Enviroment and Climate Regional Accession Network ECRAN

ENVIRONMENT AND CLIMATE REGIONAL ACCESSION NETWORK (ECRAN)

ECRAN IED/Chemicals Working Group - *Activity 2.8.2*
Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED

Introduction
Ike van der Putte

ECRAN coordinator WG ECENA; WG IED/Chemicals

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Enviroment and Climate Regional Accession Network ECRAN

Project summary

Duration	36 months
Implementation period	01 October 2013 – 31 September 2016
Value	4,999,720 EUR
No of Key Experts	4 (1290 man-days)
Non-key experts	4409 man-days
Beneficiary countries	Albania, Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, Kosovo*, Serbia and Turkey

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From RENA towards ECRAN

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- Follow up of the Regional Environmental Network for Accession (RENA), building on the results achieved in the field of environment and climate change;
- Endorsement by the beneficiaries: Join Statement endorsed during the 3rd ministerial Meeting (September 2012, Brussels, belgum).

Overall objective (same as in RENA):

" to strengthen the regional cooperation between EU candidate countries and potential candidates and assist them on their way towards transposition and implementation of the EU environment and climate *acquis* and policies "

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Results to be achieved

Enviroment and Climate Regional Accession Network ECRAN

Improved institutional set-up and technical working arrangements established;

Enhanced public participation in environmental and climate planning and decisionmaking process;

Improved quality of transposition and implementation of the EU environmental and climate acquis;

Improved skills in relation to enforcement of the legislation;

Improved strategic planning and investments;

Experience-sharing and networking activities established;

Enhanced cross-border cooperation in relation to environmental and climate policies, legislation and investments.

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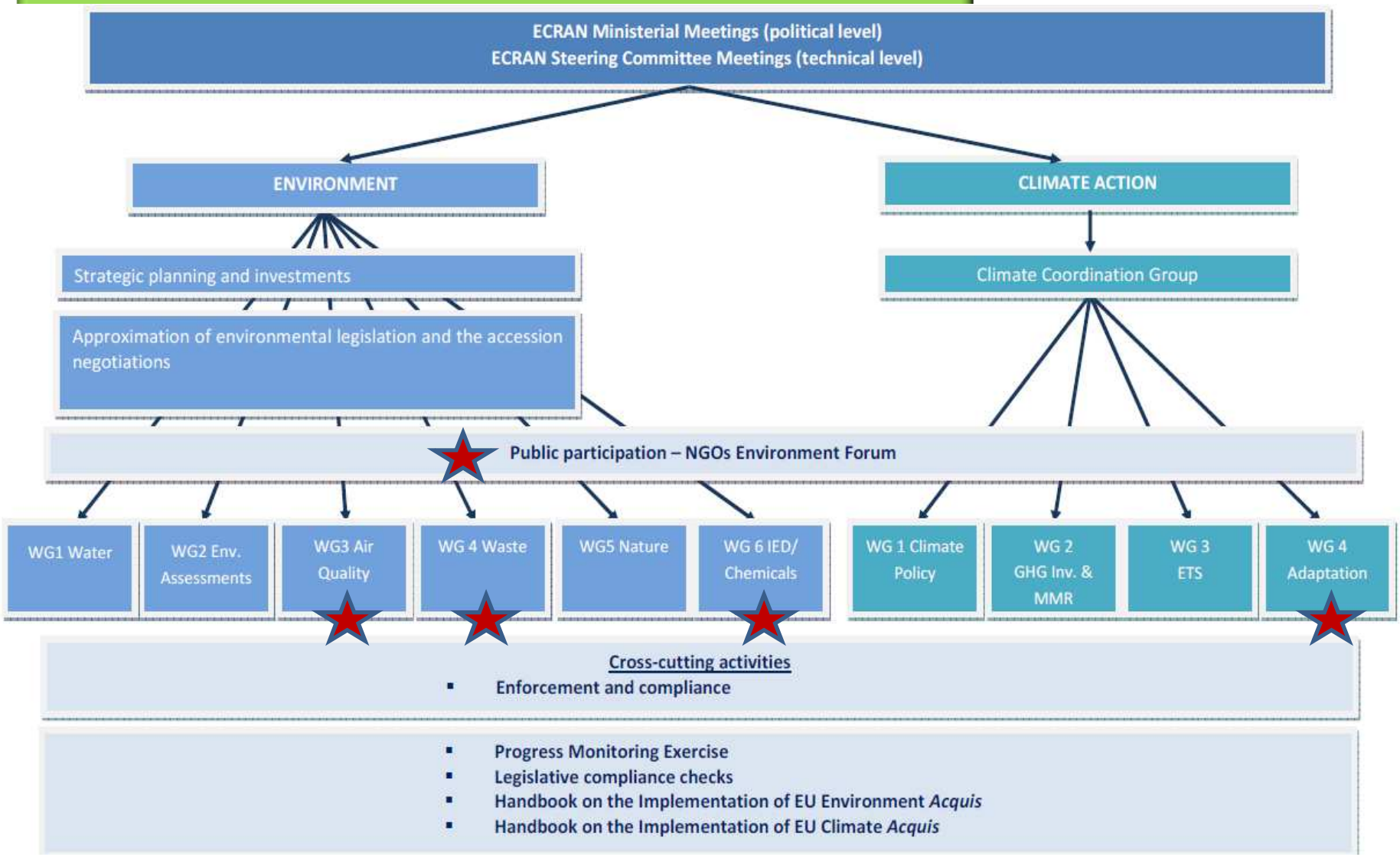
ECRAN Structure

Enviroment and Climate Regional Accession Network ECRAN



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Planned activities

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- EF Public Participation:

✓ Creation of regional Environment Forum with selected NGOs (minimum 1 and maximum 3 NGOs per country);

✓ Organisation of annual meetings with the EC;

✓ Design and delivery of tailor made training programme.

Enhanced public participation in environmental and climate planning and decisionmaking process

- Enforcement and Compliance (ECENA):

✓ Capacity building for inspectors and permit writers on selected topics and selected pilot sites (IPPC, IED, IRAM/easy tools, REACH and CLP, TFS, Environmental Crime, etc);

✓ External country assessments on the implementation and enforcement of the selected EU acquis in the country,

✓ Coordination and cooperation with other relevant networks (IMPEL, INECE, Interpol, etc.).

Improved skills in relation to enforcement of the legislation

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Planned activities

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- Progress Monitoring:

✓ Tables of Concordance, Implementation Questionnaires and preapration of draft and final PM Reports for the years 17, 18 and 19;

- Legislative compliance checks (legal assisstance for approximation)
- Update of the Handbook on the implementation of the EU environmental and climate acquis;

- Approximation of environmental legislation and the accession negotiations:

✓ Strengthening the capacities for accession negotiations on Chapter 27 through tailor made capacity building programme using practical work and exchange of experience with EU MS;

✓ National peer reviews on the level of implementation of the EU environmental legislation and administrative capacity to carry out the implementing obligations.

Improved quality of transposition and implementation of the EU environmental andclimate acquis

Improved institutional set-up and technical working arrangements established

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Planned activities

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- Strategic Planning and Investments Working Group:

✓ Strategic planning
  - ✓ Meta-planning (preparation of country specific meta- plans, roadmaps) for development of necessary planning documents for the EU accession process
  - ✓ Capacity building on the role of planning documents in approximation process and management of the process for chapter 27 using approximation policy documents
  - ✓ Regional trainings for the Strategic Planning Working Group and sector specific Working Groups to assess the situation and agree on strategic planning documents to be developed in the selected sectors

✓ Cost recovery and tariff setting (or economic/financial analysis)
  - ✓ One per country national round table discussions on the structure of costs, financial flows, cost recovery, polluter pays and other principles
  - ✓ Regional trainings on economic-financial analysis and cost recovery (waste management, water management etc.)

✓ Capacity building for IPA project fiche preparation
  - ✓ Regional trainings on IPA II Regulation and its Implementing Rules

Improved strategic planning and investments;
Enhanced cross-border cooperation in relation to environmental and climate policies, legislation and investments.

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Planned activities

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- Water Management Working Group:

✓ Selection of pilot site (river basin);

✓ Practical support in development of the specific part of the River Basin Management Plan provided for the selected pilot site;

✓ Capacity building on cost recovery and tarrif setings in cooperation with the Strategic Planning and Investments Working Group;

✓ Capacity building on the implementaion and differencies between water framework Directive and Marine Strategy Directive

- Environmental Assessments Working Group:

✓ Selection of pilot sites;

✓ Practical support in the development of SEA plans for the selected pilot sites;

✓ Capacity building for Environmental Assessments in cooperation with Nature and Water Management Working groups;

✓ Regional Train the Trainers programme followed by the national trainings at local level.

Enhanced cross-border cooperation in relation to environmental and climate policies, legislation and investments; **Improved** quality of transposition and implementation of the EU environmental andclimate acquis; **Experience-sharing** and networking activities established.

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Planned activities

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- Air Quality Working Group:
- ✓ Capacity building for transposition and implementation of Air Quality Framework Directive;
- Waste Management Working Group:
- ✓ Review of national waste management plans/strategies;
- ✓ Capacity building for transposition and implementation of Waste Framework Directive;
- IED/Chemicals WG:
- ✓ Capacity building on transposition and implementation of IPPC/IED, REACH and CLP and usage of BREFs and BATs

- Nature Working Group:
- ✓ Selection of pilot sites;
- ✓ Development of appropriate assessments for selected pilot sites;
- ✓ Practical support in the development of participatory management plan for the selected pilot site;
- ✓ Public awareness seminars to promote the benefits of Natura 2000 sites;
- ✓ Training programme;
- ✓ Establishment of regional network of Nature Protected Areas.

Enhanced cross-border cooperation in relation to environmental and climate policies, legislation and investments; **Improved** quality of transposition and implementation of the EU environmental andclimate acquis; **Experience-sharing** and networking activities established.

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Planned activities

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- Climate component:

✓ Capacity building on modeling, scenarios, tools and usage of quantitative models to assess climate and energy policy options and to set emission targets;

✓ Capacity building on GHG inventory process for CRF Sectors in line with the MMR requirements;

✓ Best practice document for a fully functioning MMR system;

✓ Regional Training Programme on the EU MMR and Accreditation and Verification Regulations including training missions to EU Member States;

✓ ETS Implementation and ETS strategy and roadmap development;

✓ Development of indicators to monitor the impact of climate change;

✓ Practical support for the identification of adaptation options and prioritisation of adaptation needs;

✓ Proposal for required policy changes, structures and processes for adaptation.

Improved institutional set-up and technical working arrangements established; **Improved** quality of transposition and implementation of the EU climate acquis; **Experience-sharing** and networking activities established.

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Practical arrangements

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ECRAN

- Ministerial Meetings;
- Steering Committee Meetings;
- WG Annual Meetings;
- EF Public Participation activities;
- Coordination with other relevant networks;
- Other non-capacity building activities;
- Drafting agendas, work plans, ToRs;
- Selection of TAIEX experts;
- Quality control and review;
- Invitations and lists of participants;
- Workshop Reports.

TAIEX

- Provision of experts for capacity building activities;
- Logistical arrangements for capacity building activities;
- Evaluation of delivered capacity building activities;
- Additional national support as required by beneficiary countries.

Important: continuous participation and timely nominations

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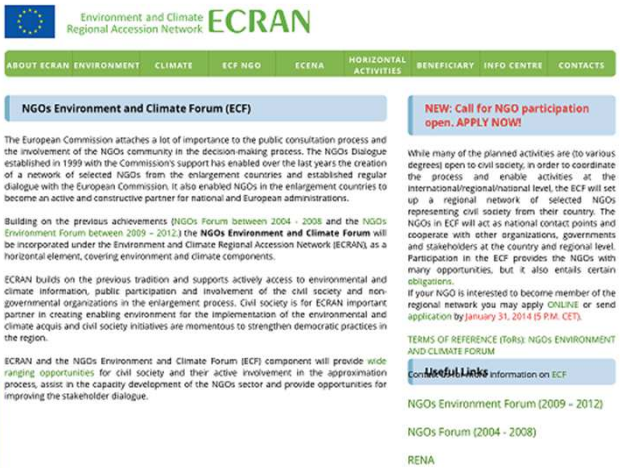
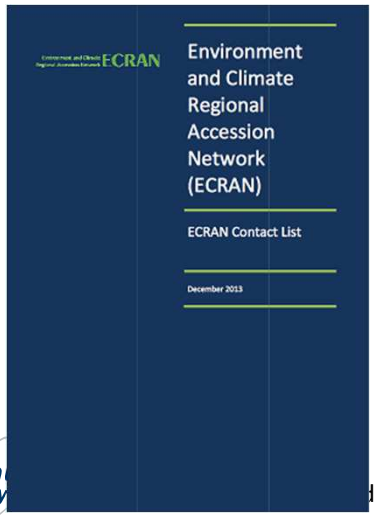
ECRAN visibility and info sharing

Enviroment and Climate Regional Accession Network ECRAN

- Website (www.ecranetwork.org)





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ECRAN IED/Chemicals Working Group - *Activity 2.8.2*
Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED

Most of the ECRAN beneficiary countries are at a different level when it comes to transposition of the EC chemicals legislation and additional efforts are needed in the area of its implementation..

Specific objective of the activity is to provide assistance in strengthening the institutions and building capacity in complying with the EC Chemicals legislation.
Emphasis will be placed on the REACH and CLP Regulations, interlinked with the Industrial Emissions Directive as these are covering major chapters in chemicals legislation and industrial pollution control

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No.	Date	Key outputs
1	end-January 2014/early February 2014	Training Needs Questionnaire and Training Needs Assessment. Proposals for pilot industries to be visited. TNA report
2	January - February 2014	Training Methodology, Training Programme and Training Materials
3	Training Workshop no. 1. Early May, 2014 13,14,15 May	Training (1) ; General introduction chemicals and procedures REACH/CLP, IED (1) Training report
4	Training Workshop no.2.Early December,2014	Training (2). Procedures REACH/CLP (2).Training Report
5	Training Workshop no 3, May 2015	Training(3). Technical aspects REACH /CLP, IED. Training Report
6	Training Workshop no.4. December 2015	Training (4). REACH/CLP downstream consequences, interlinkages with IED and other legislation; accession issues.. Training Report

Croatian accession to the European Union

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Croatia will join the European Union on 1 July 2013 and therefore the REACH, CLP, Biocides and PIC Regulations, as well as all other EU Chemicals legislation, will apply to companies established in Croatia from that date. The application of some provisions of the REACH regulation is subject to transitional measures as laid down in the Accession Treaty (Treaty concerning the accession of the Republic of Croatia).

In order to comply with the obligations to register and notify chemical substances to the European Chemicals Agency, Croatian companies will have access to the related IT tools: IUCLID 5 and REACH-IT.

Related links

- ECHA's Q&A for Croatian companies pre-registering and registering under REACH
- List of CLP and REACH national helpdesks
- The ECHA Helpdesk

See also

- EUR-LEX - legislation in Croatian
- Text of the Accession Treaty
- ECHA-Term
- ECHA-Term Leaflet and Quick Guide

Key material in Croatian

The Agency offers a series of publications to help companies to comply with the REACH, CLP and Biocidal Product Regulation. You can find related guidance and IT manuals in 23 EU languages by consulting the Support section of the ECHA website. Our work plans, annual reports, fact sheets and various regulatory

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Chemicals management in the EU

Arnold van der Wielen

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EU chemicals management

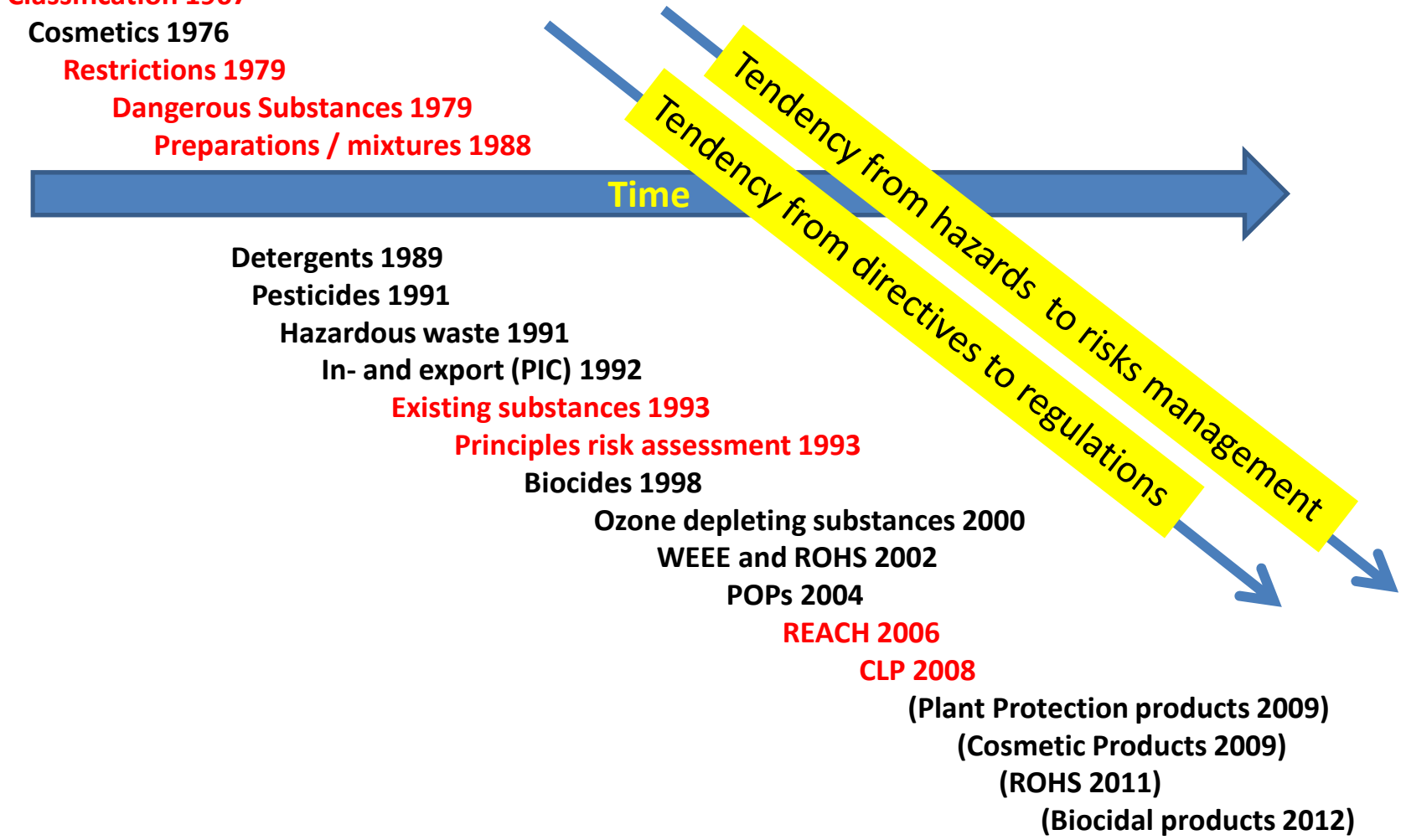
- **Common goal related to chemicals**
  - Ensure a high level of protection of human health and the environment
  - Facilitate free movement of goods in EU
  - Enhance economic growth
- **International acts**
  - Agreements (e.g. WTO), conventions (e.g. Basel, Climate change, PIC Rotterdam, POP Stockholm) and protocols (Montreal, Kyoto)
  - Binding for parties, who signed
- **International programs**
  - Non-binding programs (e.g. UNCED Agenda 21, SAICM, GHS)

UNCED:	United Nations Conference on Environment and Development
WTO:	World Trade Organization
PIC:	Rotterdam Convention on Prior Informed Consent
POP:	Stockholm Convention on Persistent Organic Pollutants
SAICM:	Strategic Approach to International Chemicals Management

Structure of EU legislation

- **Treaty (last: Lisbon 2007)**
  - Harmonised measures
  - Protective measures
- **Directives**
  - Many different directives related to manufacturing, use and disposal of chemicals, including very specific uses
  - Implementation in national legislation necessary
- **Regulations**
  - Directly applicable to EU citizens without national transpositions
- **National/Regional Acts**
- **National/Regional Enforcement**

Development of EU legislation



Development of EU Chemicals management

- **In the past (1960 -1990):**
  - Chemicals management predominantly based on hazards
  - Major role for C&L
- **Since 1990:**
  - **Introduction of precautionary principle**
  - Development of risk assessment methodology and tools
  - **Chemicals management to be based on risk assessment**
- **Since 2000:**
  - Development of socio-economic analysis methodology and tools (embedded in REACH)

Precautionary principle

- **Definition and role of PP**
  - General reference included in Article 191 in the TFEU
  - Applicable to fields of environment and health
  - Interpreted by the European Commission in 2000
  - Further expanded on by EU Courts
- **The PP underpins major EU legislation**
  - REACH
  - Food Safety Legislation
  - Various environmental legislation
  - In principle, strong public and political support for a high level of environmental and health protection in the EU
  - Legislative frameworks built on precaution often less problematic than individual decisions

TFEU: Treaty on the Functioning of the European Union

Practical experience with PP (jurisprudence)

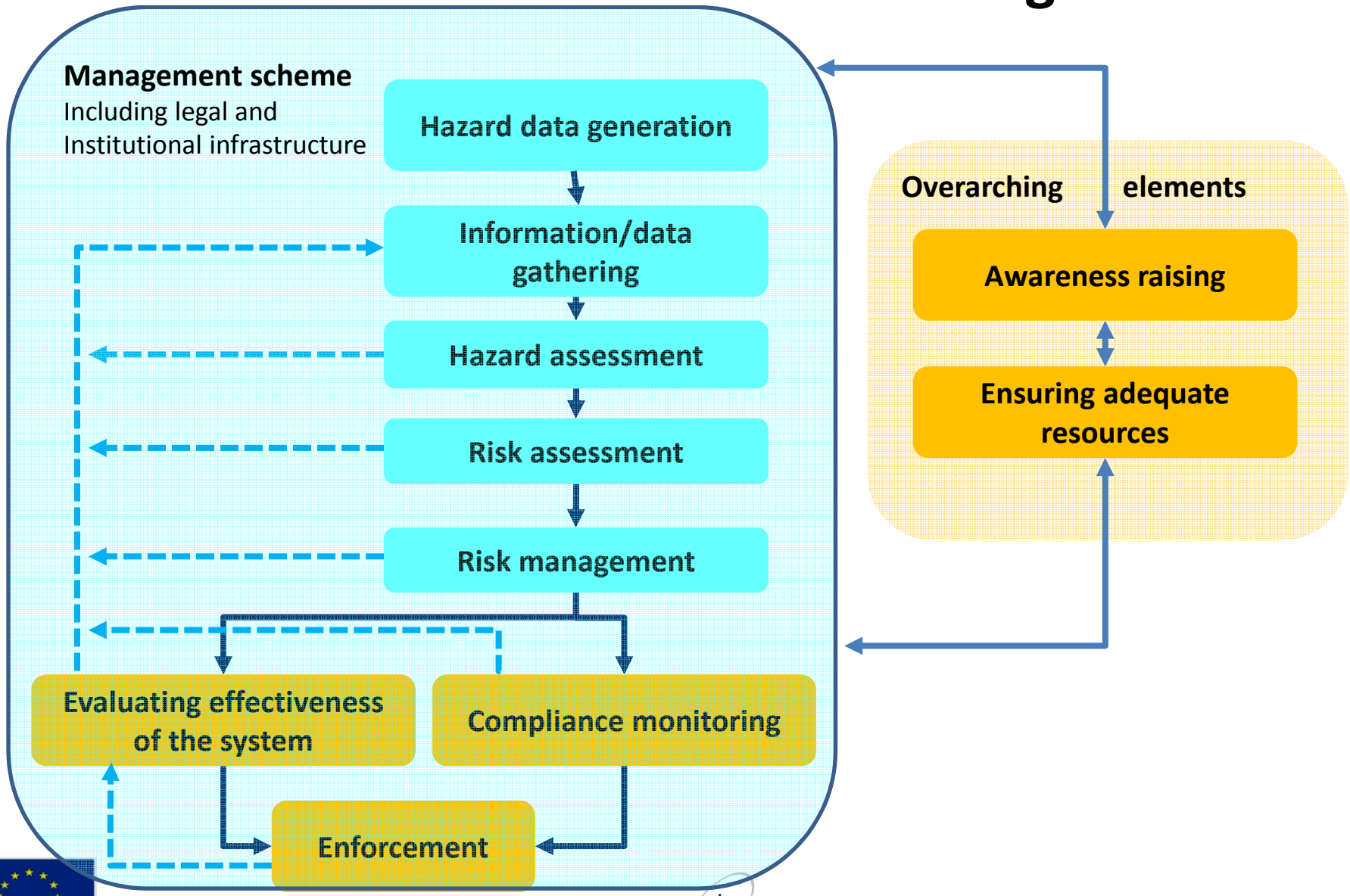
- Review limited to manifest error and ultra vires
- Risks may not be “hypothetical”…
- But rather “…adequately backed up by scientific data”
- Zero-risk approach is not acceptable
- Scientific assessment must be “as thorough as possible”
- Costs and benefits should be balanced…
- …but impact assessments are not binding

Precautionary Legislation v. The Precautionary Principle

Precaution as an independent legal principle shows legal problems:

- Inconsistencies between fields of regulation
- Discretion of regulators?
- Triggers for regulation?
- Requirements on scientific assessment?
- Comparison of risks and benefits?
- Risk of arbitrariness and legal uncertainty
- Effective possibilities for redress for affected parties?

