Used by**
 - Industry: in Chemical Safety Assessment
 - Authorities: substance evaluation
- **Translation towards specific scenarios**
 - Labour protection
 - Consumer protection (articles, indirect exposure)
 - Environmental standards
 - Restrictions, authorisation
 - Reporting and notifications
 - Emission control
 - Etcetera



SDS extended
Annex XV dossier



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Dynamic to the future....