Core framework for chemicals management



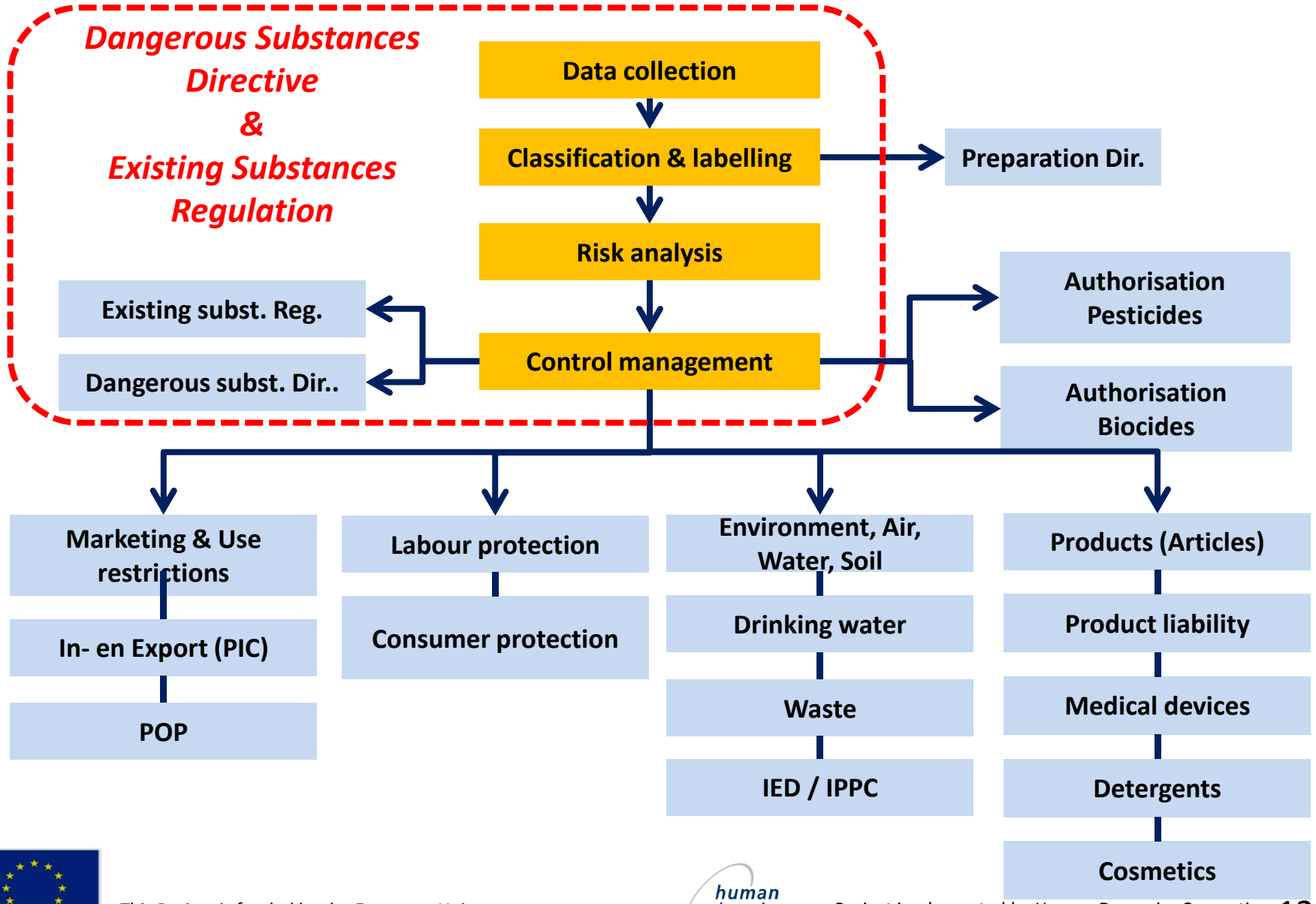
Risk management explained 1/2

- **Hazard data generation**
  - Test methods, GLP, Animal welfare, testing, data sharing
- **Information / data gathering**
  - Collection, storage, confidentiality, dissemination
- **Hazard assessment**
  - Hazard identification, hazard characterization
- **Risk assessment**
  - Hazard assessment, exposure assessment, risk characterization
- **Risk management**
  - Control measures, risk communication, exposure control, monitoring
  - Poison centres

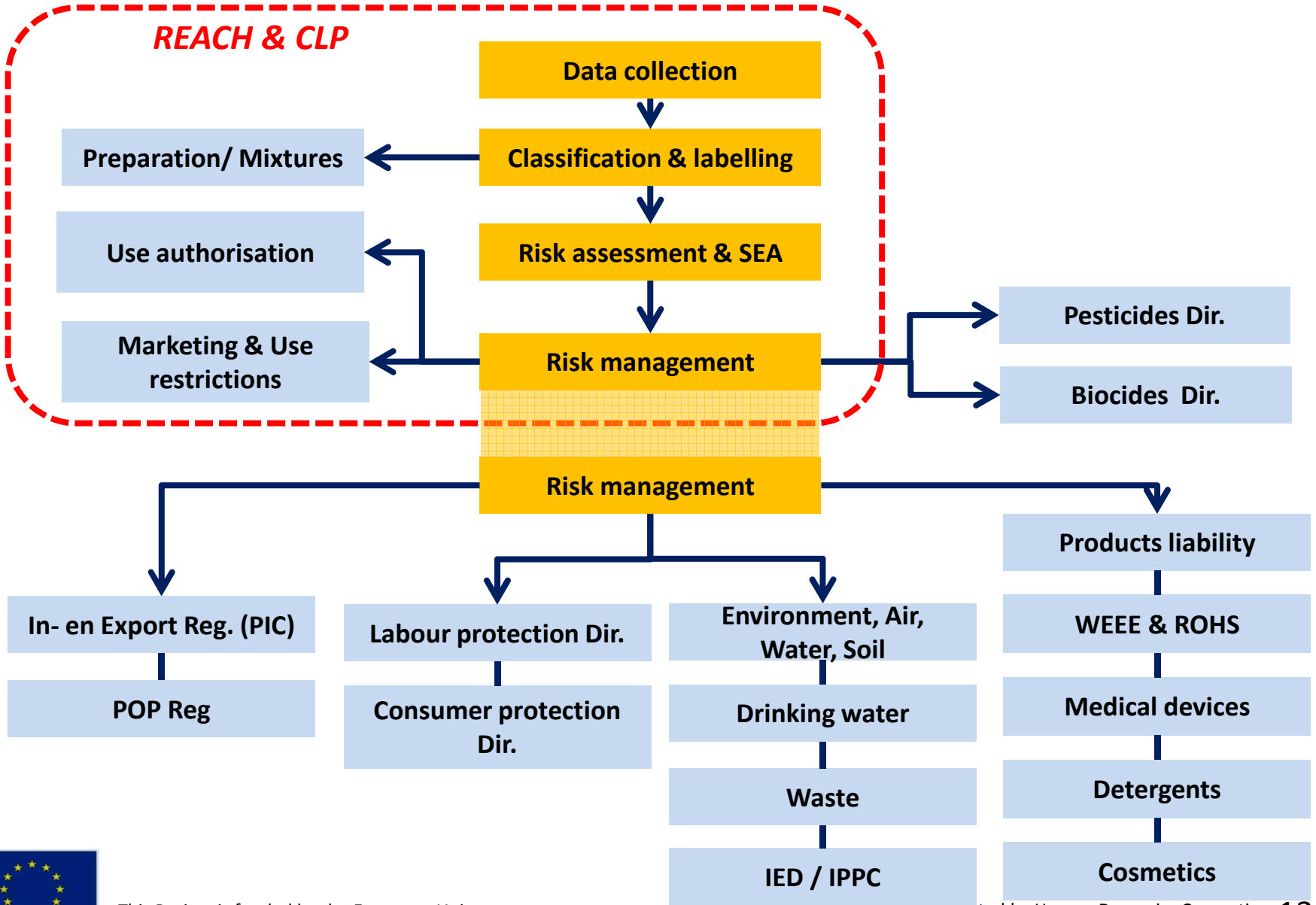
Risk management explained 2/2

- **Compliance monitoring**
  - Customs control, local control (labour, permits, emission, etc.)
- **Enforcement**
  - Sanctions, liability
- **Evaluation of the effectiveness**
  - Health impact, environmental impact, economic impact
- **Awareness raising**
  - Public awareness, awareness of decision makers
- **Ensuring adequate resources**
  - Government resources, fees and charges
  - Expertise, skills, training facilities

EU chemicals management before REACH/CLP



EU chemicals management with REACH/CLP



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 → **SDS extended**
  - Authorities: substance evaluation → **Annex XV dossier**
- **Translation towards specific scenarios**
  - Labour protection
  - Consumer protection (articles, indirect exposure)
  - Environmental standards
  - Restrictions, authorisation
  - Reporting and notifications
  - Emission control
  - Etcetera

Specific case: mercury

- **Substance of very high concern**
  - Highly toxic (historic: Minamata disease 1956 and Niigata Minimata disease 1965)
  - Wide-spread use
  - Use in consumer and professional area
  - Human intake via food (specifically via fish)
  - By bacteria transformed into methyl mercury – most toxic form:
    - neurotoxic, reprotoxic, passed through placenta and blood-brain barrier;
    - high risk of foetus and new-born

Global initiative

- **UNEP Mercury Program 2003**
- **UNEP Global Mercury Partnership February 2009**
  - 8 priority actions identified
- **Mercury Convention ("Minamata Convention")**
  - Initiated by Sweden
  - Negotiations started in February 2009
  - Concluded in 20 January 2013
  - Open for signature 7-11 October 2013 (EU + 91 nations signed)
  - Enter into force 90 days after ratified by 50 nations
  - Already ratified by USA (6 November 2013)
  - Ratification process in EU initiated in spring 2014

EU policy on mercury 1/2

- **EU mercury strategy started in 2005**
  - Comprehensive set of proposed restrictions
- **Review strategy in 2010**
- **In batteries and accumulators (Dir 2008/12)**
- **In electronic equipment (ROHS Dir 2002/95)**
- **In measuring devices for consumer use (Reg 1907/2006, REACH Annex XVII, entry 18a)**
  - Thermometers, barometers, manometers, etc.
  - Exempted are ancient instruments
- **In measuring devices for professional use (Reg 847/2012 amending REACH Annex XVII, entry 18a)**
  - Barometers, hydrometers, manometers, thermometers, etc.
  - Exempted is use for standard analysis
  - Entry into force 10 April 2014
- **Total ban of 5 phenylmercury compounds (Reg 848/2012 amending REACH Annex XVII adding entry 62)**
  - Entry into force 10 October 2017

EU policy on mercury 2/2

- **Ban of mercury export by Reg 1102/2008 amending In- and Export Reg 689/2008**
- **Reducing mercury emission from major industrial sources (IPPC → IED)**
  - Existing installations October 2007
  - Chlor-alkali industry; phase-out of mercury use
  - Sector-specific EU directives (waste incineration, large combustion plants)
  - National emission controls (cremation) in some member states
  - Adopting BAT
- **Development of BAT reference documents**
  - Chlor-alkali industry, large combustion plants, non-ferrous metal industry

Actions in Minamata Convention

- **Banning range of mercury containing products**
- **Phasing-out some non-electronic medical devices**
  - Exceptions for large measuring devices having no alternatives
- **Phasing-out use of mercury amalgam for dental fillings**
- **Developing strategies for reducing use of mercury in small-scale gold miners**
- **Public-awareness campaigns promoting mercury-free alternatives**
- **Control of mercury emission and releases from industrial facilities (coal combustion, chlor-alkali industry, smelters, waste incineration, cement clinker facilities)**
- **Implementing BAT on new power plants and facilities**

Useful websites

- European Chemicals Agency echa.europa.eu
- REACH helpdesk in Member States, examples

  www.reach-helpdesk.nl

  www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Neue-Chemikalienpolitik/Helpdesk/Reach-Helpdesk.html

  www.hsa.ie/eng/Sectors/Chemicals/REACH/
- REACH website of European Commission

  ec.europa.eu/enterprise/reach/index_en.htm
- CEFIC REACH Centrum, Industry websites

  www.reachcentrum.eu

  www.reachready.co.uk

  www.concawe.com

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Environment and Climate Regional Accession Network ECRAN

Introduction to REACH & CLP

Outline:

I: History and reason

II: REACH & CLP in brief

Arnold van der Wielen

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Part I
History of REACH & CLP

EU playing field in the past

- **Dangerous Substances Directive 1967/548**
  - 7th Amendment 1992/32
  - Notification of new substances
  - C&L of substances according to the EU system
- **Marketing & Use Directive 1976/769**
  - Many amendments
  - Restrictions in manufacture/import/use of specified substances
- **Preparation Directive 1988/379 (later 1999/45)**
  - C&L of preparations according to the EU system
- **Existing Substances Regulation 793(1993)**
  - Evaluation of existing substances

FIVE DECADES OF WORK

- 1st decade: Classification
- 2nd decade: Marketing & use restrictions
- 3rd decade: Notification new substances
- 4th decade: Risk assessment

- 5th decade: Responsibilities
  BRIDGE TO THE FUTURE

What triggers the 5th decade development?

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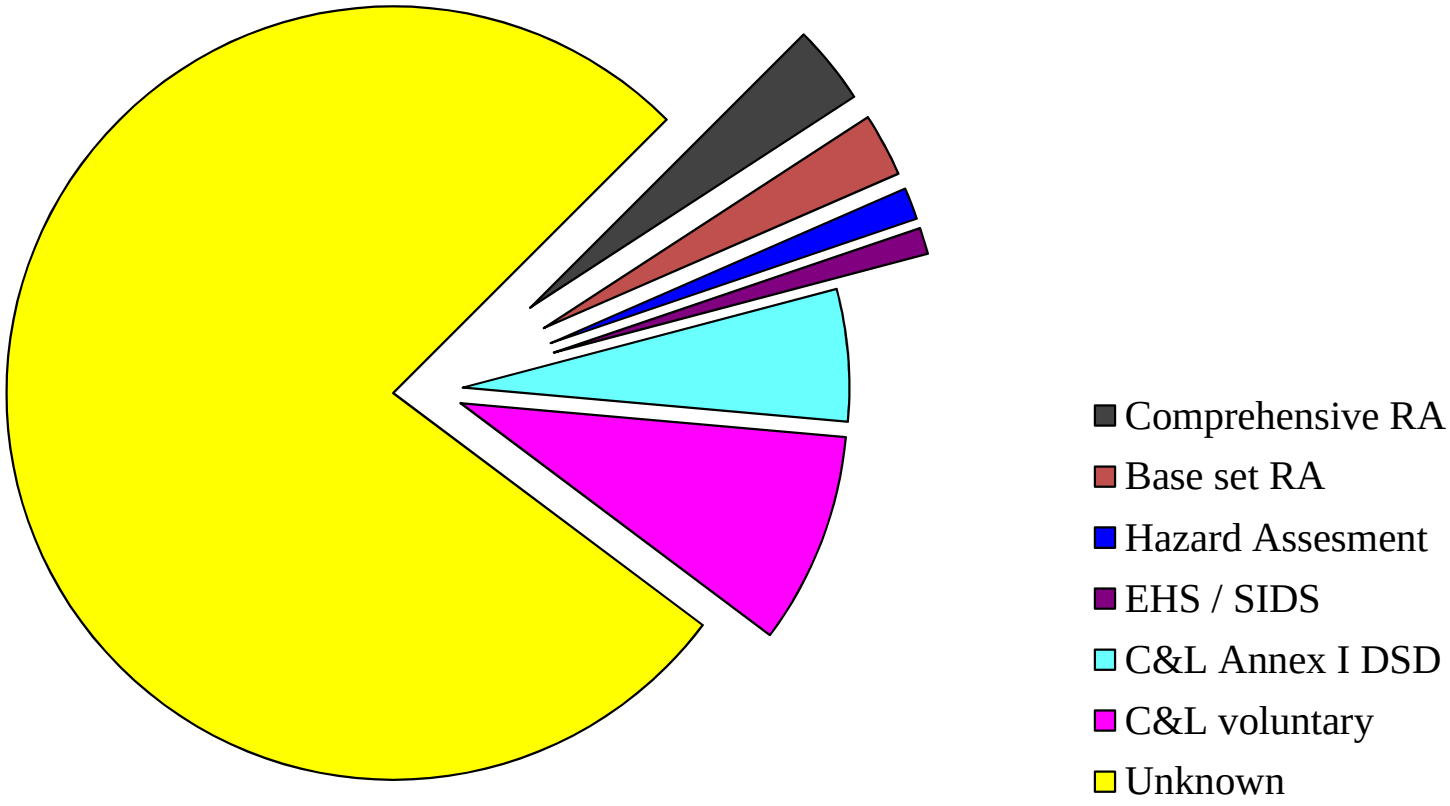
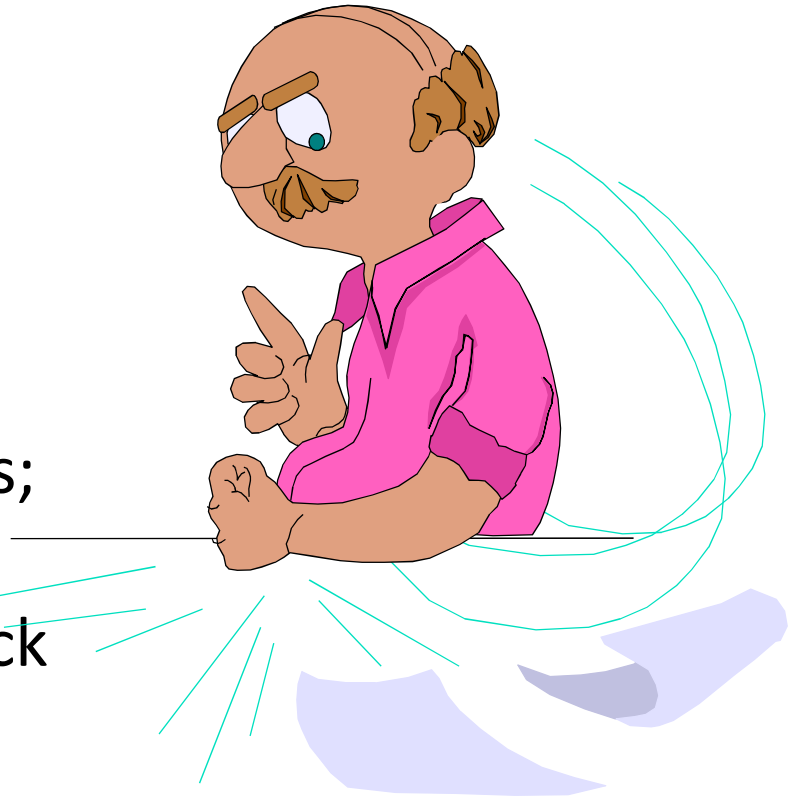
The size of the problem

Total number about 70.000 substances in EU?



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



History EU Review Chemicals Management

- **Informal Environment Council, Chester April 1998:**
  invitation to evaluate chemicals management
- **CEU Report on the Operation of the four instruments, November 1998**
- **EU Brainstorming with stakeholders, Brussels February 1999**
- **Environment Council, June 1999: Conclusions**

  → invitation to prepare a policy document
- **CEU White Paper, February 2001**
- **Environment Council, June 2001: Conclusions**
- **European Parliament, November 2001: Resolution**
- **Draft REACH Proposal, internet version, June 2003**
- **REACH proposal, October 2003**
- **REACH regulation adopted in 2006 (1907/2006)**
- **CLP Regulation adopted in 2008 (1272/2008)**

History of GHS

- Rio, 1992 – Chapter 19 of UNCED Agenda 21
- Development by IOMC, to end 2002
- UN CETDG/GHS – agreed Dec 2002
- UN ECOSOC – adopted July 2003, Rev.I 2005
- WSSD Johannesburg 2002 – operational by 20008

A Global Initiative

UNCED: United Nations Conference on Environment and Development
IOMC: Inter-Organization Programme For The Sound Management of Chemicals.
UN CETDG: Committee of Experts on the Transport of Dangerous Goods and on GHS
UN ECOSOC: UN Economical and Social Council
WSSD: World Summit on Sustainable Development

PART II
INTRODUCTION TO REACH & CLP

What has been changed

Before 1 June 2007

- Existing Substances regulation
- Dangerous Substances directive
- M&U directive
- SDS directive
- Preparation directive

After 1 June 2009

- REACH
- CLP regulation

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Basic principles of REACH

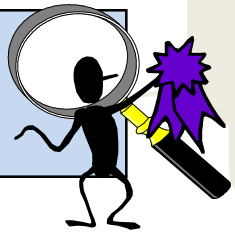
- **Sustainable development**
  - **Industry** is responsible for safe use of substances
  - **Authority** controls compliance of industry
  - **NGO's** must accept marketing of sustainable substances; no phasing-out across the board

- **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)

Main elements of REACH

Registration of all substances > 1 t/yr

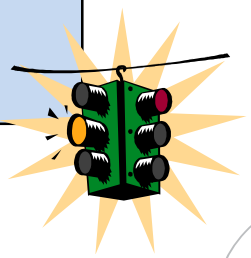
Evaluation by competent authorities



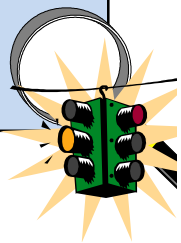
Scope:
- **evaluation required > 100 t/yr**
- **selective evaluation < 100 t/yr**
- **decisions for additional information**
- **proposal for authorisation**
- **Proposal for restriction measures**

Scope:
- **all other substances of high concern following risk assessment**

Restriction measures for substances of concern



Authorization of certain hazardous substances



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

Core issue is responsible risk management

"Employees & Public"

Data collection

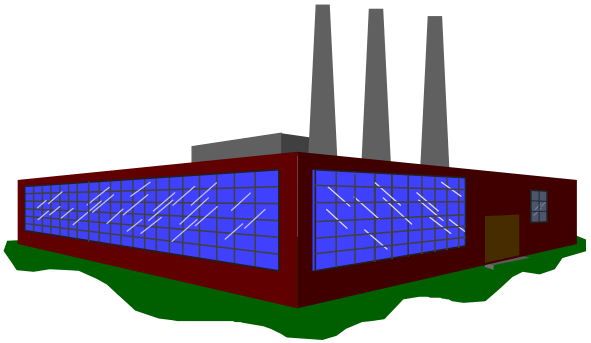
Evaluation of hazardous properties

Evaluation of exposure / emission

Risk assessment

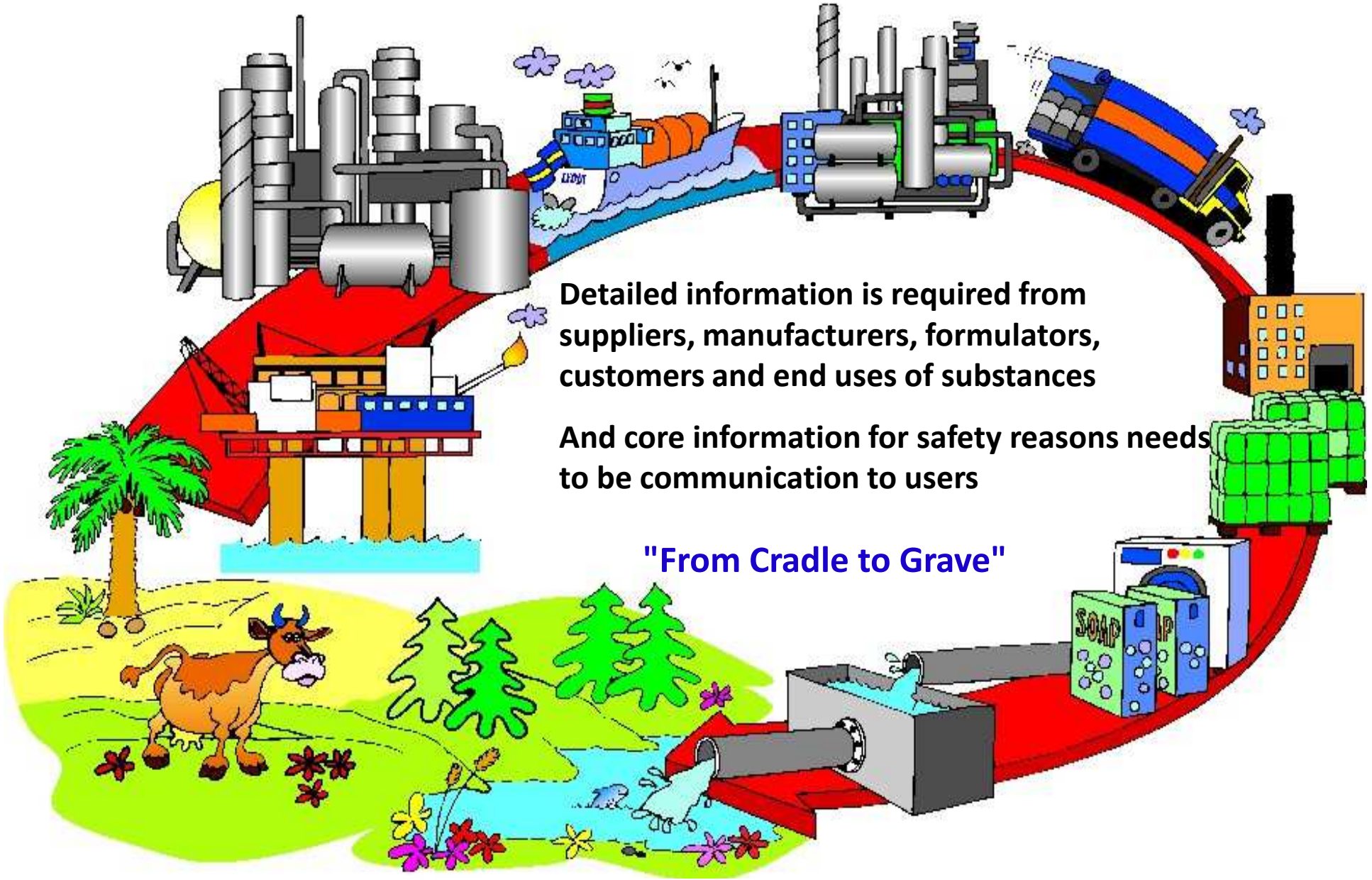
Risk reduction measures

Belongs to responsibility of industry



Chemical industry

Communication up- and down supply chain



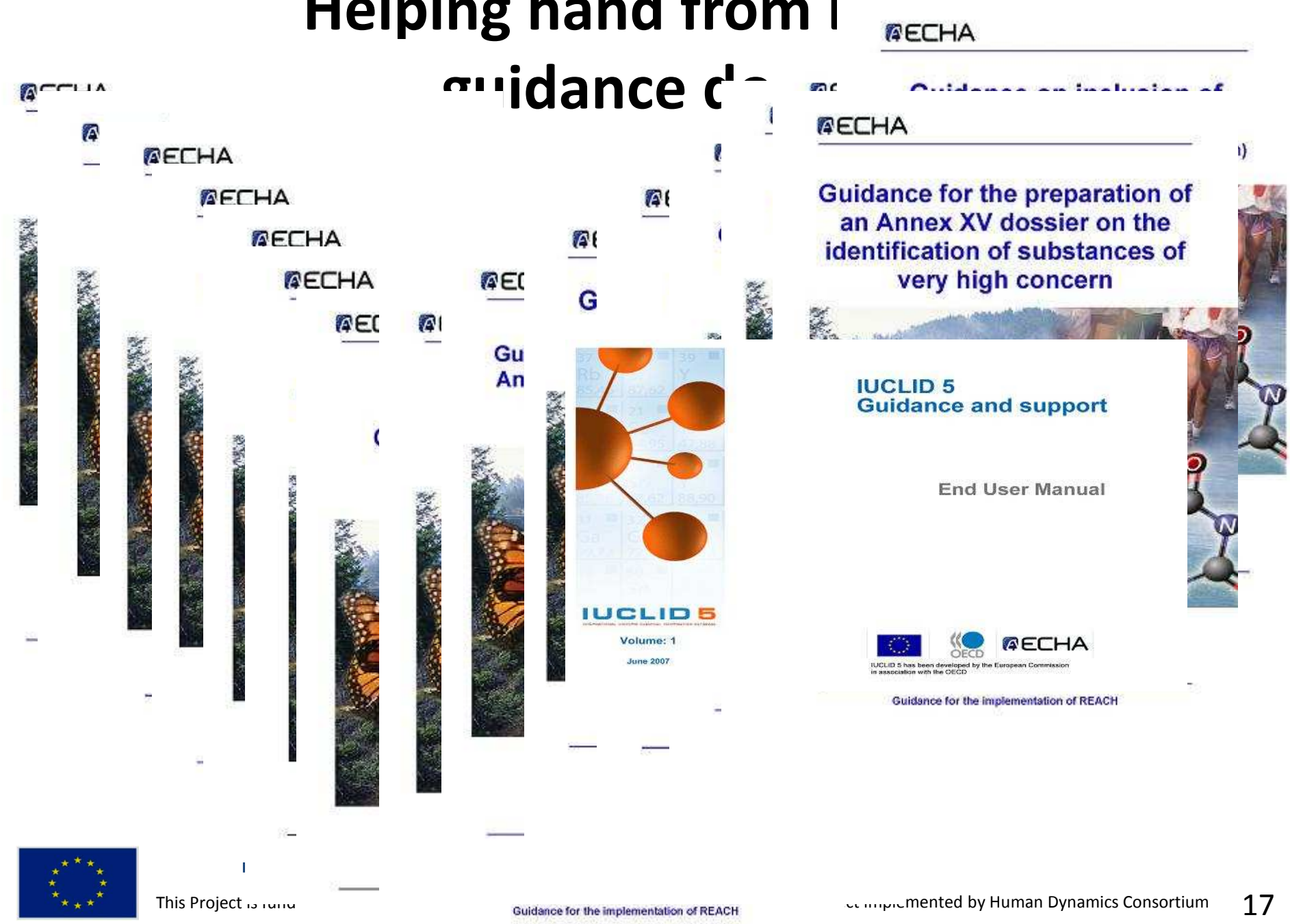
Legal structure of REACH

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

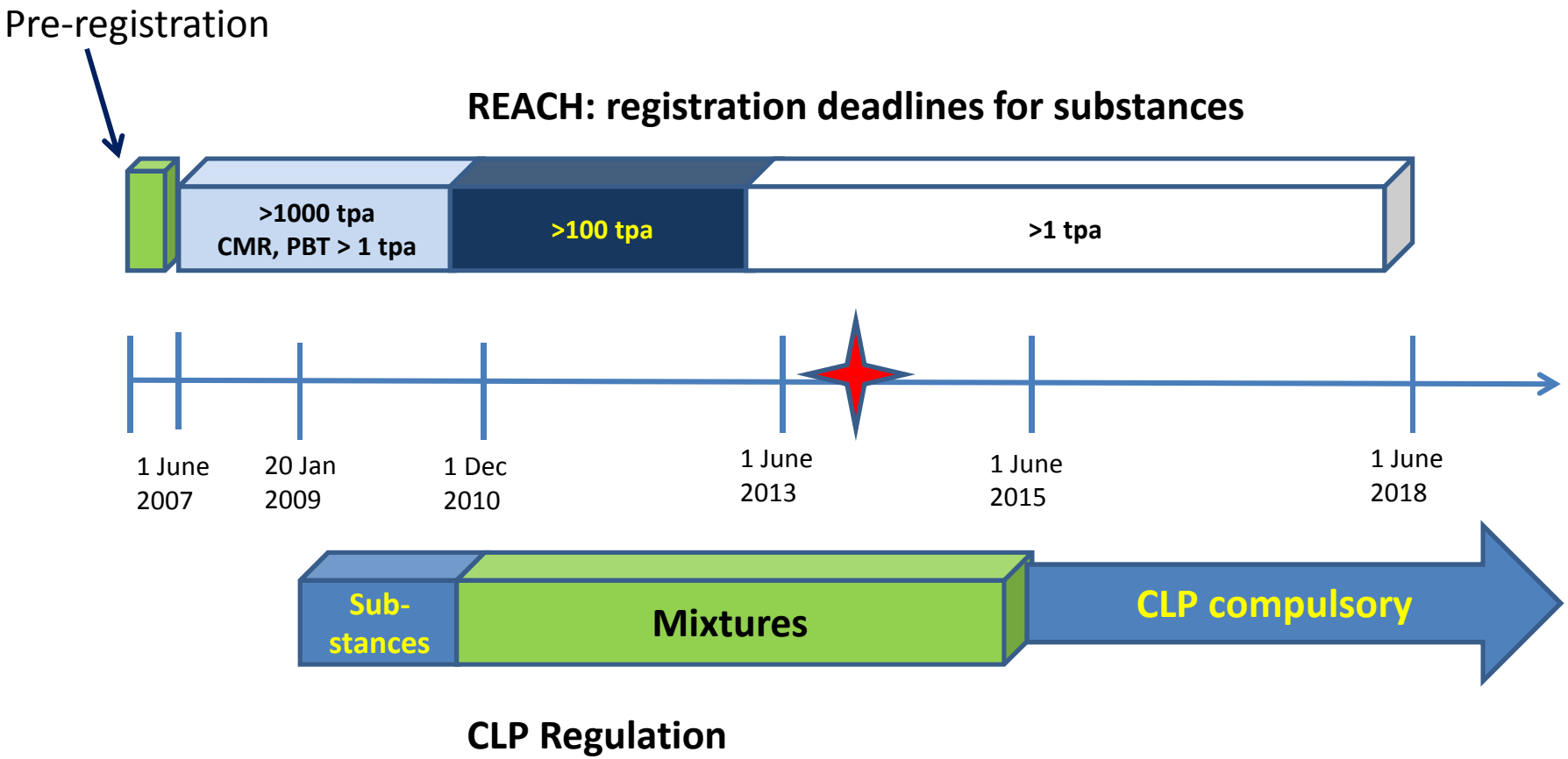
Helping hand from ECHA guidance d



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

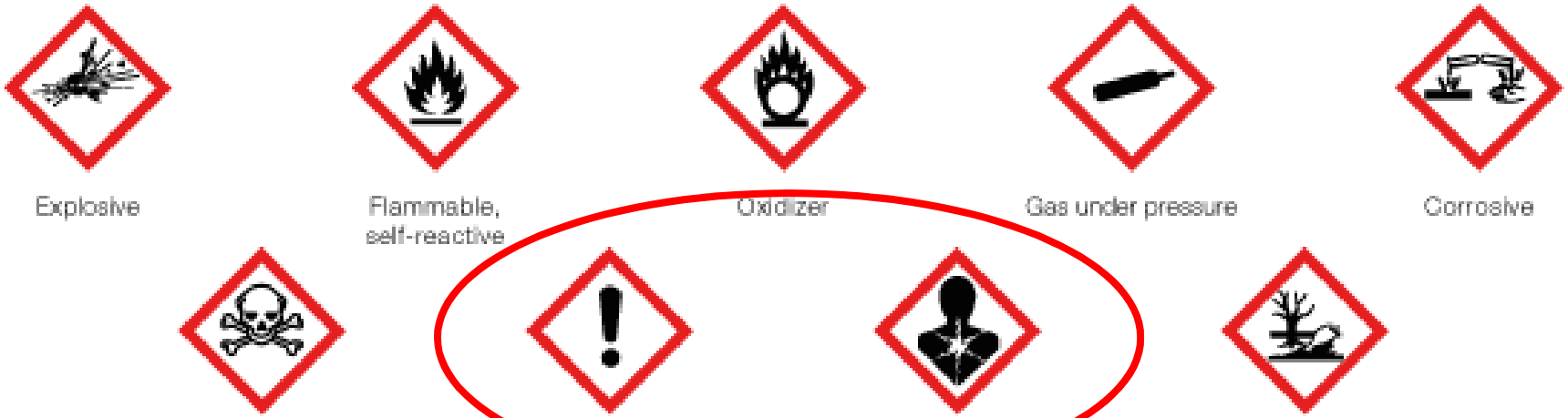
Critical CLP & REACH timelines



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

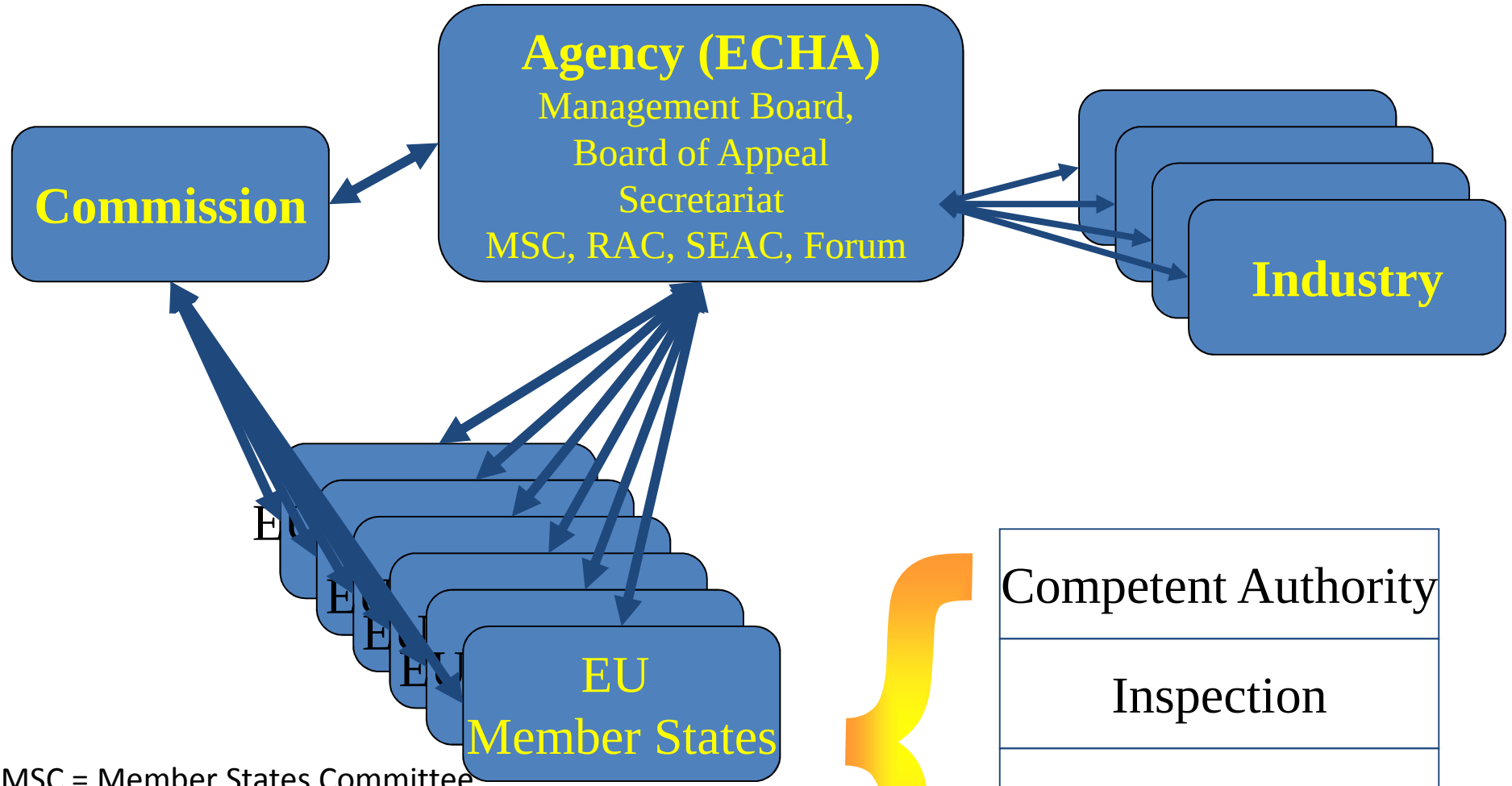
Acute toxicity Categories 1 to 3

Dermal sensitizer, irritant, specific target organ toxicity Category 3, acute toxicity Category 4

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

Hazardous to the aquatic environment

Organisation of REACH & CLP



MSC = Member States Committee

RAC = Risk Assessment Committee

SEAC = Socio-Economic Analysis Committee

- Competent Authority
- Inspection
- Experts
- Representatives

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Legal structure of CLP

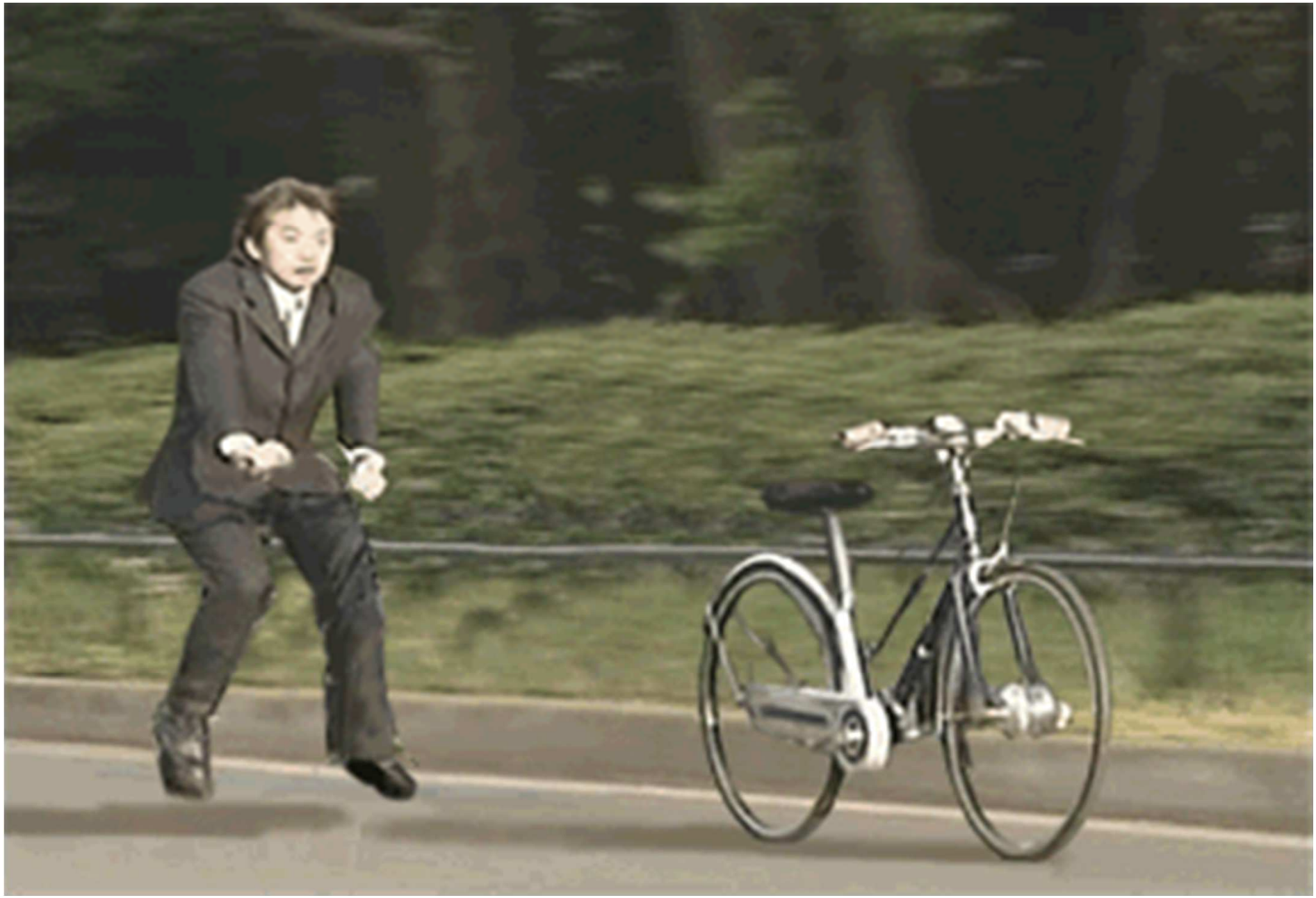
- **Legal „body text“ on general rules and principles**

  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

Dynamic to the future….

Environment and Climate
onal Accession Network ECRAN



Environment and Climate Regional Accession Network ECRAN

Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED

REACH specific - REGISTRATION

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Main goals

- Better protection of humans and the environment
- the competitiveness of the european chemicals industry...

REACH & CLP Implementation – Challenging for Industry as well as for Authorities

- Pre-registration - Late Pre-registration
- Registration – SIEFs – CSR –

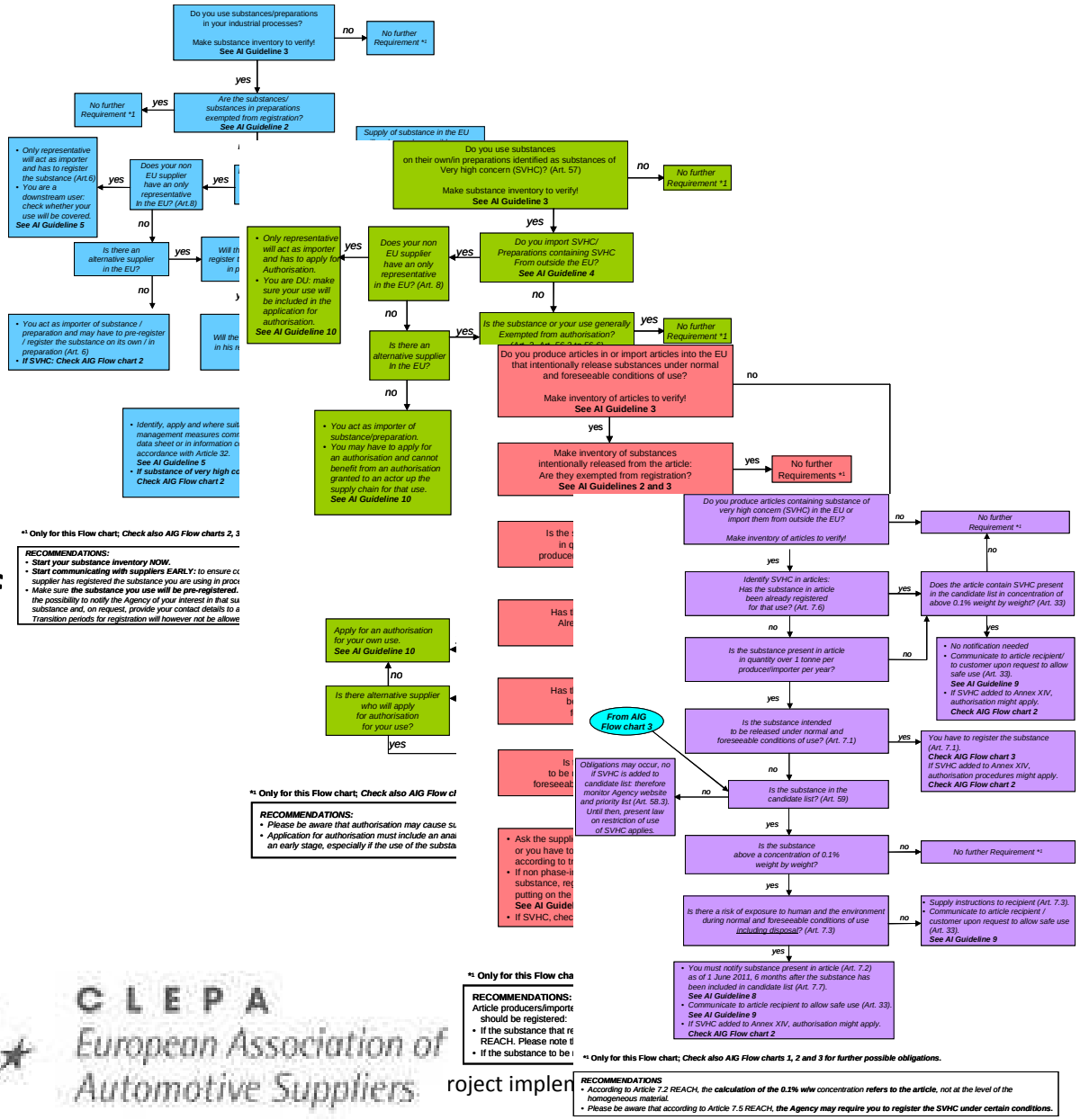
  - ESs – Dossier submission – up-dates
- Legal text - Guidance documents - The Directors' Contact Group (DCG)

- Restrictions
- Candidate list – Authorisation
- SDS – eSDS
- CLP
- Downstream Users - communication
- Consequences for market and occupational health
- Compliance - Enforcement

CLEPA: How to comply with REACH - a step-by-step process

Environment and Climate Regional Accession Network ECRAN

- Flow chart 1: **Registration of substances**/substances in preparations used in industrial (including engineering) processes
- Flow chart 2: **REACH authorisation** procedures
- Flow chart 3: **Registration of substances** intended to be released from **articles**
- Flow chart 4: **Notification of substances in articles** and obligation to communicate information



This Project is fu roject implen

CLEPA European Association of Automotive Suppliers

EKOTOXIKOLOGICKÉ CENTRUM BRATISLAVA s.r.o.

Home page | About company | We offer | Actual infos | REACH | Useful links | Sitemap | Contact | EN

- Consulting services
- REACH
- CLP
- Safety data sheet (SDS)
- Biocides
- Cosmetics
- Chemicals legislation
- OHS
- Workshops and seminars

- Actual information
- Software products
- Testing
- Archive
- Legislation outside EU

Consider the REACH legislation for the EU's success?

Select Poll: Consider the REACH legislati

Consider the REACH legislation for the EU's success?

Yes	243	59.9%
No	163	40.1%

Number of Voters : 406
First Vote : Monday, 04 July 2011 05:25
Last Vote : Tuesday, 15 April 2014 14:50

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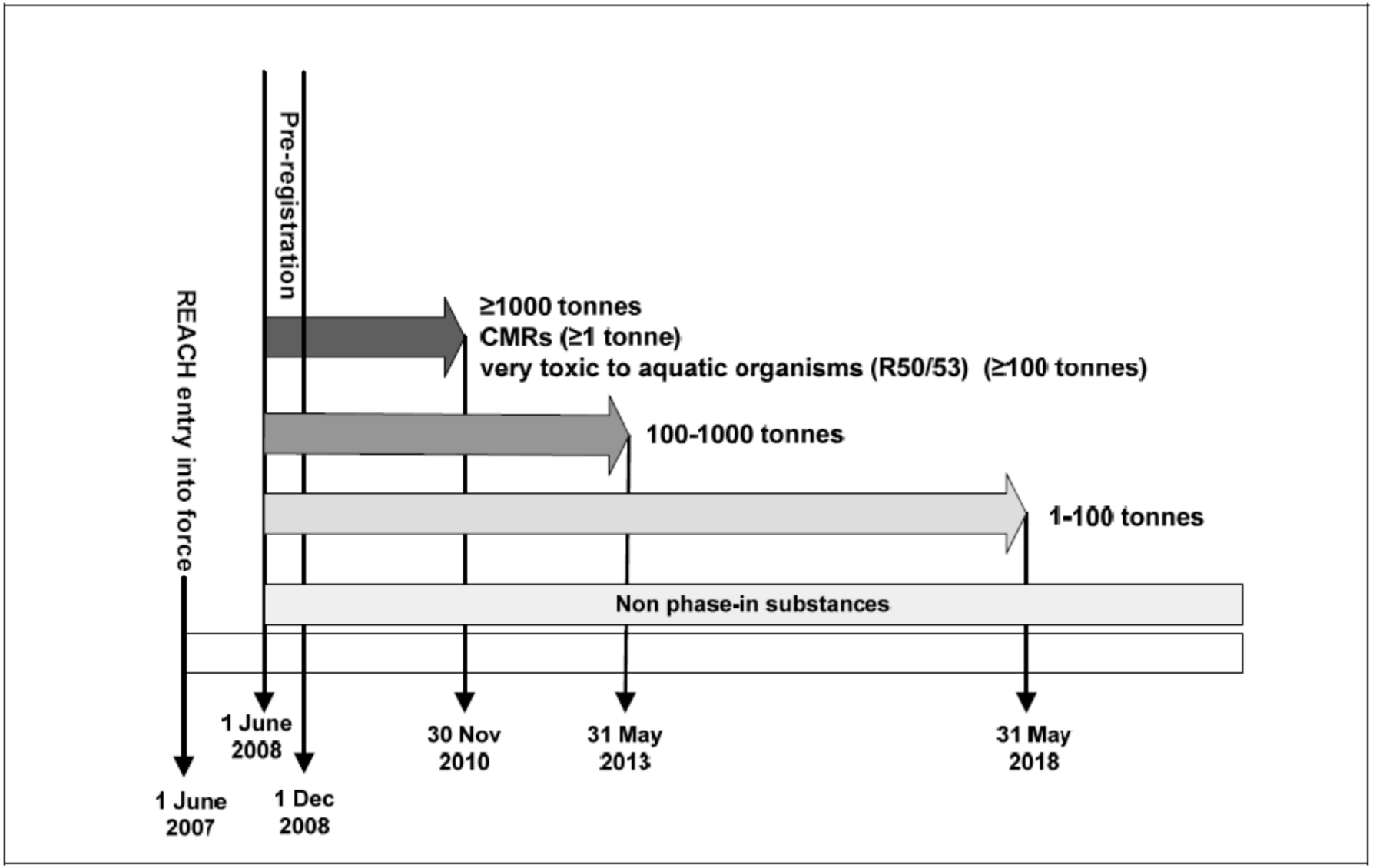
Registration deadlines



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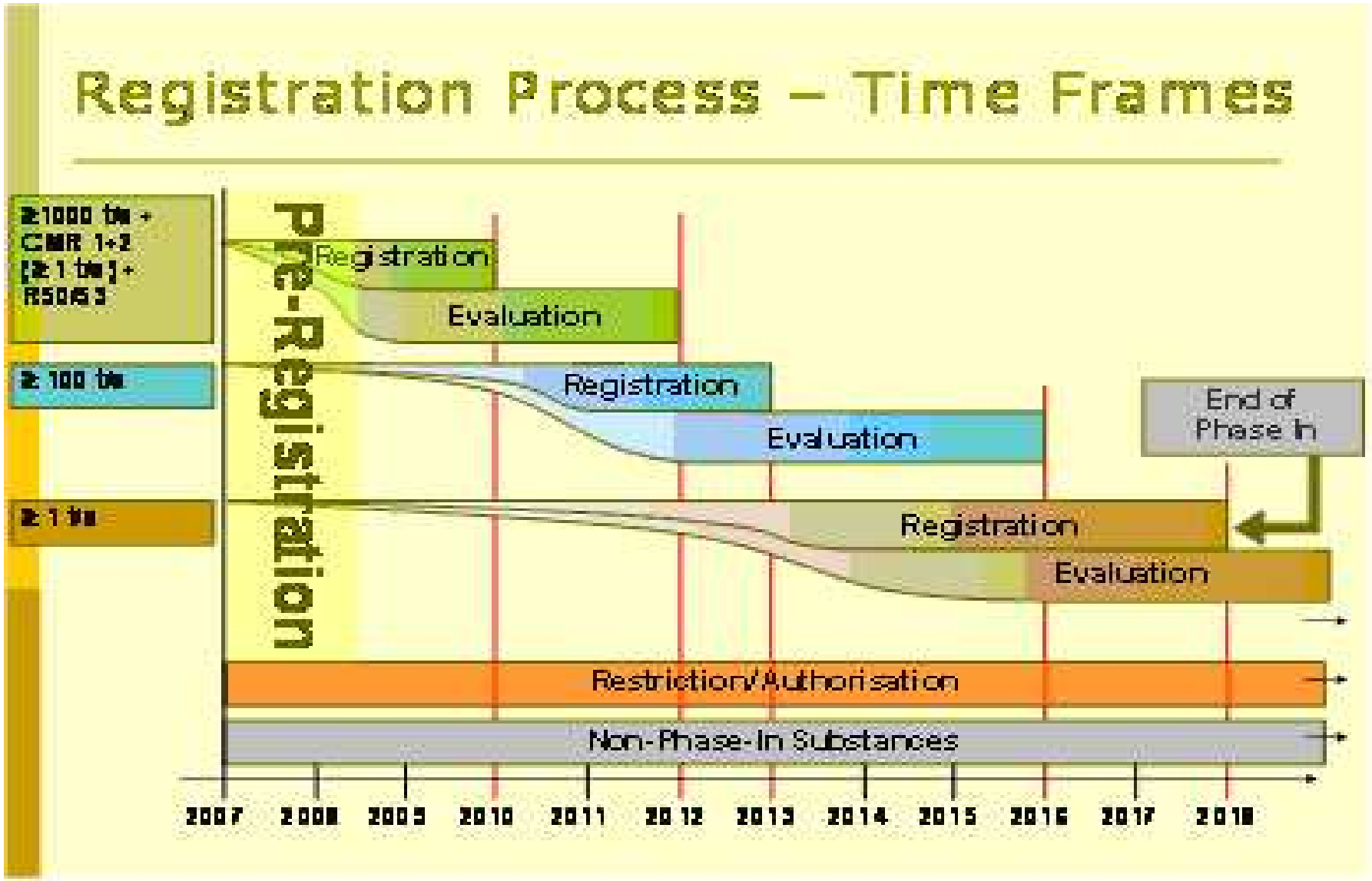
Registration Process – Time Frames



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REACH: Registration

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Registration not required (selection) for

- substances for use in research activities
- polymers
- radioactive substances
- substances in drugs or nutrient additives
- REACH appendix IV (e.g. water, natural oils)
- REACH appendix V (e.g. minerals, coal)
- already registered or re-imported substances

- biocides, cosmetics, medicines, food…

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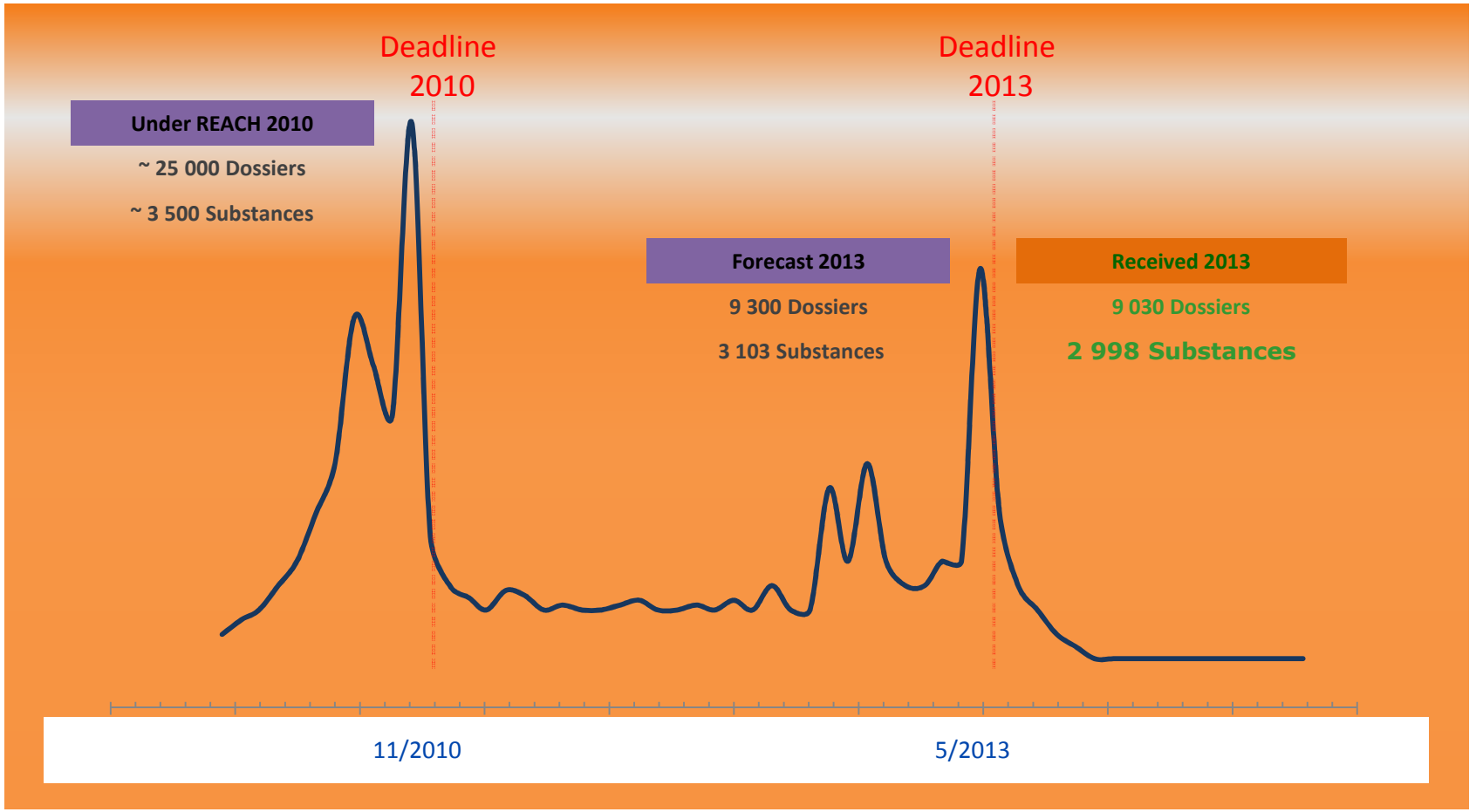
REACH Registration
1st and 2nd Registration milestones



Dossiers and Substances – overview

Registration types	
Standard registrations (all uses)	7 232
Registrations as intermediate only	1 798
Total registration dossiers	**9 030**

Substances	
Substances registered	**2 998**

All dossiers have been checked for completeness. Low number of rejections (< 1%)

Comparison with forecast

- Overall numbers in line with the forecast
- Difference in the substances registered
  - ~ 1000 announced by industry but not registered
  - ~ 800 registered but not announced
- Possible reasons?
  - Shifts in business
  - Overestimation
  - Production volumes different than expected
  - Business strategy

✓ No concern from downstream users or trade association reported to ECHA

SMEs

Registrations by company size	2010	2013
Registered by a large company	86%	81%
Registered by an SME (based on the numbers of dossiers)*	14%	19%
Medium company	9%	11%
Small company	4%	6%
Micro company	1%	2%

***The number of companies declaring SME size was 25%**

Registrations received by 31 May 2013

The tables below provide detailed figures on the number of registrations received by 31 May 2013, which have been granted a registration number.

Overall summary and detailed statistics

Summary for the 2013 deadline

Summary for the 2013 deadline	
Number of registrations (dossiers)	**9 030**
Number of registrants (companies)	**3 188**
SME registrants	**1077**

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Joint submission

Joint submission is a fundamental principle of REACH. Its aim is to reduce costs and avoid unnecessary testing on animals. This table provides a breakdown of the number of registrations submitted in a joint submission (multiple registrants) compared to individual submissions (single registrants). The number of these individual registrations shows cases where there is only one company registering a particular substance, but also cases where one or more companies have registered the same substance individually (ie. not in a joint submission). The latter cases may indicate a breach of the legal obligation to share data and register jointly.

Registrations in joint submissions	8 317
Lead	2 156
Member	6 161
Individual registrations	713
Total	**9 030**

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Company role

Registrations by role	2010	2013
Manufacturer	45%	40%
Manufacturer and importer	16%	12%
Importer	20%	25%
Only Representative of a non-EU manufacturer	19%	23%

Non-EU companies can export to the European Union through two different routes under REACH: either via an importer who has registered the substance, or by appointing an Only Representative.

Breakdown by role in the supply chain

The table below shows the breakdown of registrations according to the role as manufacturer, manufacturer and importer, importer and Only Representative.

Non-EU companies that export to the European Union can use two different registration mechanisms under REACH: either via an importer who has registered appropriately the substance, or by appointing an Only Representative who acts on behalf of their existing customers. The number of registrations received from importers and Only Representatives thus indicates that REACH is functioning for non-EU companies.

Role in the supply chain	
Manufacturer	3 611
Manufacturer and importer	1 083
Importer	2 250
Only Representative of a non-EU manufacturer	2 086
Total	**9 030**

ECHA
EUROPEAN CHEMICALS AGENCY

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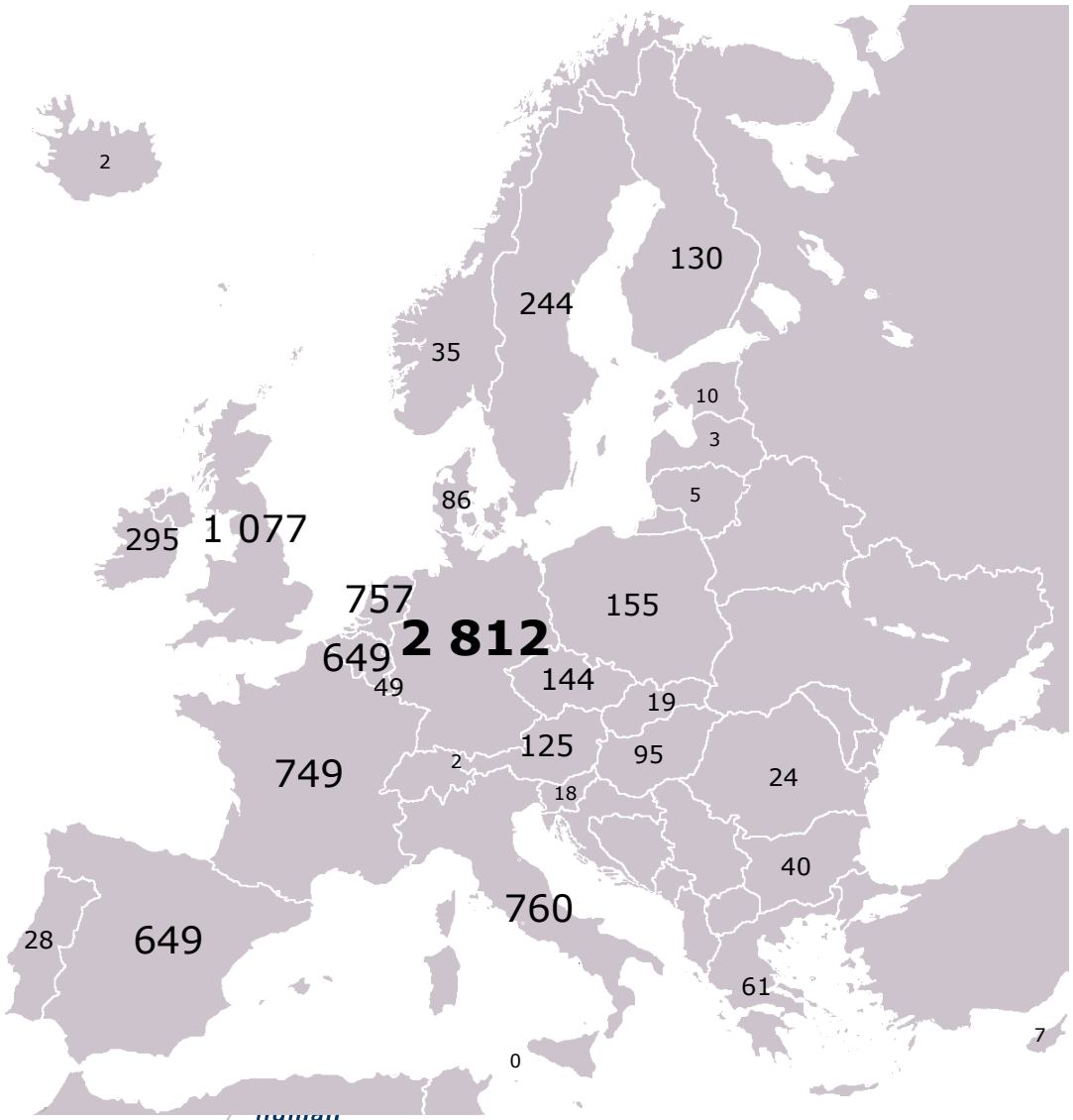
2013 Registrations

Country	Registrations	%
Germany	2812	*31%*
United Kingdom	1077	*12%*
Italy	760	*8%*
Netherlands	757	*8%*
France	749	*8%*
Belgium	649	*7%*
Spain	649	*7%*
Ireland	295	*3%*
Sweden	244	*3%*
Poland	155	*2%*
Czech Republic	144	*2%*
Finland	130	*2%*
Austria	125	*1%*
Hungary	95	*1%*
Denmark	86	*1%*
Greece	61	*1%*
Luxembourg	49	*1%*
Bulgaria	40	*0%*
Norway	35	*0%*
Portugal	28	*0%*
Romania	24	*0%*
Slovakia	19	*0%*
Slovenia	18	*0%*
Estonia	10	*0%*
Cyprus	7	*0%*
Lithuania	5	*0%*
Latvia	3	*0%*
Iceland	2	*0%*
Liechtenstein	2	*0%*
Malta	0	*0%*



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Registration - next steps (I)

- Contact lead registrants that have not registered
  - Survey on-going
- Verify confidentiality claims in dossiers
- Publish non-confidential information from dossiers online

Search substances on ECHA home page

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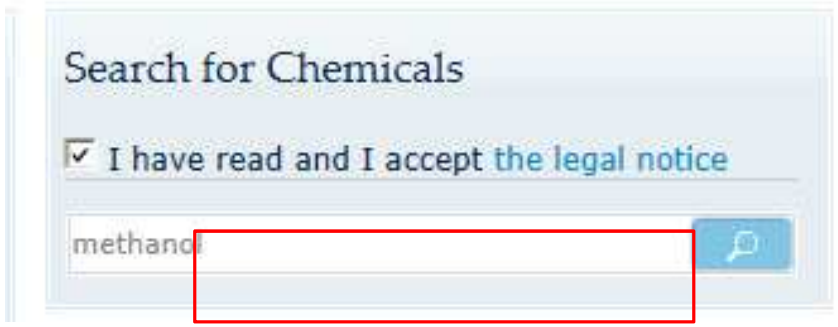
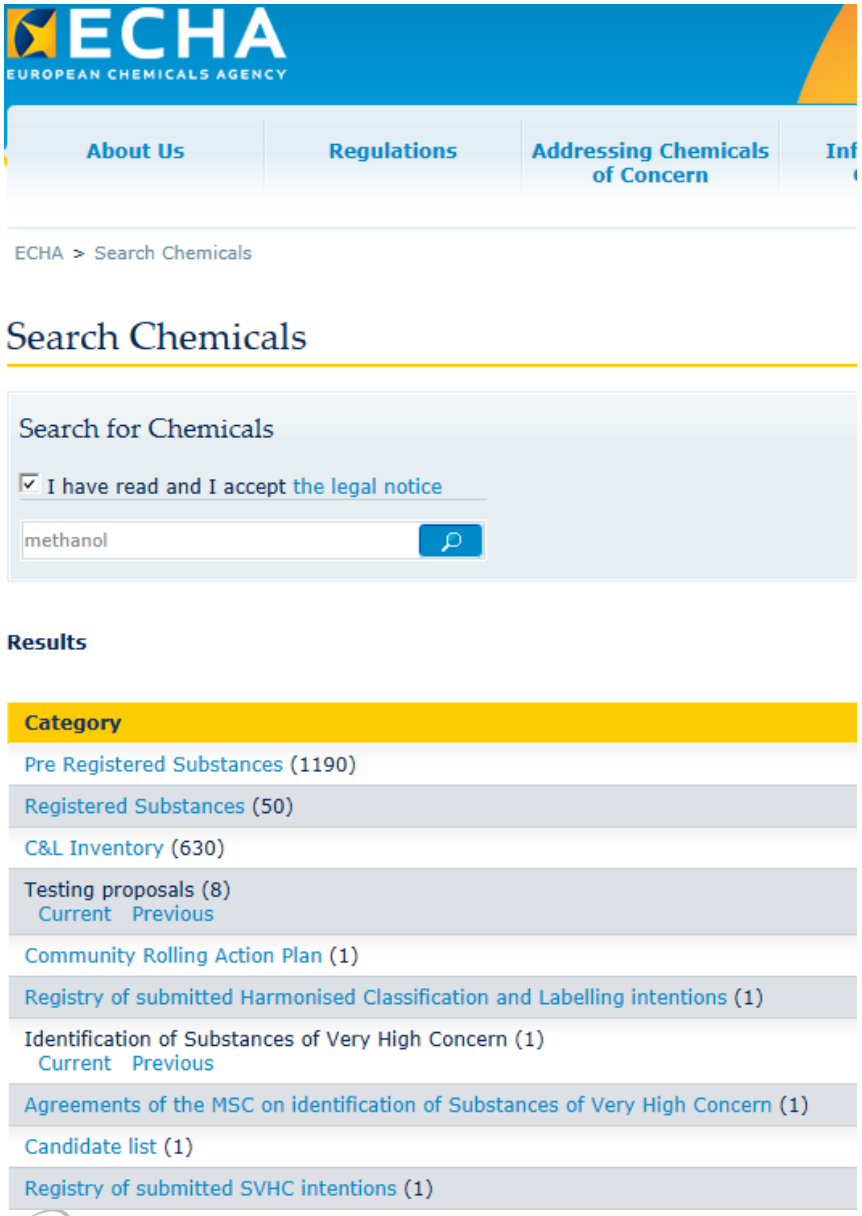




Registration - next steps (II)

- Examine testing proposals (by 1 June 2016)
  - 770 proposals in 376 dossiers
- Include dossiers in pool for screenings and data analysis: Compliance Checks, CoRAP, SVHC, CLH
- Start preparations for 2018, with a focus on SMEs

Registration - next steps (III)

Actions for industry:

- Registrants
  - Prepare safety data sheets for clients in the supply chain
    - registration numbers
    - exposure scenarios giving advice on safe use
  - Keep information up-to-date

- Downstream users
  - Verify if substances and uses are registered
  - If not, action needed

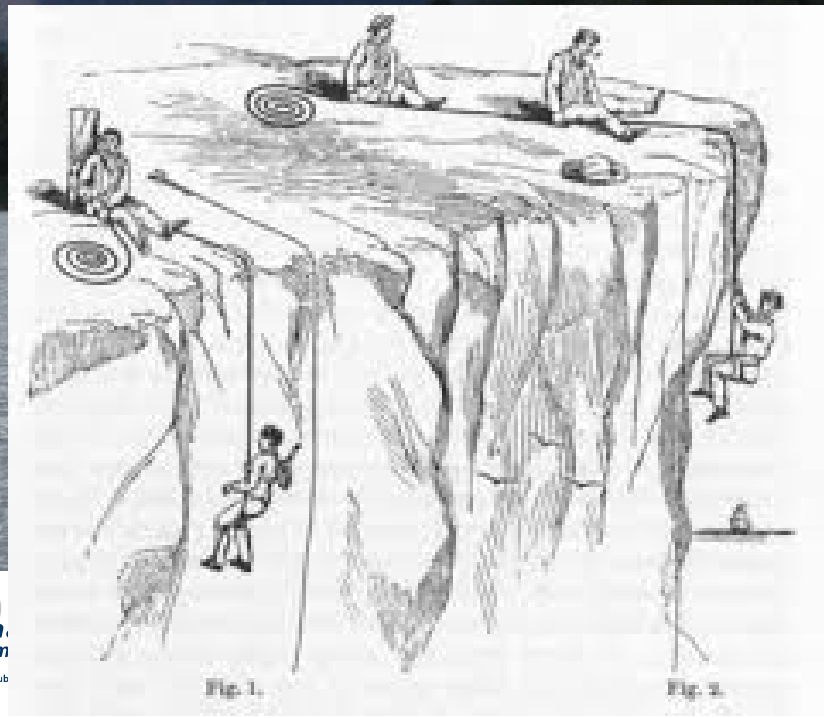
2013 Summary

- **Over 7 400** substances registered since 2008
- Vast **information** already available **online** in the world's biggest public regulatory database of chemicals
- Information flowing in the **supply chain**
- **Informed decisions** being taken by companies
- **Aims of REACH** gradually being achieved

2010

2013

2018



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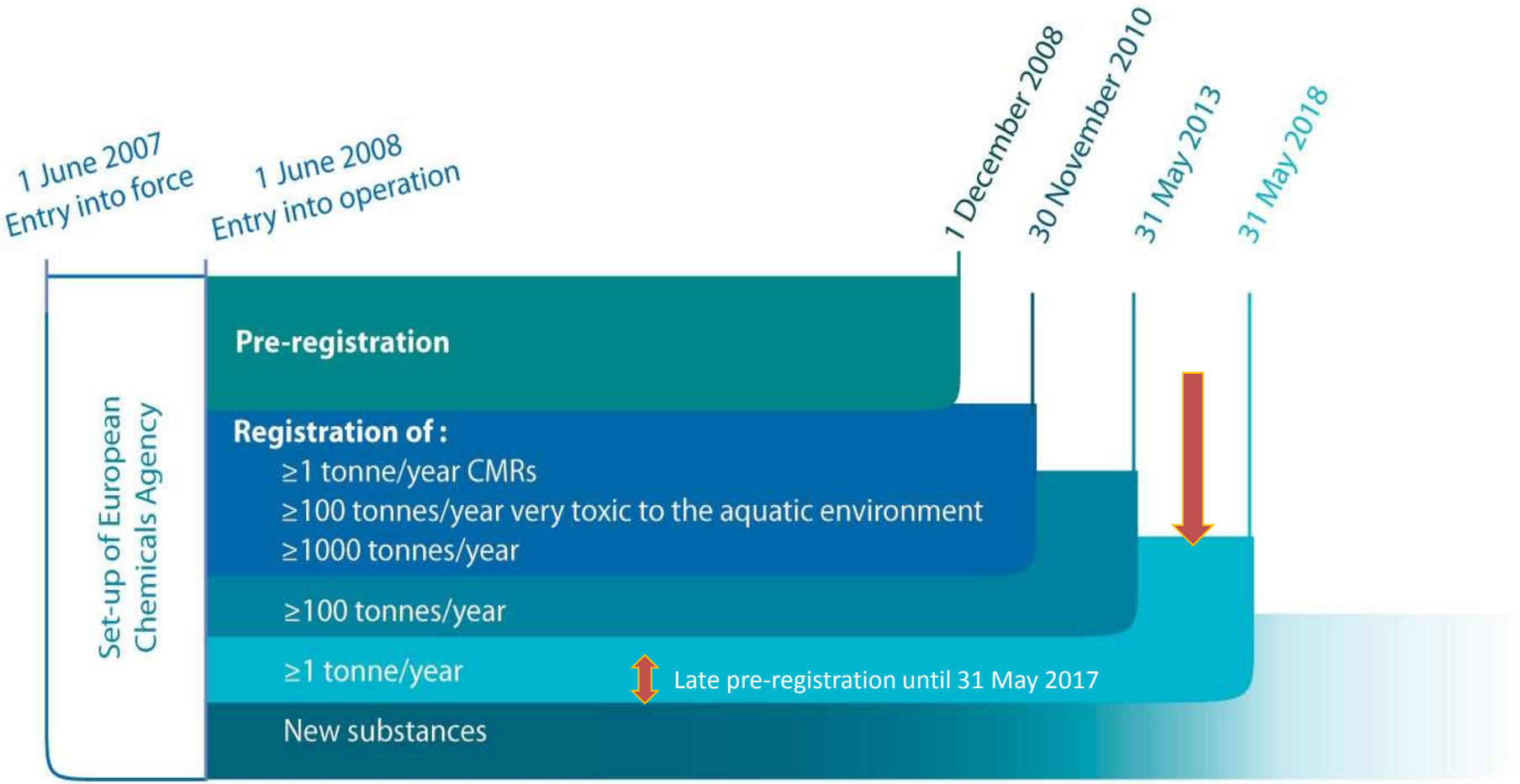
REACH Registration deadlines



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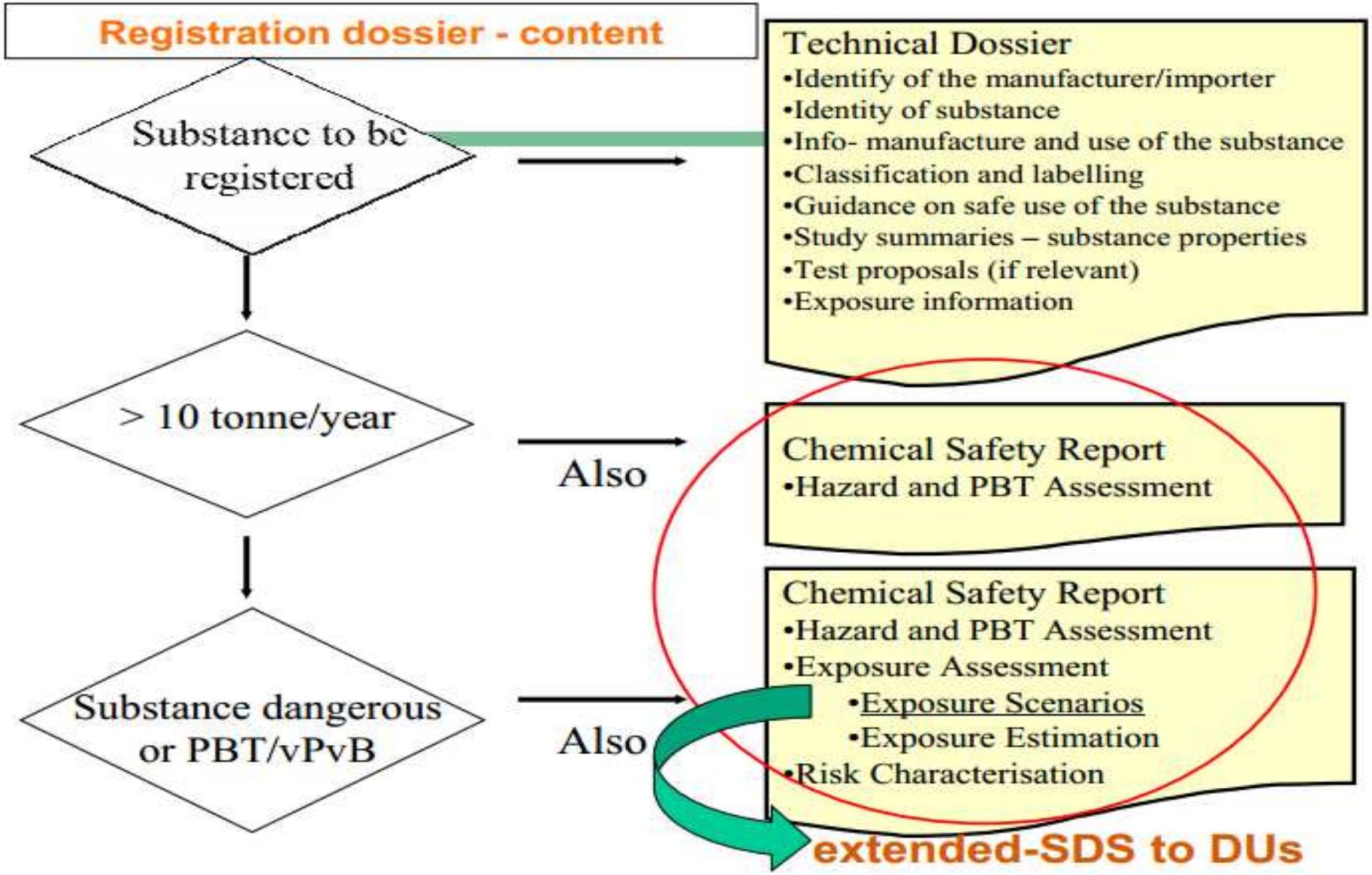

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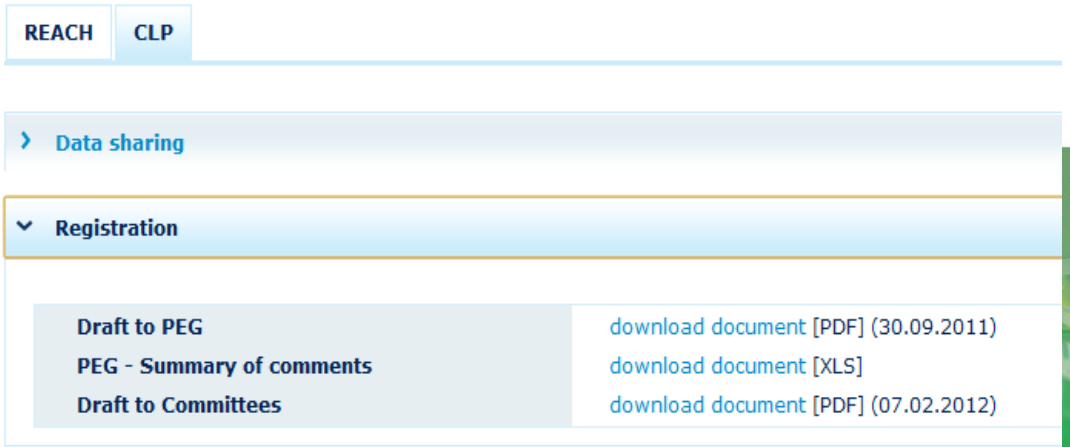
CSA – CSR - Dossier

- **Data**
- REACH requirements

- ECHA Guidelines



Overview of the CSA Process

REACH is based on the principle that industry should manufacture, import or use substances or place them on the market in a way that human health and the environment are not adversely affected.

The chemicals safety assessment (CSA) is the instrument to:

- **Assess the intrinsic hazards of substances** including determining the hazard classification, further characterising hazards, including where possible derivation of no-effect-levels (Derived No-effect-Levels for human health, Predicted No-Effect-Concentrations for environment), and assessing properties relating to persistence, bioaccumulation and toxicity (PBT). This includes generation of new information if needed.

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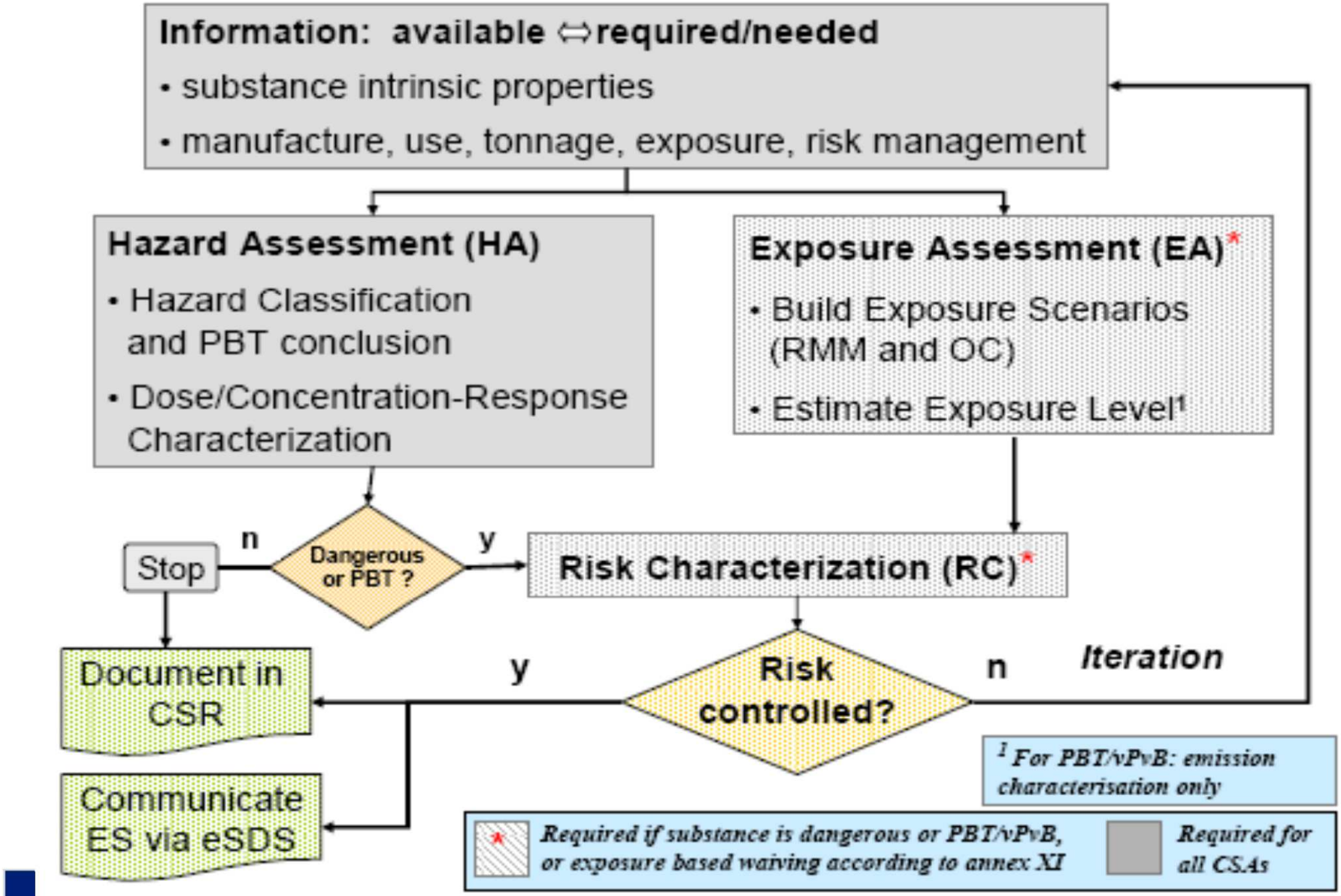
Overview of the CSA process



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KEY CONCEPTS FOR THE CSA

Duty to prepare the CSA:

- required when a substance is manufactured or imported at 10 tonnes or more per year
- assessment shall be documented in a CSR to submited as a part of registration dossier

Primary aim is to define the conditons of use (OC and RMM) under which the risk can be controlled

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PNEC(s) / DNEL(s) / DMEL(s)

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➔ ***PNEC*** = Predicted no effect concentration

- the concentration of a chemical in any compartment below which unacceptable effects on the aquatic ecosystem and its organisms will most likely not occur during long term or short term exposure.

➔ ***DNEL*** = Derived no effect level

- DNEL defined in REACH: the level of exposure above which humans should not be exposed.
- The risk to humans can be considered to be controlled if the exposure levels estimated do not exceed the appropriate DNEL.

➔ ***DMEL*** = Derived minimal effect level

- reference risk level considered to be of very low concern and should be seen as a tolerable level of effects

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PNEC derivation

- **Aim** - to derive a Predicted No-Effect-Concentration for long and/or short term exposure of a given environmental compartment ($PNEC_{comp}$).
- **Environmental compartments**:
  - Water (fresh, marine)
  - Sediment
  - Soil
  - Air
  - Microorganisms in sewage treatment plants (STP)
  - Assessment of secondary poisoning
- Dose descriptors: [mg/L; mg/kg]

  LC50/EC50 (lethal (effect) concentration 50)
  NOEC (no observed effect concentration)
- Endpoints of interest: mortality (LC50), growth and reproduction (EC50, NOEC)

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General principles

➔ 2 types of the effect of a chemical on organisms:

➔ ***Effects with a threshold:***

↳ The dose of a chemical must reach a certain level in order to elicit any adverse effect = a chemical is thought to be harmless at sufficiently low concentrations.

➔ Type of chemicals: non-carcinogens and non-genotoxic carcinogens

➔ ***Effects without a threshold:***

↳ No safe dose of a chemical exists = an adverse effect may be elicited at any level

➔ exposure level regarded as “acceptable”

➔ Type of chemicals: genotoxic carcinogens and germ cell mutagens

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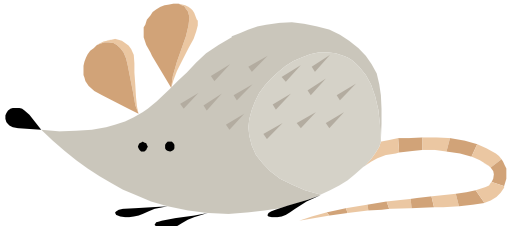
Dose descriptor



= a value obtained from a toxicity test, or an epidemiological study on human population

➔ Usually the dose needed to induce a specified adverse effect (e.g. 50% lethality), or the highest dose not causing adverse effects (e.g. NOAEL).

➔ Typically used dose descriptors are LD50, LC50, T25, NOAEL, LOAEL, BMDL10, RR, OR, and SMR.

- **LD50** = dose of a substance that kills 50% of animals in a specified time exposed by oral or dermal route.
- **LC50** = concentration of a substance that kills 50% of animals in a specified time exposed by inhalation route.
- **T25** = the chronic dose that will give 25% of the animals' tumours at a specific tissue site after correction for spontaneous incidence.
- **NOAEL** = the *highest dose leve*l or concentration of the substance used in test at which no significant adverse effects were observed.
- **BMD10 =** the dose that produces a 10% excess risk in the experimental dose range, if compared to background level.
- **RR** = relative risk = the probability of an event (developing a disease) occurring in exposed people compared to the probability of the event in nonexposed people
- **OR** = odds ratio = the ratio of the odds that the cases were exposed to the odds that the controls were exposed.
- **SMR** = standardized mortality ratio = the ratio of deaths observed to deaths expected per year in the population of interest, if the age specific death rates were the same as a standard population.

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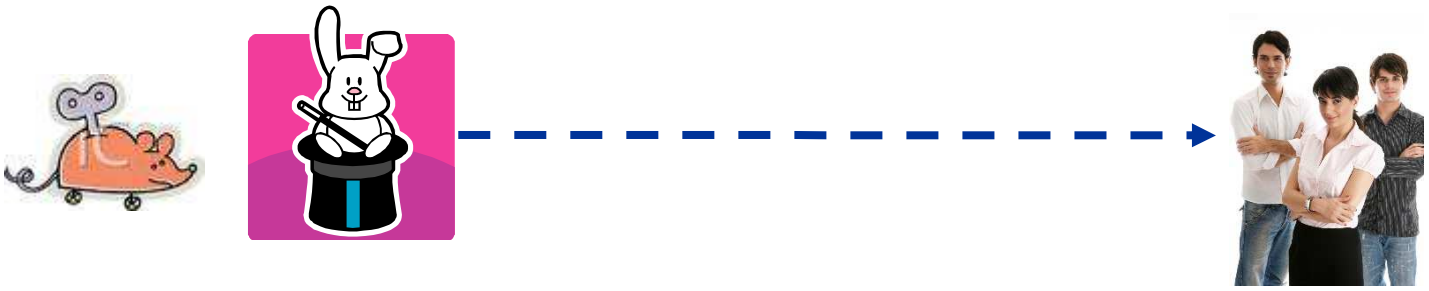
Assessment factors (DNELs)

= numerical values addressing differences between experimental data and the human situation taking into account the uncertainties in the extrapolation process and the available data set.



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Derivation of DNEL

In order to derive endpoint-specific DNEL(s) for the relevant exposure pattern (duration, frequency, route and exposed human population), the overall AF is applied directly to the corrected dose descriptor:

$$\text{Endpoint-specific DNEL} = \frac{\text{NOAEL}_{\text{corr}}}{\text{AF}_1 \times \text{AF}_2 \times \ldots \times \text{AF}_n} = \frac{\text{NOAEL}_{\text{corr}}}{\text{Overall AF}}$$

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DMEL derivation

➔ 2 methodologies:

- The 'Linearised' approach, and
- The 'Large Assessment Factor' approach.

Both based on risk extrapolation and risk evaluation, using as dose-descriptors T25, BMD10 or BMDL10.

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The 'Linearised' approach

- The assumption of a linear dose response relationship between tumour formation and exposure.
- T25 as the default dose-descriptor
- Correction of T25 and application of allometric scaling
  - Next step - *high to low dose* extrapolation to arrive at the DMEL (an exposure level that is considered to represent a risk level where the likelihood that effects (cancer) are avoided is appropriately high and of very low concern).
    - If a benchmark dose (BMD10 – derived dose assumed to give 10% of the animals' tumours) is used as the dose descriptor, a lower extrapolation factor need to be used.

High to low dose risk extrapolation factor (HtLF)		Default value systemic tumours
High-to-low-dose extrapolation	In case of e.g.:	For T25 ; for BMD10
	- 10^{-5} risk	25.000 ; 10.000
	- 10^{-6} risk	250.000 ; 100.000

DMEL (based on a T25) for e.g. a risk for cancer of one per 100.000 exposed is arrived at in the following way:

$$\text{DMEL representing a } 10^{-5} \text{ risk} = \frac{T25_{corr}}{AF_1 \times \ldots \times HtLF} = \frac{T25_{corr}}{AS \times 25.000}$$

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DNEL(s) ≠ DMEL(s)

➔ **DNEL** represents a derived value below which exposures should be controlled.

= level of exposure which should not be exceeded, indicating control.

➔ **DMEL** is a reference risk level considered to be of very low concern due to a high likelihood that effects are avoided for the particular Exposure Scenario under consideration

➔ should be seen as a **tolerable level of effects**.

➔ **DMEL** expresses an exposure level corresponding to **a low risk**, since for non-threshold effects the underlying assumption is that a no-effect-level cannot be established.

➔ Cancer risk levels of 10^{-5} and 10^{-6} could be seen as indicative tolerable risks levels when setting DMELs for workers and the general population.

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Qualitative approach

- ➔ No reliable dose descriptor available
  - ➔ acute toxicity, irritation/corrosion, sensitisation, and mutagenicity/carcinogenicity.
- ➔ qualitative indications of the potency of the substance used for developing exposure scenarios with risk management measures (RMM) and operational conditions (OCs) for controlling risk.
- ➔ Management of risks for which no DNEL values can be derived:

  "the higher the hazard, the stricter the risk management that should be put in place".

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Selection of critical DNEL/DMEL

➔ The critical DN(M)EL selected for the (semi-) quantitative risk characterisation should be the **lowest DN(M)EL** obtained for the relevant combination of population/route/exposure pattern.

➔ Risk characterisation ratios (RCRs):

RCR = Exposure/DNEL

RCR = PEC/PNEC

- If Exposure < DNEL ..... Risk adequately controlled
- If Exposure > DNEL → Risk NOT adequately controlled

➔ *Non-threshold effects* - Risk characterisation entails a comparison between the estimated exposure and the DMEL.

= a semi-quantitative Risk Characterisation.

REACH - RC for the leading health effect = the toxicological effect that results in the most critical DNEL/DMEL for a given exposure pattern (duration, frequency, route and exposed human population) associated with an exposure scenario.

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Source: **REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

1.0.1. The objective of the human health hazard assessment shall be:

— to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC, and

— to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

6.3. The risk characterisation consists of:

— a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL,

— a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs, and

— an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

6.5. For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.

8.1. Where a Chemical Safety Report is required, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios set out in the annex to the Safety Data Sheet.

COMMUNICATION IN THE SUPPLY CHAIN

Environment and Climate ECRAN

Shared responsibility and communication in the market

Once a substance is classified as dangerous or is found to be a PBT/vPvB, exposure assessment is required to demonstrate control of risks for the entire life cycle of a substance

This is a shared responsibility for all actors in the supply chain, except those:

- transporting chemicals,
- treating waste for recycling or final disposal and
- using chemicals in private households.

[10] Companies re-introducing recovered substances (on its own or in preparations) as products into the market must however check whether or not they have to register these recovered substances.

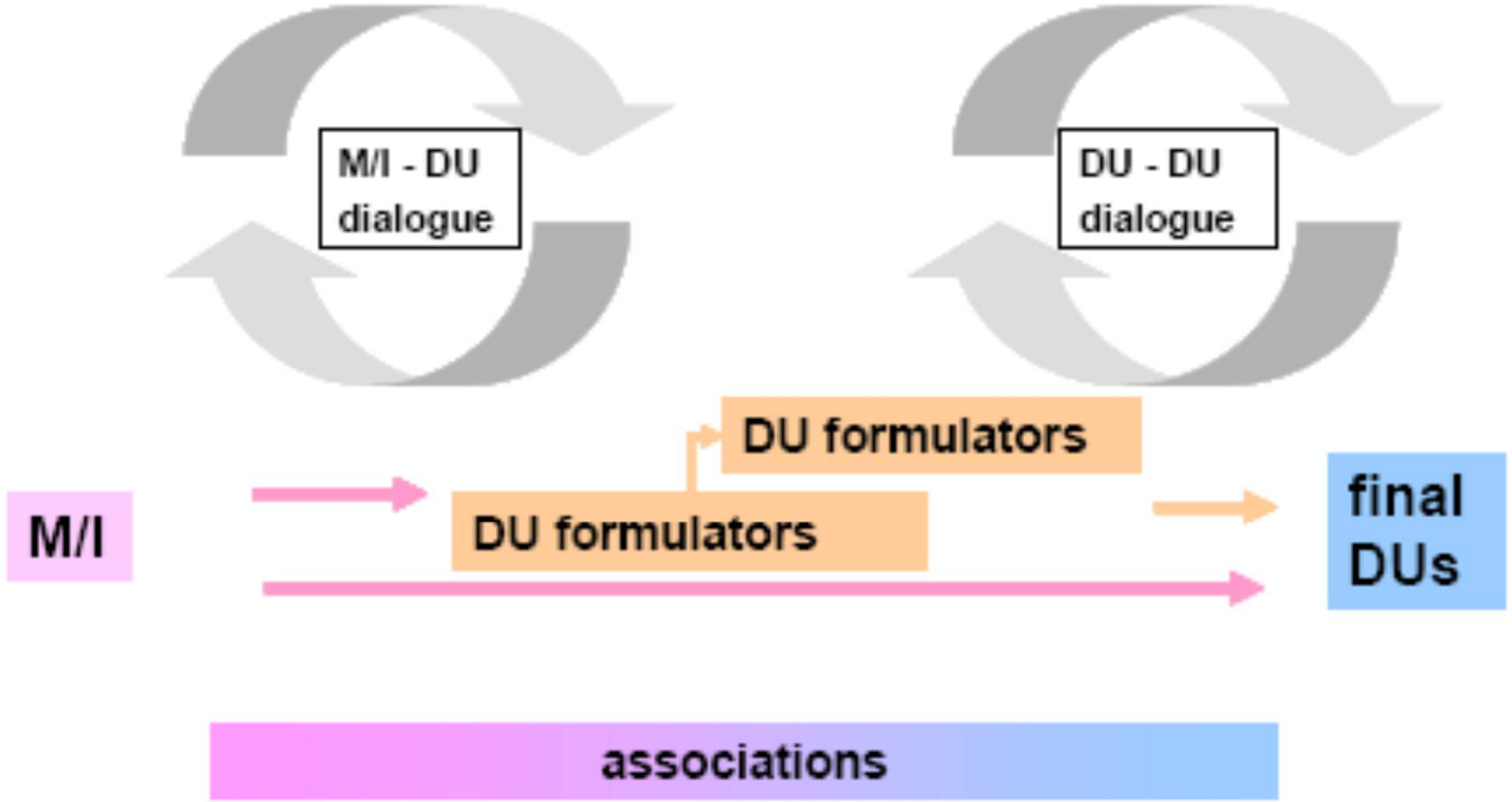
Dialogue in the supply chain

- **Interaction before registration:**
  - The downstream user has the right to make known his use(s), including supporting information on the conditions of use in writing one year before the corresponding registration deadline by the latest.
  - Also the manufacturers and importers may start a dialogue with representative customers to get more knowledge on the general or specific conditions of use downstream.
- **Interaction after registration:**
  - The downstream user can make his use known for registered substance at any time after registration.
  - The M/I is obliged to process the received information in order to decide whether:
    - he can include the use in one of the already existing exposure scenarios or
    - the registration needs to be updated with a new exposure scenario or
    - whether he is unable to support the use based on health and environment concerns.

Overall Dialogue process

- Identification of uses
- ES building
- Conducting CSA

- Making uses known to M/I
- Informing about conditions of use
- Giving feedback on ES



SDS-eSDS

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- **Communication in supply chain**
  - **Basic and binding document**
  - Limit values – DNELs, PNECs
  - National laguages
  - National specifics...
- Who is really responsible?
  - Producer or importer from EU / outside
  - Importer / distributor / market company
- When to up-date?
- What will happen once I get e-SDS???
  - Nothing / panic ?
  - Customers understand?

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(Pre)registration...??

- **Pre-registration/Registration** – duty to act - limiting the production and import
- ??Missed?? ??or not in compliance??

!out of the market!

- **Late pre-registration**
  - ?by other entity?
- New production? / import?:
  - late pre-registration
  - or ELINCS registration
  - or direct **REGISTRATION**

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Project implem

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Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED

REACH specific – EVALUATION, AUTHORISATION and RESTRICTION

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REACH & CLP Implementation – Challenging for Industry as well as for Authorities

- Pre-registration - Late Pre-registration
- Registration – SIEFs – CSR –
  - ESs – Dossier submission – up-dates
- Legal text - Guidance documents - The Directors' Contact Group (DCG)
- Restrictions
- Candidate list – Authorisation
- SDS – eSDS
- CLP
- Downstream Users - communication
- Consequences for market and occupational health
- Compliance - Enforcement

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Evaluation

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.

Evaluation under REACH focuses on three different areas:

- **Examination of testing proposals submitted by registrants**
- **Compliance check of the dossiers submitted by registrants**
- **Substance evaluation**

Once the evaluation is done, registrants may be required to submit further information on the substance.

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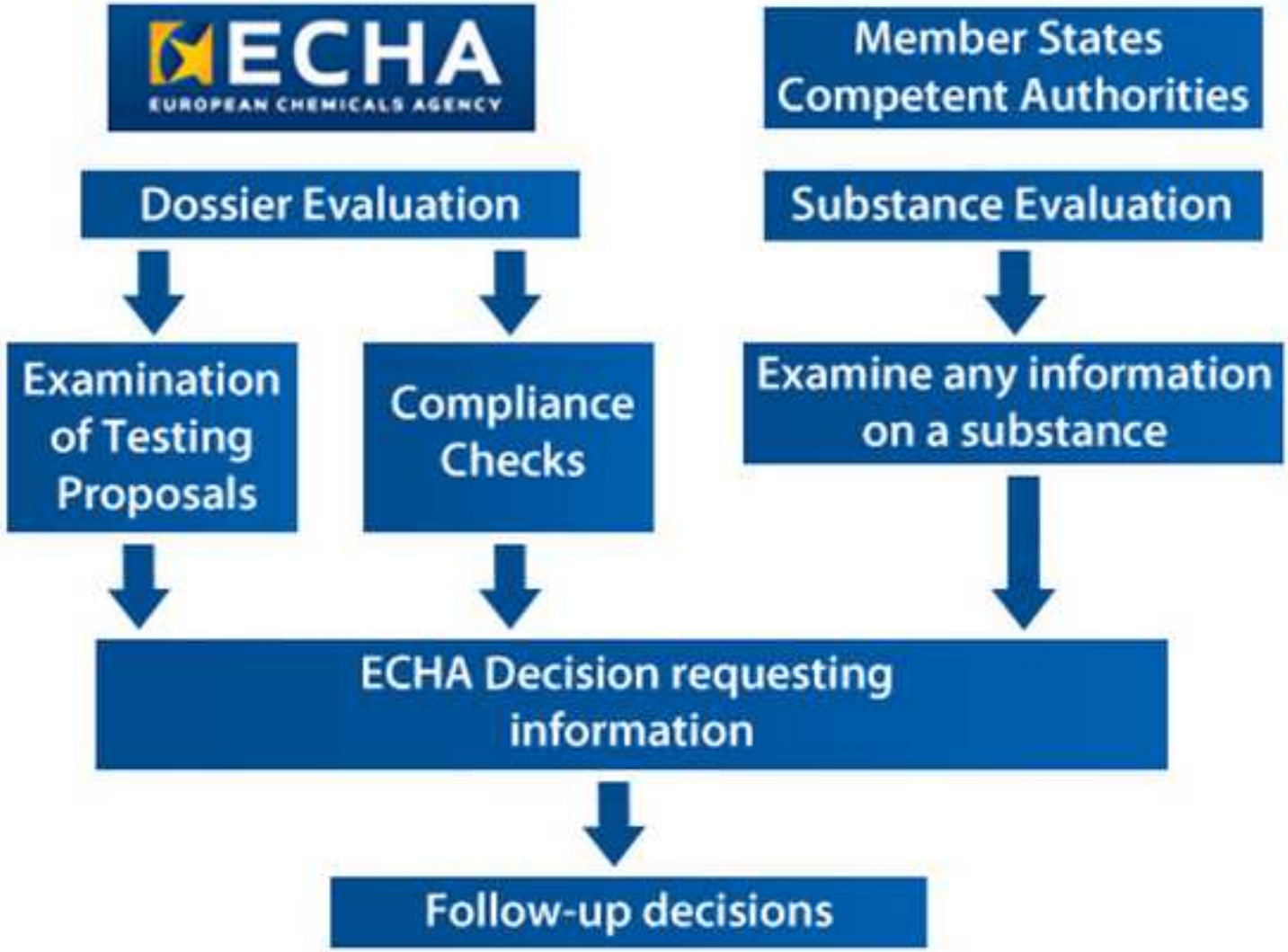
Evaluation: Overview



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ECHA Dossiers Evaluation

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TABLE 1: REGISTRATION DOSSIERS CHECKED BY TONNAGE BAND

Tonnage band	Total number of registrations submitted for the 2010 deadline (1 March 2011)	Registrations checked for compliance (31 December 2013)	Proportion checked
≥ 1000 t/a	17 551	1 063	6.0 %
100 to 1000 t/a	1 013	58	5.7 %
10 to 100 t/a	481	6	1.2 %
1 to 10 t/a	727	3	0.4 %
Total	19 772	1 130	5.7 %

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Compliance Check by ECHA

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TABLE 2: COMPLIANCE CHECKS CONCLUDED IN 2013, BY TONNAGE BAND

Tonnage band	Concluded with draft decisions	Concluded without action	Total
≥ 1000 t/a	500	323	823
100 to 1000 t/a	56	29	85
10 to 100 t/a	8	3	11
1 to 10 t/a	2	7	9
Total	566	362	928

Following 61 % of the compliance checks in 2013, ECHA concluded that the dossiers did not comply with the checked REACH information requirements and draft decisions were sent to the registrants. By the end of 2013, one fifth of these have become decisions taken.

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Enhancing concern-driven targeted checks

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In 2013, ECHA enhanced the computer-assisted selection of registration dossiers for targeted compliance checks and continued implementing this approach **to address severe non-compliances in all dossiers**. For targeted checks, computers are used to filter the whole registration database, picking out dossiers with a higher potential to be deficient in priority endpoints called areas of concern.

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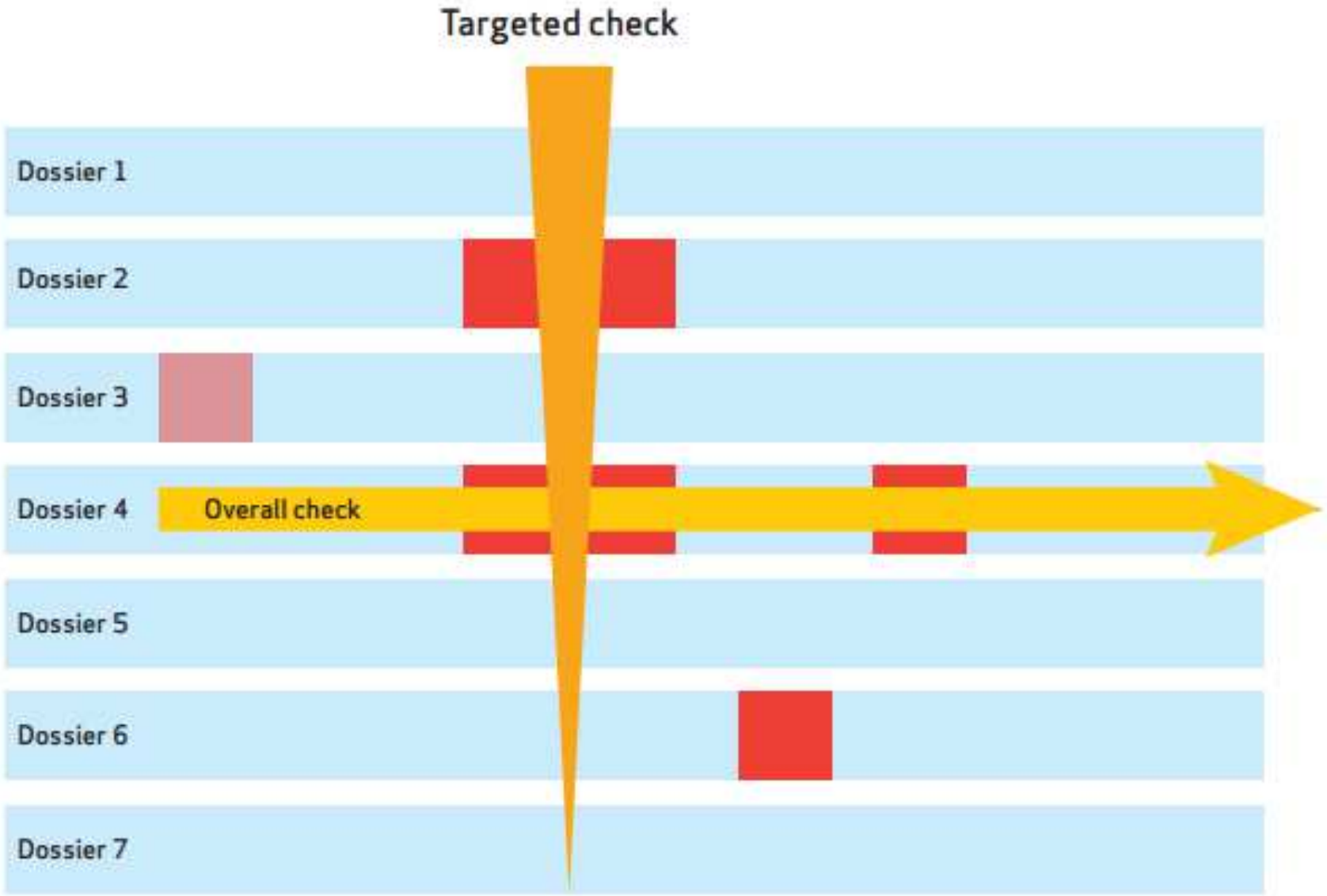

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TABLE 3: OUTCOME OF COMPLIANCE CHECK IN 2013, BY SELECTION CRITERIA

	Outcome Type					
Reason for selection	Concluded without further action[6]	Closed after draft decision[7]	Decision taken without amendment: Article 51(3)	Decision taken after ECHA MSC agreement:[8] Article 51(6)	Commission to take the decision: Article 51(7)	Total
Concern-driven overall CCh	20	3	22	3	0	48
Random	10	3	7	2	0	22
CCh targeted at areas of concern	273	84	83	0	0	440
CCh targeted to SID	6	0	6	0	0	12
CCh triggered by the substance evaluation process	41	4	8	4	0	57
CCh targeted to SID issues found during TPE	0	27	19	0	0	46
CCh targeted to other issues[9]	12	0	5	0	0	17
Total	362	121	150	9	0	642

TABLE 4: INFORMATION REQUESTED BY COMPLIANCE CHECK DECISIONS (SORTED BY ANNEX)

Type of information requested	Number of decisions
Exposure assessment and risk characterisation: Annex I	19
Robust study summaries: Annex I, 1.1.4 and 3.1.5	3
Information regarding identification and verification of the composition of the substance: Annex VI, 2	43
Brief general description of the identified use: Annex VI, 3.5	2
C&L according to CLP: Annex VI, 4	5
Physicochemical properties: Annex VII, 7	61
Toxicological information: Annex VII, 8	4
Toxicological information: Annex VIII, 8	15
… of which: *In vitro* cytogenicity study in mammalian cells: Annex VIII, 8.4.2	8
… of which: *In vitro* gene mutation study in mammalian cells: Annex VIII, 8.4.3	9
…of which: Screening for reproductive/developmental toxicity: Annex VIII, 8.7.1	1
Sub-chronic toxicity study, 90-day: Annex IX, 8.6.2	20
Pre-natal developmental toxicity: Annex IX, 8.7.2	20
Two-generation reproduction toxicity study:[10] Annex IX and X, 8.7.3	6
Ecotoxicological information: Annex IX, 9	4

Adoption of decisions under dossier evaluation

1. The Agency shall notify its draft decision in accordance with Articles 40 or 41, together with the comments of the registrant, to the competent authorities of the Member States.

2. Within 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency.

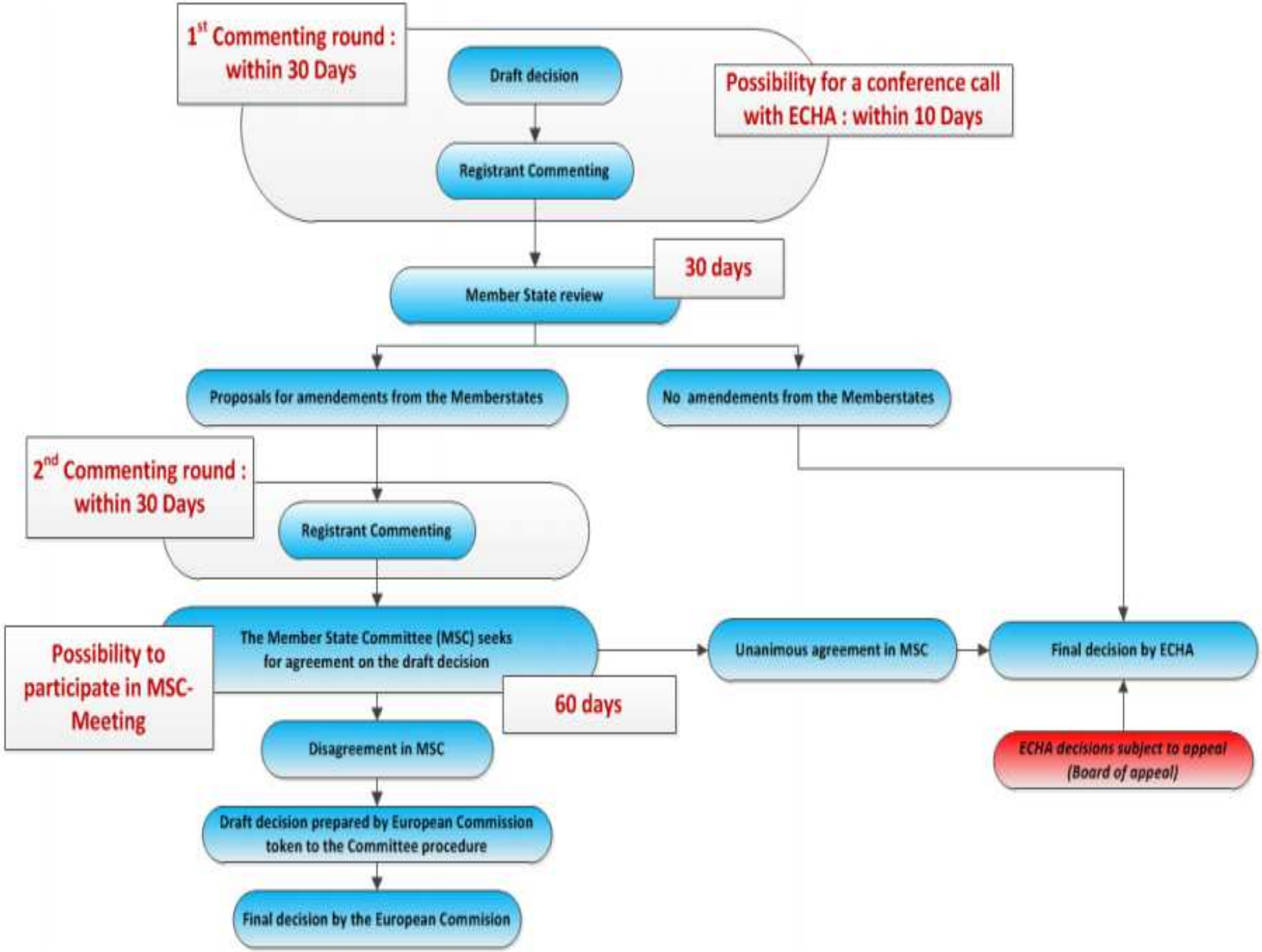
3. If the Agency does not receive any proposals, it shall take the decision in the version notified under paragraph 1.

4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

5. The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account.

6. If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

7. If the Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 133(3).


1st Commenting round : within 30 Days
Draft decision
Registrant Commenting
Possibility for a conference call with ECHA : within 10 Days
Member State review
30 days
Proposals for amendements from the Memberstates
No amendements from the Memberstates
2nd Commenting round : within 30 Days
Registrant Commenting
The Member State Committee (MSC) seeks for agreement on the draft decision
60 days
Possibility to participate in MSC-Meeting
Unanimous agreement in MSC
Final decision by ECHA
Disagreement in MSC
ECHA decisions subject to appeal (Board of appeal)
Draft decision prepared by European Commission token to the Committee procedure
Final decision by the European Commision

Incompliances (selection)

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- Unclear identity of the registered substance;
- Deficient justifications for adaptation to the standard information requirements, deviations from guidance, …
- Robust study summaries: insufficient level of detail provided;
- Classification and labelling: not in line with the hazards identified or harmonized classification and labelling;
- Inconsistencies IUCLID – CSR;
- …

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1. Keep your dossier up-to-date

Relevant for low-tonnage registrants

It is your duty to submit and maintain a compliant registration, so be proactive: Integrate REACH compliance into your quality management system.

Your registration dossier must be consistent and reflect the reality of your business.

Keep talking in the SIEF (substance information exchange forum) and in your supply chain, even after receiving your registration number.

Check REACH-IT regularly: This is ECHA's way of contacting you about issues found in your dossier. If you receive a message, you need to respond promptly.

When you prepare your dossier, use all available support material from ECHA, including guidance, IUCLID plug-ins (particularly the Validation Assistant) and Chesar.

ECHA's webinars are an easy and interactive way to learn about common pitfalls and how to avoid them.

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2. Know how to react if you get a (draft) decision

Relevant for low-tonnage registrants

Start to think carefully about how you will respond immediately after receiving a draft decision. The 30-day commenting period is your chance to give your views and bring your dossier into compliance.

It is even more important to keep talking in the SIEF if you receive a (draft) decision because it may impact on many registrants with the same substance: Endeavour to coordinate and respond to ECHA with one voice.

Understand the REACH decision-making procedure: The room for manoeuvre and the strict timing gets tighter as the process rolls on.

Remember ECHA and the Member States take regulatory action to help you and your customers to use the substance safely.

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3. Substantiate your reasoning if you adapt the standard testing regime

Relevant for low-tonnage registrants

Be specific on the legal basis for any adaptations you make and state it clearly at each endpoint; then justify and document how you have fulfilled the conditions that allow such an adaptation.

The adaptation needs to be adequate for the risk assessment, with a comparable level of confidence as the test it aims to replace.

For QSAR (quantitative structure-activity relationship), this means attaching the documentation in the right format in the right place, justifying fully why the model is valid and how it was applied to the substance. Just providing a number from an unspecified model will not do.

For read-across and category approaches, this means showing that the substances are very likely to be similar (eco-)toxicologically, preferably with a data matrix. A read-across hypothesis without a proper justification and supporting data will not be accepted.

If you need to propose a new test after all, do so explicitly by selecting "experimental study planned" at the endpoint in your IUCLID file.

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4. The chemical safety report should reflect the actual uses and risks

If your substance is PBT (persistent, bioaccumulative and toxic) after careful assessment and checking the Candidate List, show clearly in the chemical safety report how you are minimising its release.

When you derive the DNEL (derived no-effect level), justify and document any deviation from the default assessment factors presented in REACH Guidance R.8 with scientific arguments that are specific to your substance.

When assessing the exposure, consider the scope of exposure assessment based on the hazards identified for the substance.

When using a model for estimating exposure, consider the domain of applicability of the model, use appropriate modelling parameters and justify their selection.

The exposure scenarios in the report must be transparent, have exhaustive coverage and each must be specific. The operational conditions and the risk management measures have to be provided in sufficient detail and should ensure safe use.

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For testing proposal examinations, the options for the draft decision are:

- a decision accepting the testing proposal;
- a decision accepting the testing proposal with modifications of the testing conditions;
- a decision accepting or rejecting the testing proposal but requiring one or more additional tests;
- a decision rejecting the testing proposal, or
- a decision covering any of the three first options.

For a decision covering any of the first three options, where several proposals are submitted for the same substance and the same tests are proposed, an agreement as to who carries out the tests must be reached.

ECHA
EUROPEAN CHEMICALS AGENCY

Registrant's comments on draft decisions

Pursuant to Article 50(1) of the REACH Regulation, registrants have the possibility to comment on a draft decision prepared by ECHA or a competent authority of a Member State as a result of the evaluation of a registration dossier, i.e. compliance check, testing proposal examination or substance evaluation. Registrants are encouraged to use the present web-form only once, i.e. do not submit comments several times.

This web-form shall serve to registrants as a secure way to provide comments to an ECHA or a Member State competent authority draft decision (Article 50(1) REACH Regulation), as well as to provide comments to any proposal for amendment (Article 51(5) REACH Regulation). Registrants can in both cases comment within 30 days of receipt of the draft decision. The web-form should only be used after having received a specific invitation to comment that will arrive together with the draft decision through REACH-IT and should include the communication number from the draft decision.

ECHA and the competent authorities of the Member States as the case may be, will take any comments received into account and may amend the draft decision accordingly. If the registrant does not provide comments on the draft decision, the decision will be taken as notified to the registrant.

Please fill in the following fields. Compulsory fields are marked with an asterisk (*). When done, click the submit button below.

* Communication number	
* Registration number(s)	
* Substance name/IUPAC name	
CAS number	
EC number	
* Registrant	
* Comments submitted by *(contact person and address)*	
* Email	

* Comments refer to - select -

(Please select whether your response comments refer to a draft decision after a Compliance Check, a Testing Proposal examination or Substance Evaluation)

* Status of the draft decision - select -

(Please clarify whether your response comments refer to the initial draft decision or to the amendments proposed by the Member State competent authorities (MS-CAs))

No action towards the registrant

There is no administrative action if the dossier is considered compliant with the information requirements provided in REACH. However, this does not necessarily mean that there are no shortcomings in the dossier. A new additional compliance check can still start at any time.

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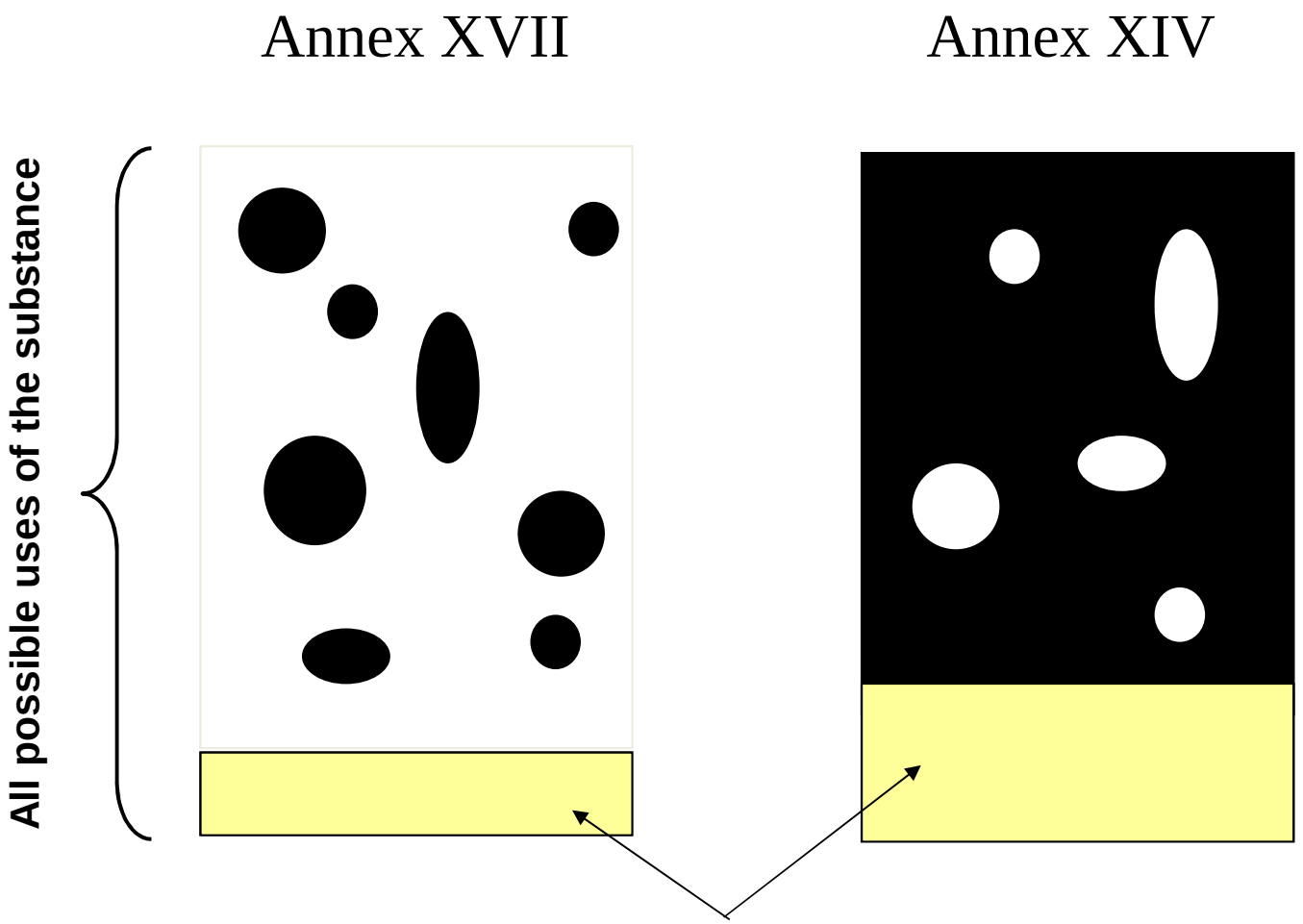
Restrictions & Authorization



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Restriction & Authorisation under REACH
Authorisation vs. Restriction

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Authorisation

- Ensure ***risk from SVHC are properly controlled*** & good functioning of the internal market
- ***Progressive replacing of SVHC*** by alternative substances or technologies, when technically and economically viable
- **Scope is limited** to the Downstream use of a substance
- Authorisation covers **all uses unless specifically exempted**

Restriction

- Address **a unacceptable risks** to human health or Environment that requires ***community wide action***
- **Covers wide scope**
  - Manufacturing
  - Use
  - Placing on the market
  - Substance
  - Substance in preparation
  - Substances in articles
  - all risks (not limited to SVHC)
- Limited to uses **focused on** by the restriction

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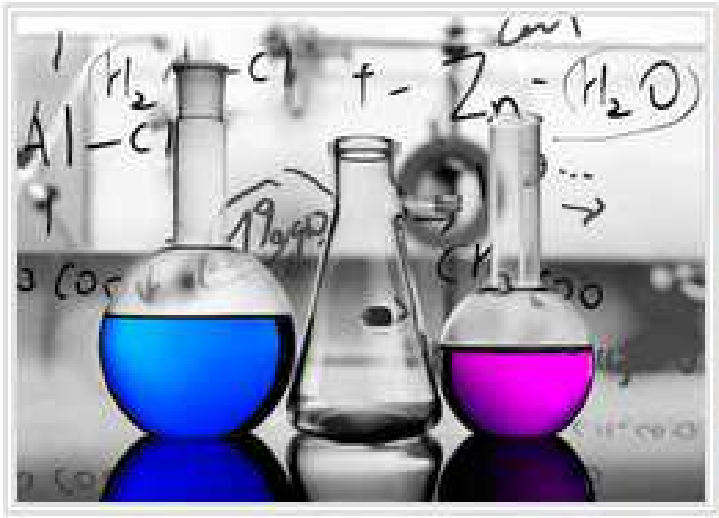
Authorisation

ECHA EUROPEAN CHEMICALS AGENCY

Substances of very high concern identification | Recommendation for inclusion in the Authorisation List | Applications for authorisation



Under the REACH Regulation, the route to authorisation starts when a Member State or ECHA, at the request of the Commission, proposes a substance to be identified as a substance of very high concern (SVHC). Where the substance is identified as an SVHC it is included in the Candidate List, for eventual inclusion in the Authorisation List. The SVHC identification process includes a period of public consultation which lasts for forty five days.

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COVER NOTE

from:	European Commission
date of receipt:	5 February 2013
to:	COREPER/Council
Subject:	Roadmap on Substances of Very High Concern

Delegations will find attached Commission document.

Environment and Climate Regional Accession Network ECRAN

Considering the long term, Vice President Tajani and Commissioner Potočnik have agreed to have **all currently known SVHCs included in the candidate list by 2020**. This second commitment means that by 2020, we will need to analyse the information on a large number of substances, not only to determine the relevance of SVHCs that are known today, but also to identify new potential SVHCs that will come out of REACH registration and evaluation.

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SVHC Roadmap implementation plan

A plan has been developed on how to implement the SVHC Roadmap until 2020. The SVHC Roadmap implementation plan focuses on how the following work can be organised, coordinated and carried out:

- Screening to identify new substances of concern, and

- Analysing the risk management options (RMOs) appropriate to the particular substance of concern.

The implementation plan also provides an outline of how progress monitoring and communication towards stakeholders and the general public is envisaged.

› Roadmap implementation plan, December 2013 [PDF]

› **Finding and analysing new substances for regulatory risk management**

› **Screening**

› **RMO analysis**

See also

› SVHC Roadmap to 2020 [PDF] [EN]

› The Candidate List

Substance specific groups

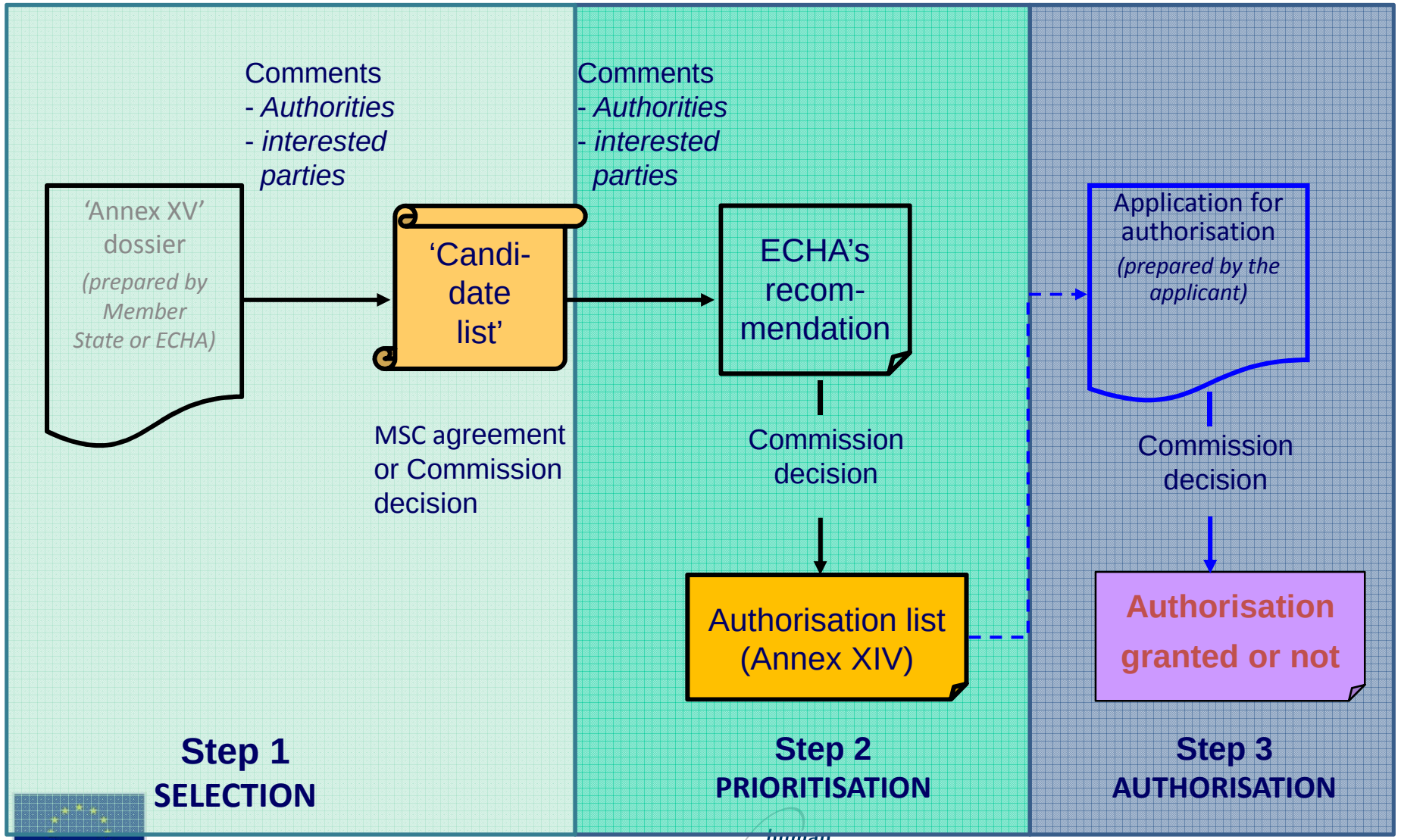
› PBT Expert Group

› ED Expert Group

› CMR Coordination Group

› Sensitiser Coordination Group

Three steps in authorisation process



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Substances with the following hazard properties may be identified as Substances of Very High Concern (SVHCs):

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances);

- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII);

- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances;

After a two-step regulatory process, SVHCs may be included in the Authorisation List and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

Candidate List

of Substances of Very High Concern for Authorisation

The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorisation procedure.

Companies may have immediate legal obligations following such inclusion which are linked to the listed substance on its own, in preparations and articles.

Further documentation or more detailed information on the identification process of substances of very high concern can be found on the web pages of ECHA's Member State Committee.

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Candidate List 151 (last updated: 16 December 2013)

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Candidate List table

Note: The EC number includes both anhydrous and hydrated forms of a substance and consequently the entries cover both these forms. The CAS number included may be for the anhydrous form only, and therefore the CAS number shown does not always describe the entry accurately.

› Candidate List introduction

Substance Details

Substance Name	Pitch, coal tar, high temp.
EC Number	266-028-2
CAS Number	65996-93-2
Date of inclusion	2010/01/13
Reason for inclusion	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)
Decision number	ED/68/2009
IUCLID 5 Substance Dataset	
Substance composition	-
Supporting documentation	

EC number, CAS number: the EC number includes both anhydrous and hydrated forms of a substance and consequently the entries cover both these forms. The CAS number included may be for the anhydrous form only, and therefore the CAS number shown does not always describe the entry accurately.

Note:
The previously used common names for Lead oxide sulfate (EC no. 234-853-7) and [Phthalato(2-)]dioxotrilead (EC no. 273-688-5) (basic lead sulfate and dibasic lead phthalate, respectively) are ambiguous and therefore have been replaced.

Substance Name	EC Number	CAS Number	Dossier submitted by	Submission date	Scope	
Perboric acid, sodium salt; sodium perborate	234-390-0; 239-172-9		Denmark	03/02/2014	CMR	Details
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Sweden	03/02/2014	CMR	Details
Cadmium chloride	233-296-7	10108-64-2	Sweden	03/02/2014	CMR; Other;	Details
Sodium peroxometaborate	231-556-4	7632-04-4	Denmark	03/02/2014	CMR	Details
Trixylyl phosphate	246-677-8	25155-23-1	Austria	05/08/2013	CMR	Details
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3	1937-37-7	Netherlands	05/08/2013	CMR	Details
Dihexyl phthalate	201-559-5	84-75-3	Germany	05/08/2013	CMR	Details
Cadmium sulphide	215-147-8	1306-23-6	Sweden	05/08/2013	CMR, Other	Details
Lead di(acetate)	206-104-4	301-04-2	Netherlands	05/08/2013	CMR	Details

Imidazolidine-2-thione; (2-imidazoline-2-thiol)	202-506-9	96-45-7	Sweden	05/08/2013	CMR	Details
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4	573-58-0	Netherlands	05/08/2013	CMR	Details
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	Germany	04/02/2013	CMR, PBT	Details
Dipentyl phthalate (DPP)	205-017-9	131-18-0	Poland	04/02/2013	CMR	Details
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3	Germany	04/02/2013	PBT	Details
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	Germany	04/02/2013	PBT	Details
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1	Germany	04/02/2013	PBT	Details
Cadmium	231-152-8	7440-43-9	Sweden	04/02/2013	CMR, Other	Details
4-Nonylphenol, branched and linear, ethoxylated *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]*	-	-	Germany	04/02/2013	ED	Details
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	Germany	04/02/2013	PBT	Details
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	Germany	04/02/2013	CMR, PBT	Details

Autorization List (Annex XIV)

- 5-tert-butyl-2,4,6-trinitro-m-xylene,
- Alkanes,C10-13,chloro (short chain chlorinated paraffins; SCCPs),
- Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified,
- 4,4'-Diamino diphenyl methane (MDA),
- Bis (2-ethylhexyl) phthalate (DEHP),
- Benzyl butyl phthalate (BBP),
- Dibutyl phthalate (DBP)

  - sunset dates: ***21 Aug 2014 - 25 Feb 2015***
  - latest application dates: ***21 Feb 2013 - 21 Aug 2013***

COMMISSION REGULATION (EU) No 143/2011

of 17 February 2011

amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH')

In Annex XIV to Regulation (EC) No 1907/2006 the following table is inserted:

'Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date (1)	Sunset date (2)		
1.	5-tert-butyl-2,4,6-trinitro-m-xylene **(Musk xylene)** EC No: 201-329-4 CAS No: 81-15-2	vPvB	21 January 2013	21 July 2014	—	—
2.	4,4'-Diaminodiphenylmethane **(MDA)** EC No: 202-974-4 CAS No: 101-77-9	Carcinogenic (category 1B)	21 January 2013	21 July 2014	—	—
3.	Hexabromocyclododecane **(HBCDD)** EC No: 221-695-9, 247-148-4, CAS No: 3194-55-6 25637-99-4 alpha-hexabromocyclododecane CAS No: 134237-50-6, beta-hexabromocyclododecane CAS No: 134237-51-7 gamma-hexabromocyclododecane CAS No: 134237-52-8	PBT	21 January 2014	21 July 2015	—	—

4.	Bis(2-ethylhexyl) phthalate (**DEHP**) EC No: 204-211-0 CAS No: 117-81-7	Toxic for reproduction (category 1B)	21 July 2013	21 January 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.
5.	Benzyl butyl phthalate (**BBP**) EC No: 201-622-7 CAS No: 85-68-7	Toxic for reproduction (category 1B)	21 July 2013	21 January 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.
6.	Dibutyl phthalate (**DBP**) EC No: 201-557-4 CAS No: 84-74-2	Toxic for reproduction (category 1B)	21 July 2013	21 January 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.

Restriction

Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment. A Member State, or ECHA on request of the European Commission, can propose restrictions.

Public consultation on restriction proposal

Anyone can comment on a proposal to restrict a substance. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

Comments are welcomed from the EU or beyond.

The public consultation lasts for six months.

Public consultation on SEAC draft opinions

After publishing the draft opinion of SEAC, ECHA organises another public consultation where all interested parties may comment only on the SEAC draft opinion. Other comments cannot be taken into account.

Comments are welcomed from the EU or beyond.

The consultation lasts for 60 days after the publication of SEAC's draft opinion.

List of Restrictions

The list of restrictions contains those substances (on its own, in a mixture or in an article) for which manufacture, placing on the market or use is limited or banned in the European Union.

This list is Annex XVII to REACH and includes all the restrictions adopted in the framework of REACH and the previous legislation, Directive 76/769/EEC. Each entry shows the substance or group of substances or the mixture, and the conditions of their restriction.

The latest consolidated version of REACH presents the restrictions adopted until that date. Subsequent changes are included in the amending Commission regulations.

See also

- Restrictions website of the European Commission
- Questions and Answers on Restrictions
- Guidelines related to Restriction entries [PDF] [EN]
- Restrictions under consideration

List of restrictions table

Environment and Climate Regional Accession Network ECRAN

Showing 1 - 20 of 104 results. Items per Page 20 Page 1 of 6 First | Previous | Next | Last

Entry no	Substance / group of substances / mixture	EC Number	CAS Number	Consolidated text	Appendix	New amendment (EU Regulation)	Q&A	Standards
1	Polychlorinated terphenyls (PCTs)			Page 217				
2	Chloroethylene (Vinyl chloride)	200-831-0	75-01-4	Page 217				
3	Liquid substances or mixtures, which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F; (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10; (c) hazard class 4.1; (d) hazard class 5.1.			Page 217				EN 14059:2002

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4	Tris (2,3 dibromopropyl) phosphate		126-72-7	Page 218				
5	Benzene	200-753-7	71-43-2	Page 219				
6a	Asbestos fibres, (a) Crocidolite		12001-28-4	Page 219	Appendix 7			
6b	Asbestos fibres (b) Amosite		12172-73-5	Page 219	Appendix 7			
6c	Asbestos fibres (c) Anthophyllite		77536-67-5	Page 219	Appendix 7			
6d	Asbestos fibres (d) Actinolite		77536-66-4	Page 219	Appendix 7			
6e	Asbestos fibres (e) Tremolite		77536-68-6	Page 219	Appendix 7			
6f(1)	Asbestos fibres (f) Chrysotile		12001-29-5	Page 219	Appendix 7			
6f(2)	Asbestos fibres (f) Chrysotile		132207-32-0	Page 219	Appendix 7			
7	Tris(aziridinyl)phosphinoxide	208-892-5	545-55-1	Page 220				
8	Polybromobiphenyls; Polybrominatedbiphenyls (PBB)		59536-65-1	Page 220				
9a	(a) Soap bark powder (Quillaja saponaria) and its derivatives containing saponines	273-620-4	68990-67-0	Page 220				
9b	(b) Powder of the roots of Helleborus viridis and Helleborus niger			Page 221				
9c	(c) Powder of the roots of Veratrum album and Veratrum nigrum			Page 221				

EU legislation: Oil lamps and liquid substances in decorative articles

Climate Network ECRAN

Introduction

If you want to export oil lamps or decorative articles containing liquids to the EU, you have to make sure that your products meet all legal requirements set for these products.

Lamp oils and other liquids in decorative articles can be toxic and cause injury to the lungs, if ingested. A number of EU Member States experienced a death record of two to three deaths per year caused by the ingestion of lamp oils. The majority of incidents involve young children, who appear to be attracted to the colour and smell of the oil and drink it directly from the lamp confusing lamp oils with lemonade.

In order to prevent these incidents, the EU has laid down requirements on the design of oil lamps Moreover, it prohibits the use of 'dangerous' lamp oil and other liquids used in ornamental objects and sets labelling and packaging requirements.

The Regulation **prohibits** the use of liquid substances or mixtures which are classified as **"dangerous"** in the following products:

1. Ornamental objects intended to produce light or colour effects (e.g.in ornamental lamps and ashtrays)
2. Tricks and jokes
3. Games (including games with ornamental aspects)

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When is a substance or preparation classified as "dangerous"?

Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances defines when a substance is classified as "dangerous". This Directive also defines which substances should be labelled with the above mentioned R(isk) an H(azard) phrases.
A substance is considered "dangerous" if it is classified in one of the following categories:

Explosive

Oxidising

(Highly) flammable

Toxic

Harmful or Irritant

Corrosive

Please note that Directive 67/548/EEC is currently being replaced by Regulation (EC) 1272/2008, which implements a Globally Harmonised System for the classification, labelling and packaging of chemicals (GHS).

➲ For more information on this new system and the gradual repeal of the old legislation, refer to the related document.

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IT Organization under REACH

Presented by: Ms. Shufan Qi
RPS advies- en ingenieursbureau The Netherlands

Montenegro

13 – 15 May 2014

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Registration under REACH

Covers all New and Existing substances > 1 t

Industry supplies following Information for registration:

- ✓ *Identity and Phys-Chem/Tox./Ecotox. properties*
- ✓ *Use category, exposure estimation addressing also downstream users*
- ✓ *Quantities produced*
- ✓ *Proposal for Classification and Labeling*
- ✓ *Safety Data Sheet (SDS)*
- ✓ *Provisional Risk Assessment (also for downstream use)*
- ✓ *Means of Risk management*

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IT Organisation under REACH

REACH-IT

Agency portal, workflow (for Agency and MS), etc.

IUCLID 5

- ✓Collecting & submitting information on substances for all actors:
  - ➢Industry: pre-registration/registration/application for authorisations
  - ➢Agency & MS: Annex XIV dossiers, Dossier and substance evaluation
- ✓and all regulatory programes: EC, OECD, US-EPA, etc.

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REACH-IT	IUCLID 5
Web-based application [Unique central system installed at ECHA]	1. Client-server application 2. Stand-alone application [Decentralised system, installed locally]
Restricted to REACH Regulation	Used globally, and for other regulatory purposes in addition to REACH (e.g. OECD HPV chemicals programme (HPV), EU Biocides legislation, ect.)
Application where dossiers are submitted by users	Application which captures and stores information on chemicals for various regulatory purposes, globally
Multi-party system where Industry and Autority parties co-exist	Each installation is essentially a single-party system

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REACH-IT	IUCLID 5
For registration Late Pre-registration Inquiry dossier submission NONS Notification of PPORD Substance in articles notification DU Report C&L Inventory	For registration *Prepare dossiers for (t.e.)* ✓ Registration, PPORD ✓ Annex VX *Notification of* ✓ Classification and Labelling ✓ Substances in articles ✓ Inquiries
Helpdesk REACH IT helpdesk for REACH registrants only	IUCLID5 helpdesk for users ✓REACH registrants (manufacturers, importers, downstream users, only representatives, 3rd party representatives) ✓Member States Competent Authorities ✓ECHA internally ✓European Chemical Bureau ECB (Biocides) ✓OECD users in USA, CAN, JPN, ...(companies and authorities for HPV…)

REACH-IT

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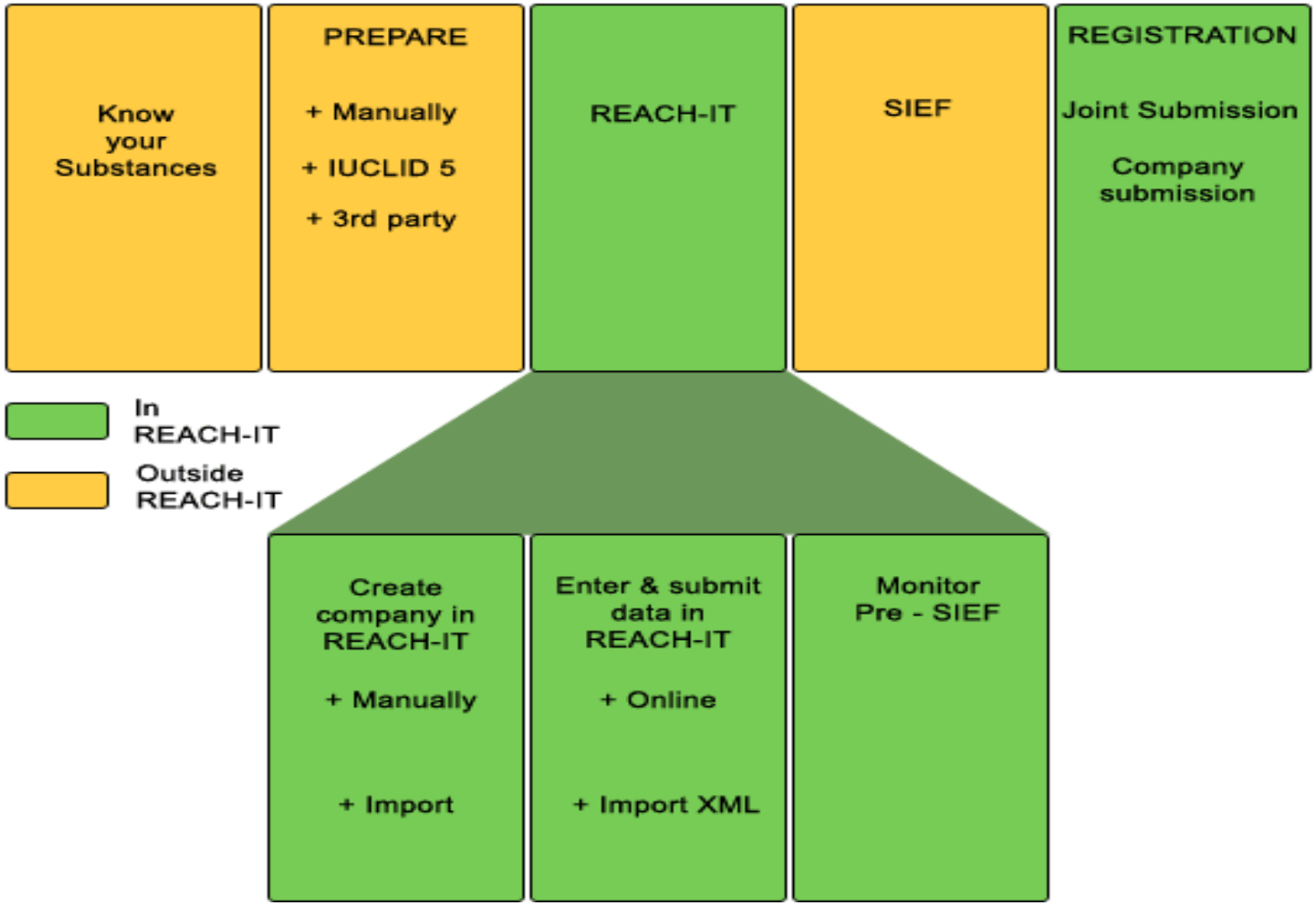

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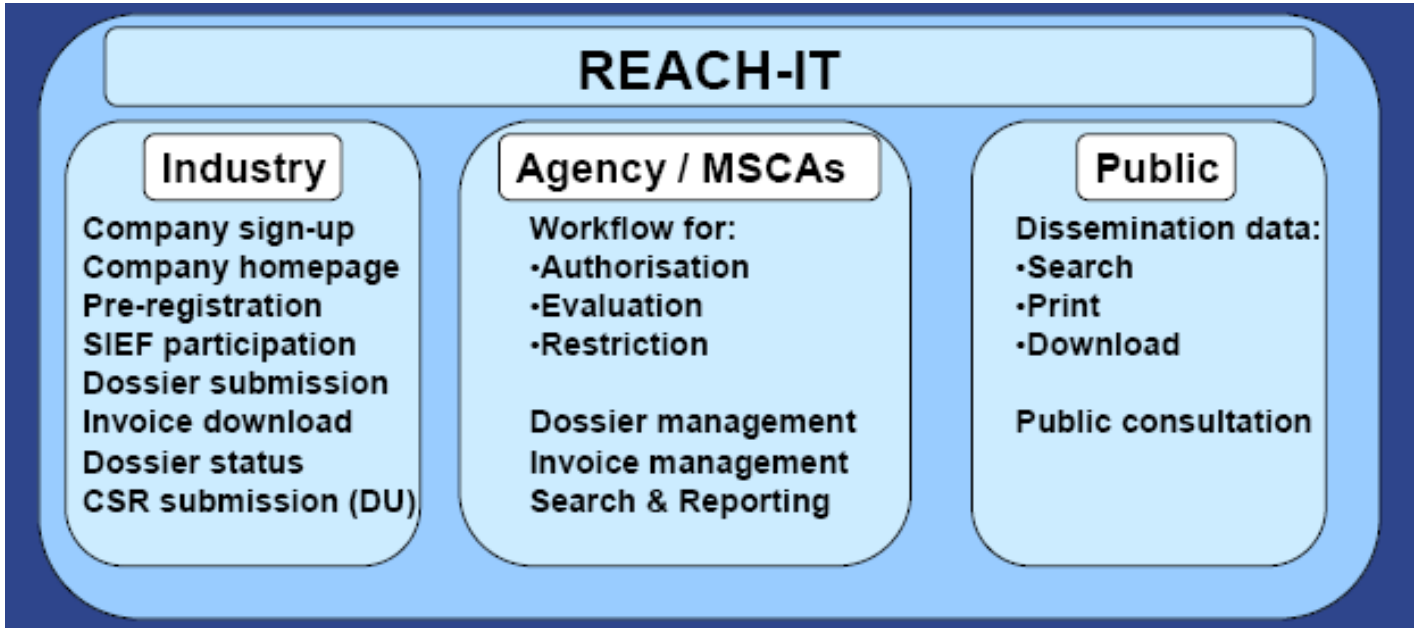

https://reach-it.echa.europa.eu/reach/public/welcome.faces

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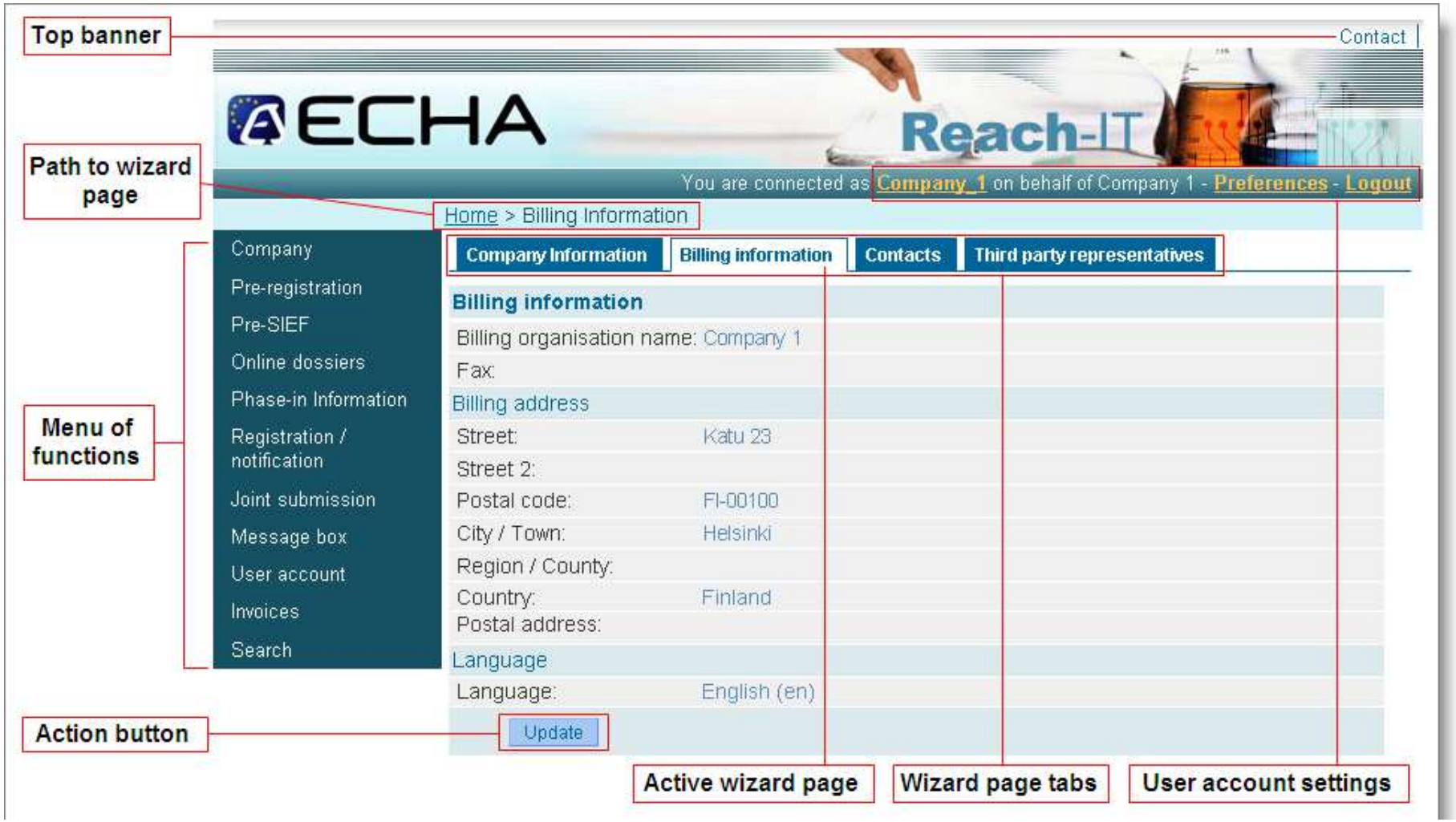

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REACH IT - Sign up

✓Create a REACH-IT account

✓Provide company information:

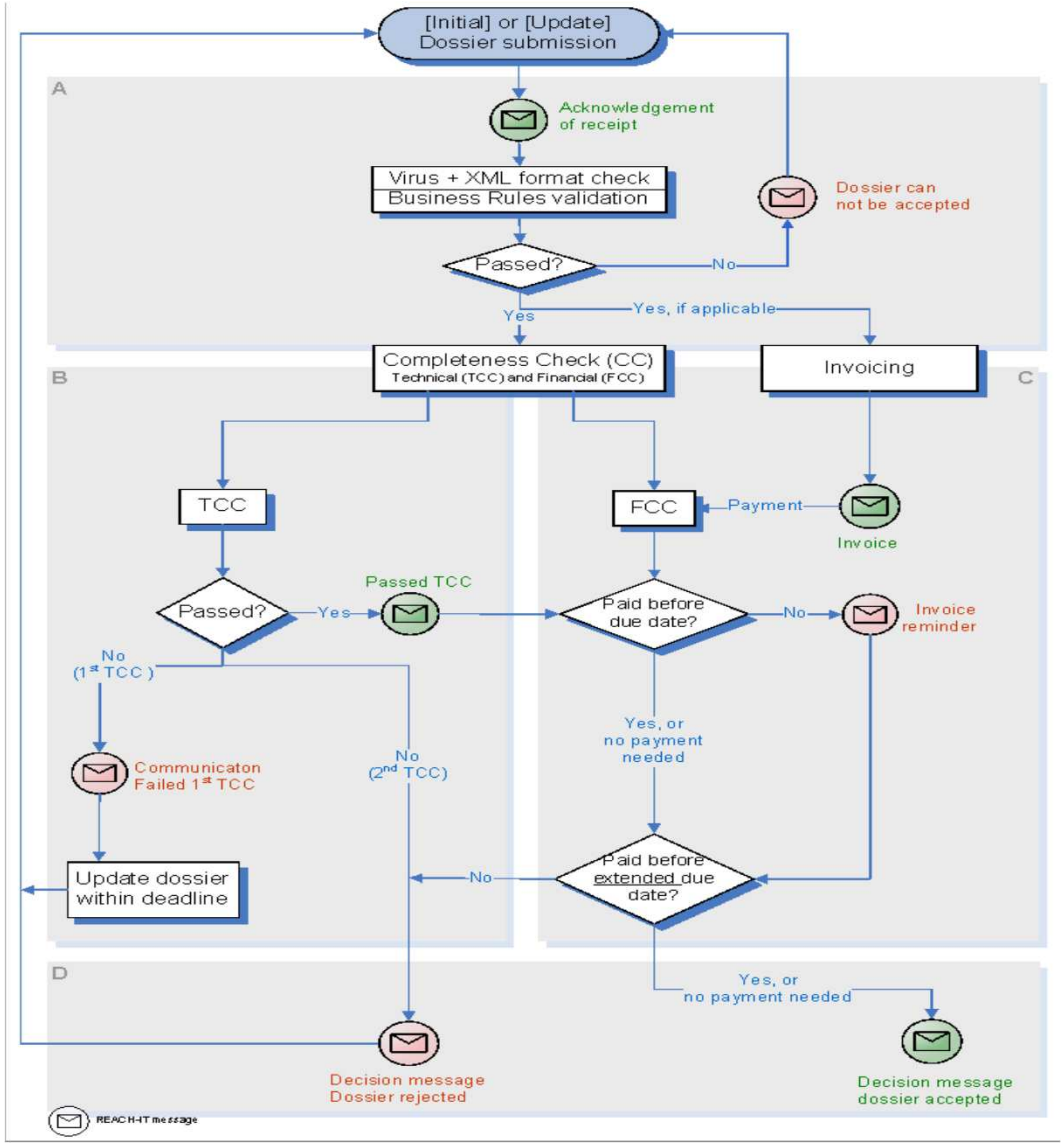
- by uploading it to REACH-IT if (via a Legal Entity definition file (LEO) in IUCLID 5)
- directly entering it in the REACH-IT application

✓Enter company billing information

✓Add information about contact persons within the company

✓Validate the entered data

Submission to ECHA



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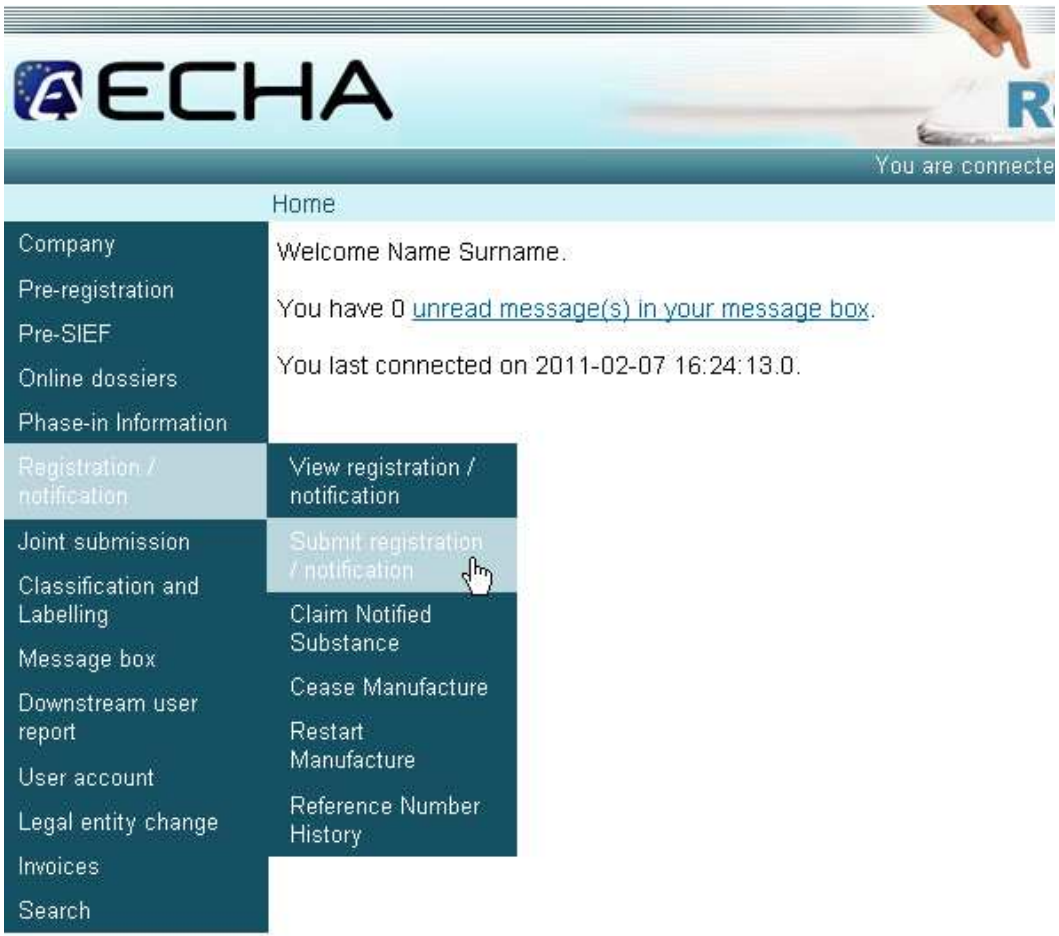
Overview of dossier types supported by REACH-IT

Dossier type	Submission	Submission update	Joint Submission
Registration	Yes	Yes	Yes
Registration of on-site isolated intermediate	Yes	Yes	Yes
Registration of transported isolated intermediate	Yes	Yes	Yes
Process and Product Oriented Research and Development (PPORD) notification	Yes	Yes	No
Classification and Labelling (C&L) notification	Yes	Yes	No
Inquiry notification	Yes	No	No
Substance in article notification	Yes	Yes	No
Downstream user report	Yes	Yes	No

Step-by-step dossier submission



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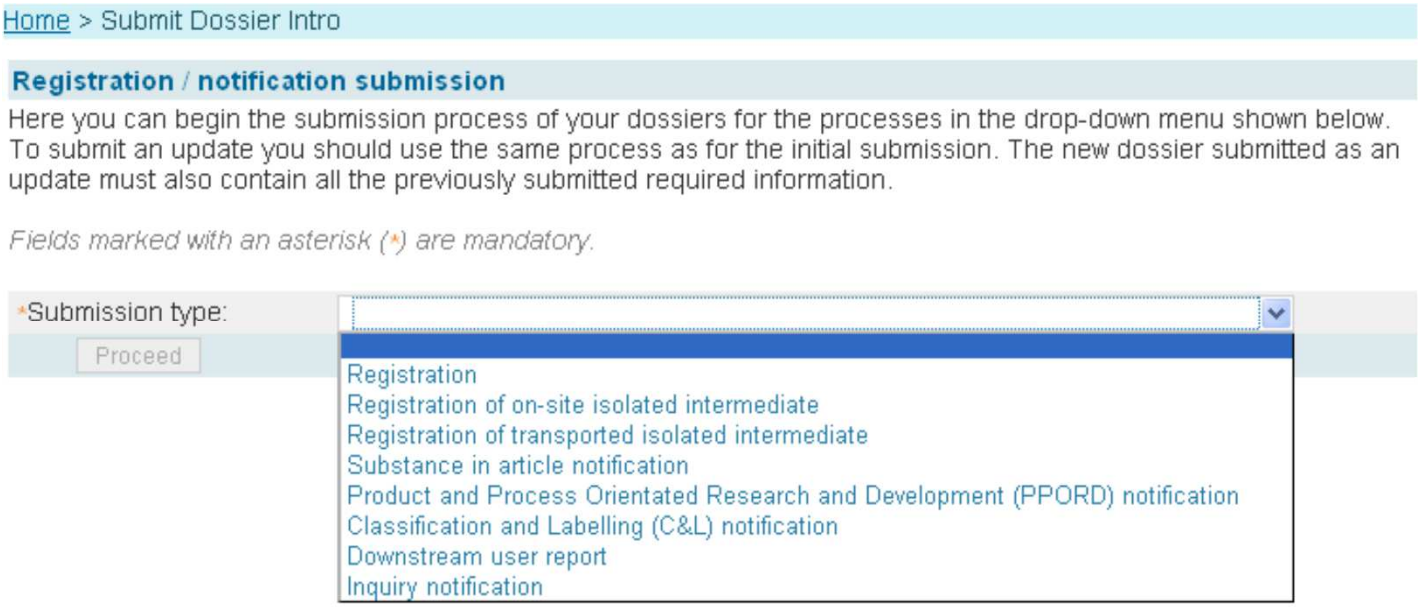

Home > Submit Dossier Intro
Registration / notification submission
Here you can begin the submission process of your dossiers for the processes in the drop-down menu shown below. To submit an update you should use the same process as for the initial submission. The new dossier submitted as an update must also contain all the previously submitted required information.
Fields marked with an asterisk (*) are mandatory.
*Submission type:
Proceed
Registration
Registration of on-site isolated intermediate
Registration of transported isolated intermediate
Substance in article notification
Product and Process Orientated Research and Development (PPORD) notification
Classification and Labelling (C&L) notification
Downstream user report
Inquiry notification

Home > Submit Dossier Intro > Submit External Dossier

Regular registration dossier submission

Please pick here using the "Browse" button the file which contains your dossier (your file should have been created using IUCLID 5 and have the extension "i5z")

* File name: Browse...

* Enter the text shown: ?

Can't read the text below? **Try another**

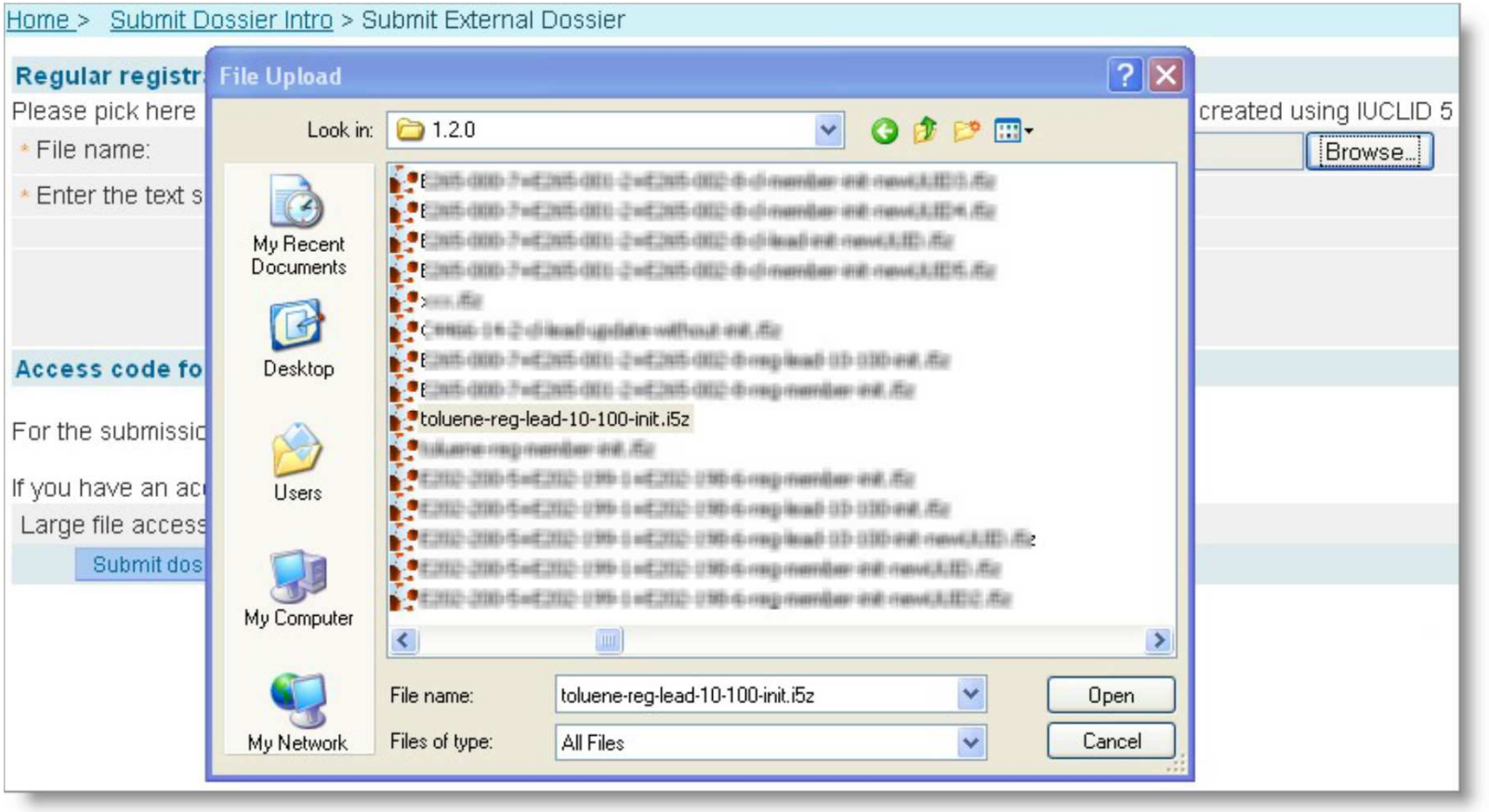
Access code for large files

For the submission of a file larger than 20 MB, please request a large file access code before submission.

If you have an access code for a large dossier, please, enter it here

Large file access code:

Submit dossier



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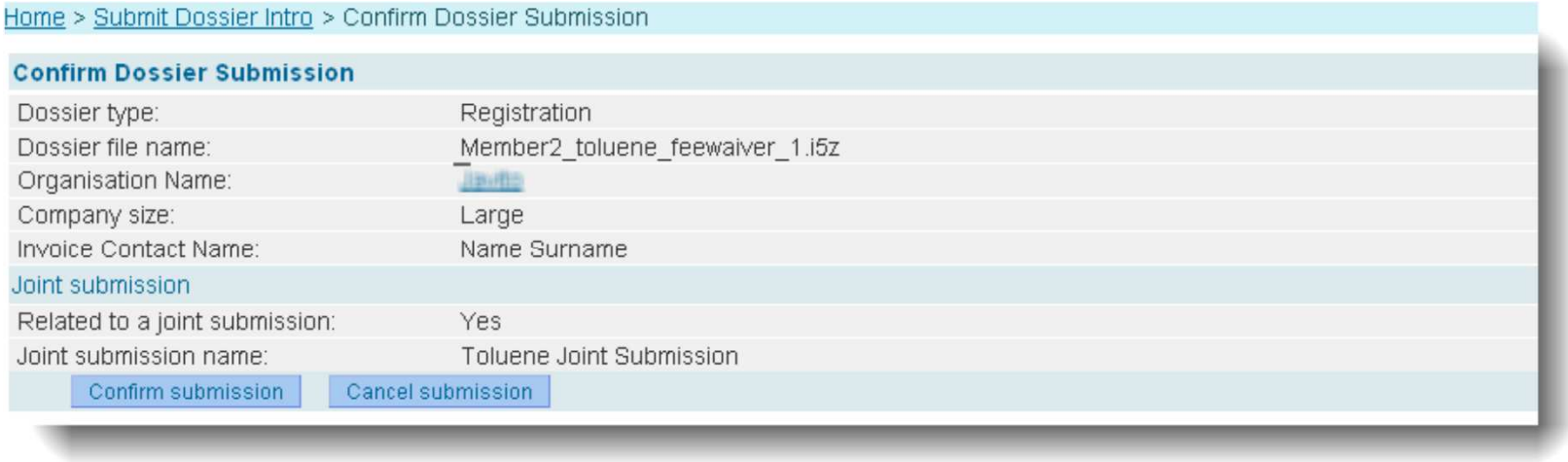

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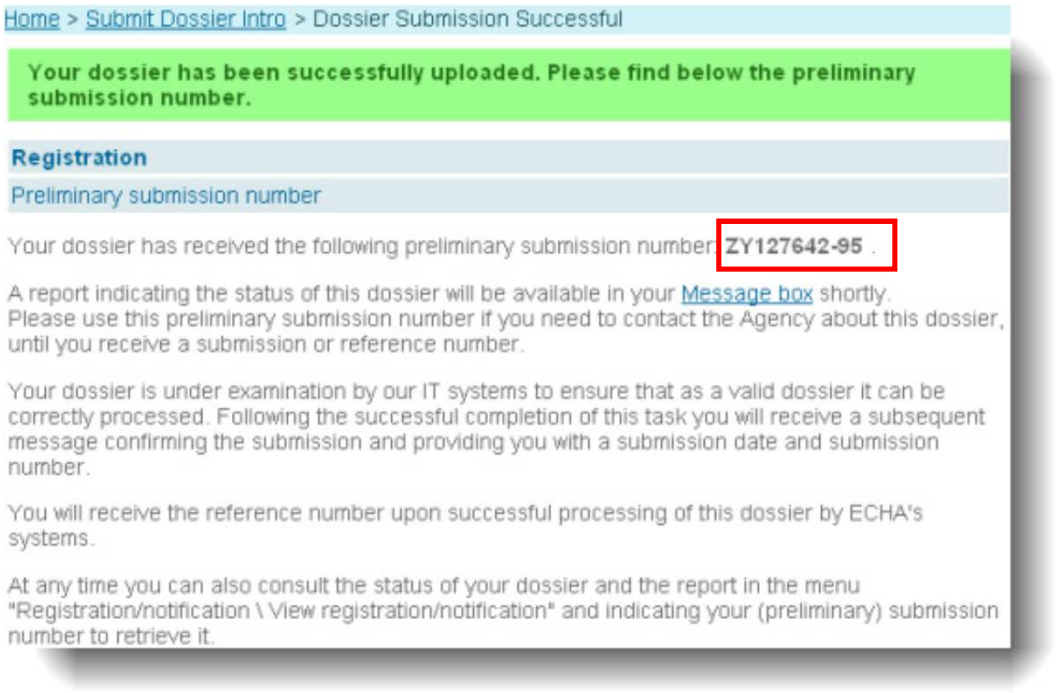
Home > Submit Dossier Intro > Dossier Submission Successful
Your dossier has been successfully uploaded. Please find below the preliminary submission number.
Registration
Preliminary submission number
Your dossier has received the following preliminary submission number: ZY127642-95 .
A report indicating the status of this dossier will be available in your Message box shortly.
Please use this preliminary submission number if you need to contact the Agency about this dossier, until you receive a submission or reference number.
Your dossier is under examination by our IT systems to ensure that as a valid dossier it can be correctly processed. Following the successful completion of this task you will receive a subsequent message confirming the submission and providing you with a submission date and submission number.
You will receive the reference number upon successful processing of this dossier by ECHA's systems.
At any time you can also consult the status of your dossier and the report in the menu "Registration/notification \ View registration/notification" and indicating your (preliminary) submission number to retrieve it.

IUDLID 5

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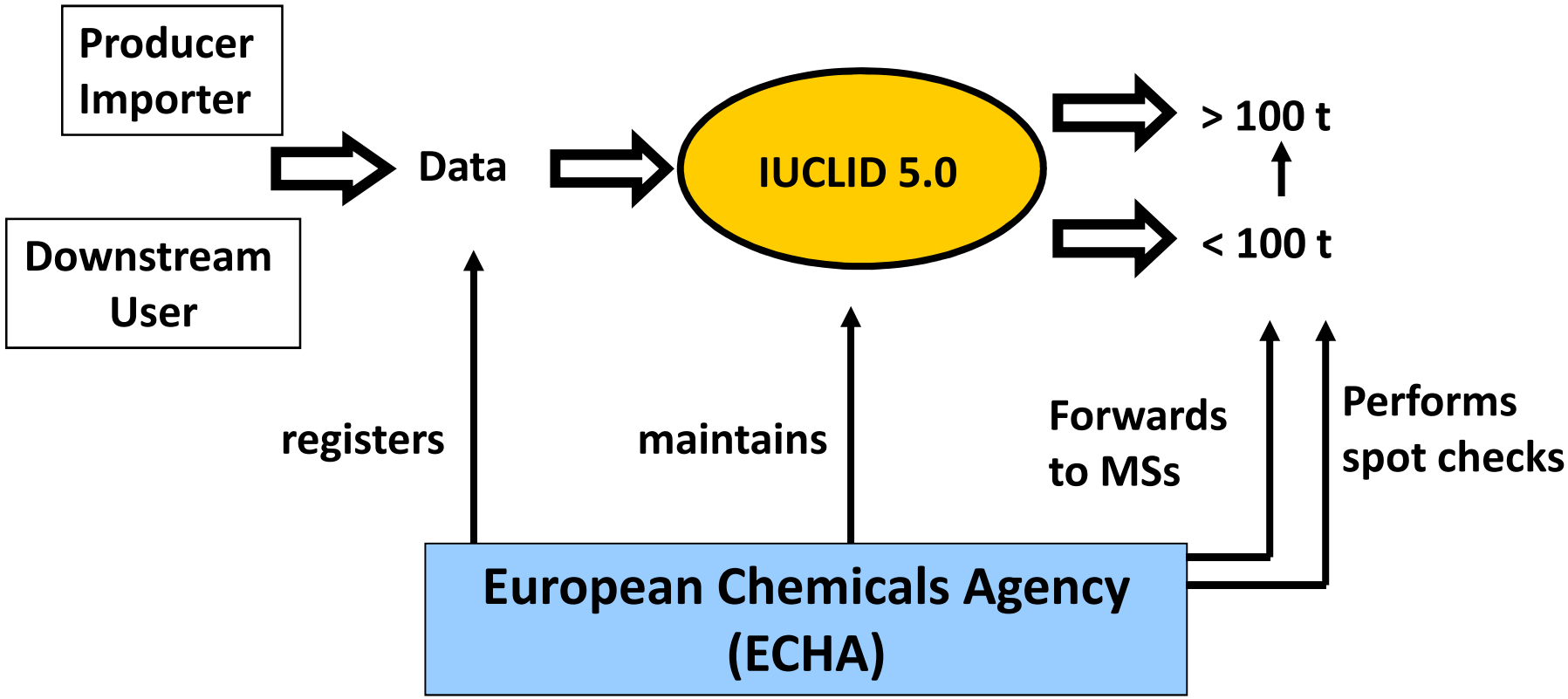

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IUCLID

✓Industry: tool for capturing data on chemicals preparing and submitting dossiers

✓Agency & MS: central data repository for all dossiers submitted; basis for dossier compliance check and substance evaluation; tool for preparing Annex XIV dossiers; basic for priority setting, data mining, etc.

✓Accessed centrally by Agency & MS CA

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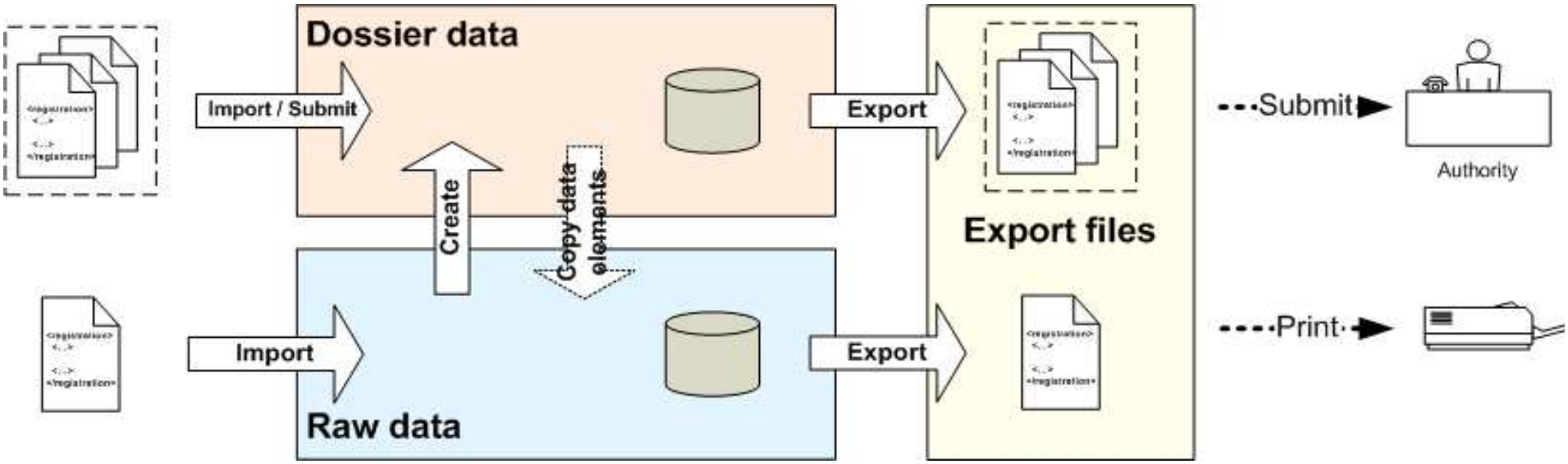
IUCLID - Operations on data



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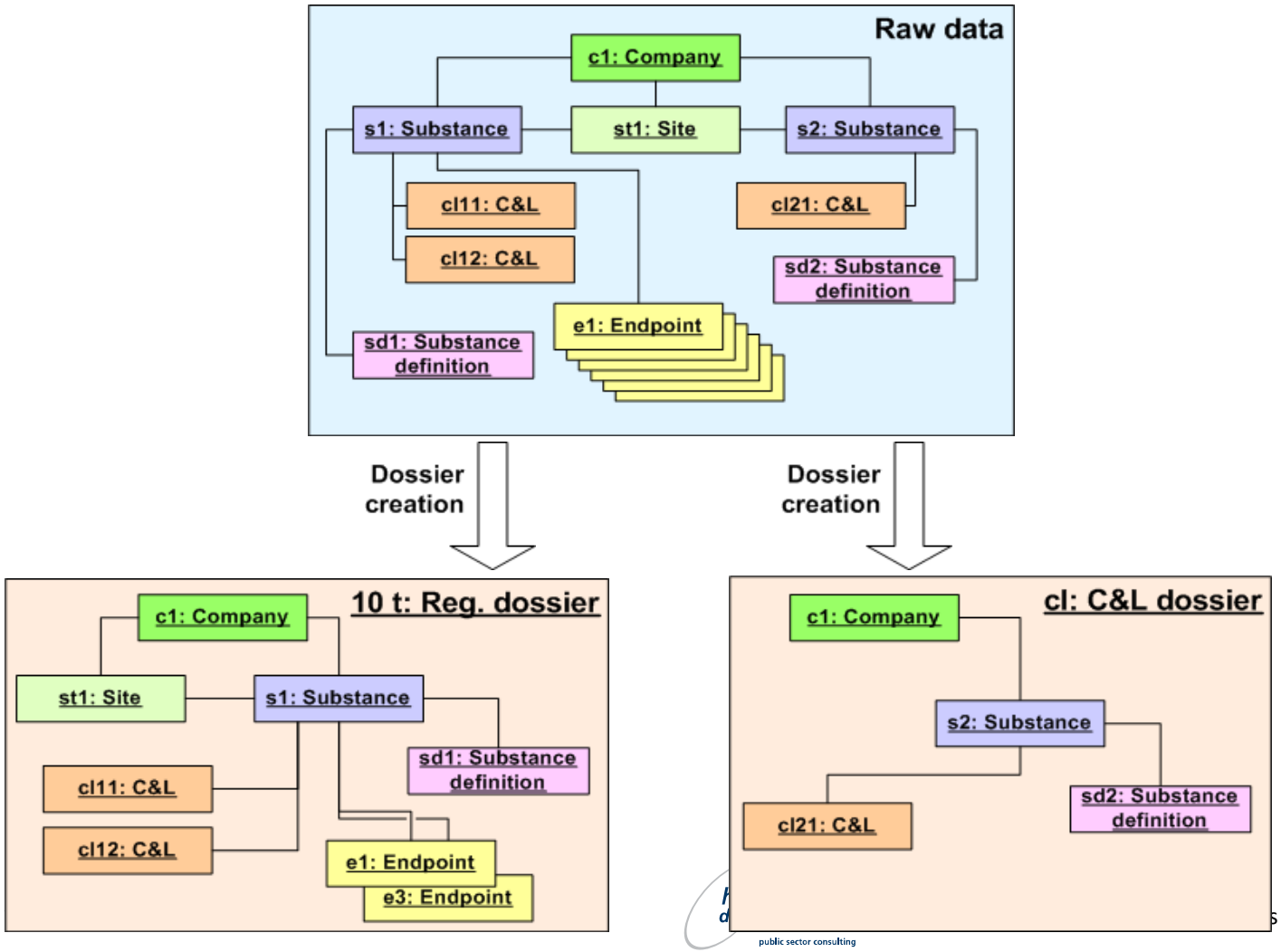
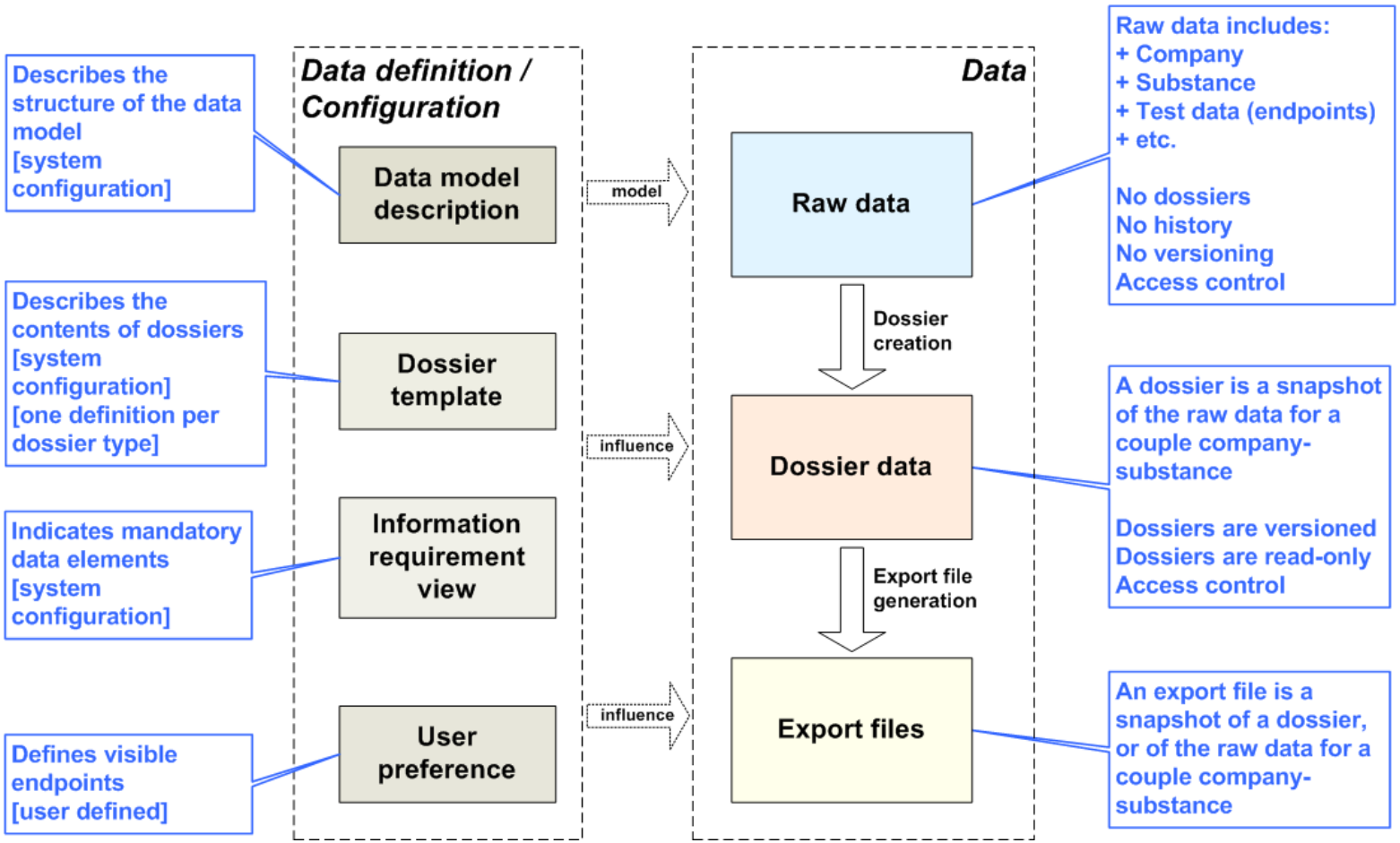
Functional overview of IUCLID - Raw data & Dossier data



Data and Data Models – The Whole Picture



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Dissemination of public REACH data

✓ECHA has the obligation to publish certain information

✓All users of the REACH-IT dissemination application are anonymous

✓Web-based interface

✓Dissemination data is stored in a dedicated database and on dedicated servers separated from the main REACH-IT application

✓Only public data is on the dissemination site

✓Data claimed to be confidential will be filtered before copied to the dissemination site

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Dissemination: data is filtered

3 types of data:

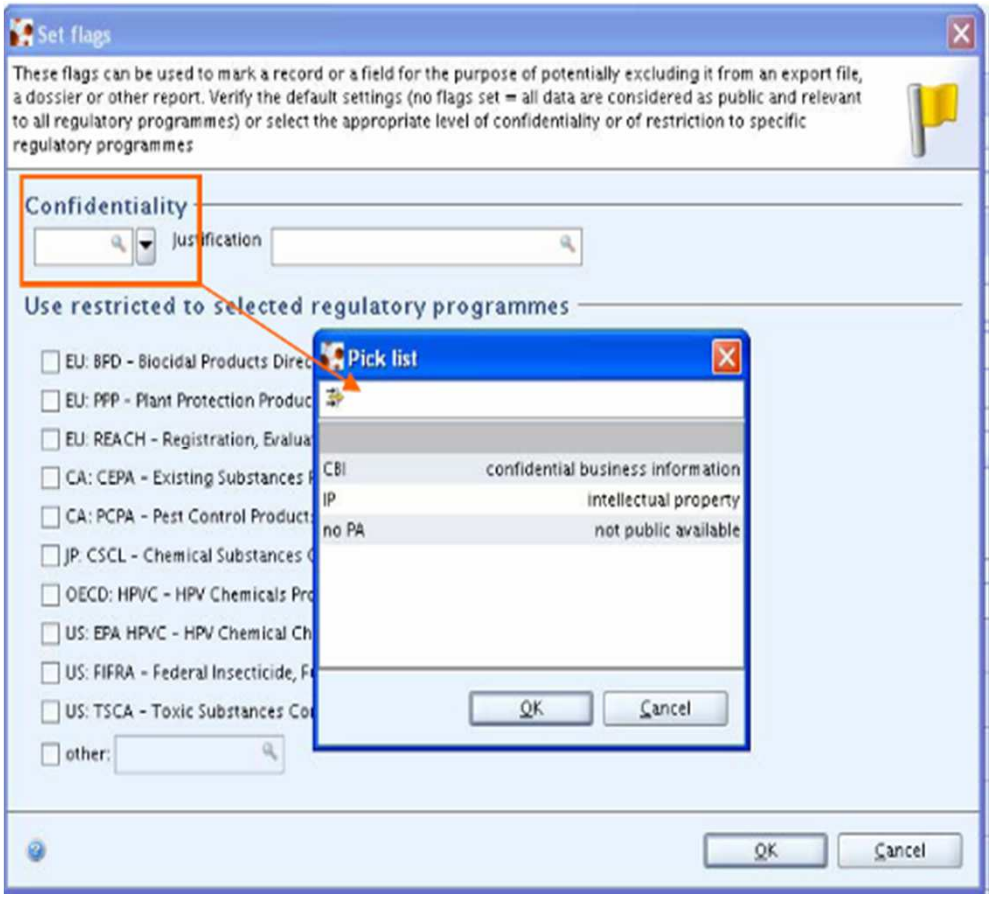
- Always public (Art. 119(1))

  e.g. EINECS, the C&L of the substance, the result of each toxicological and ecotoxicological study, etc.

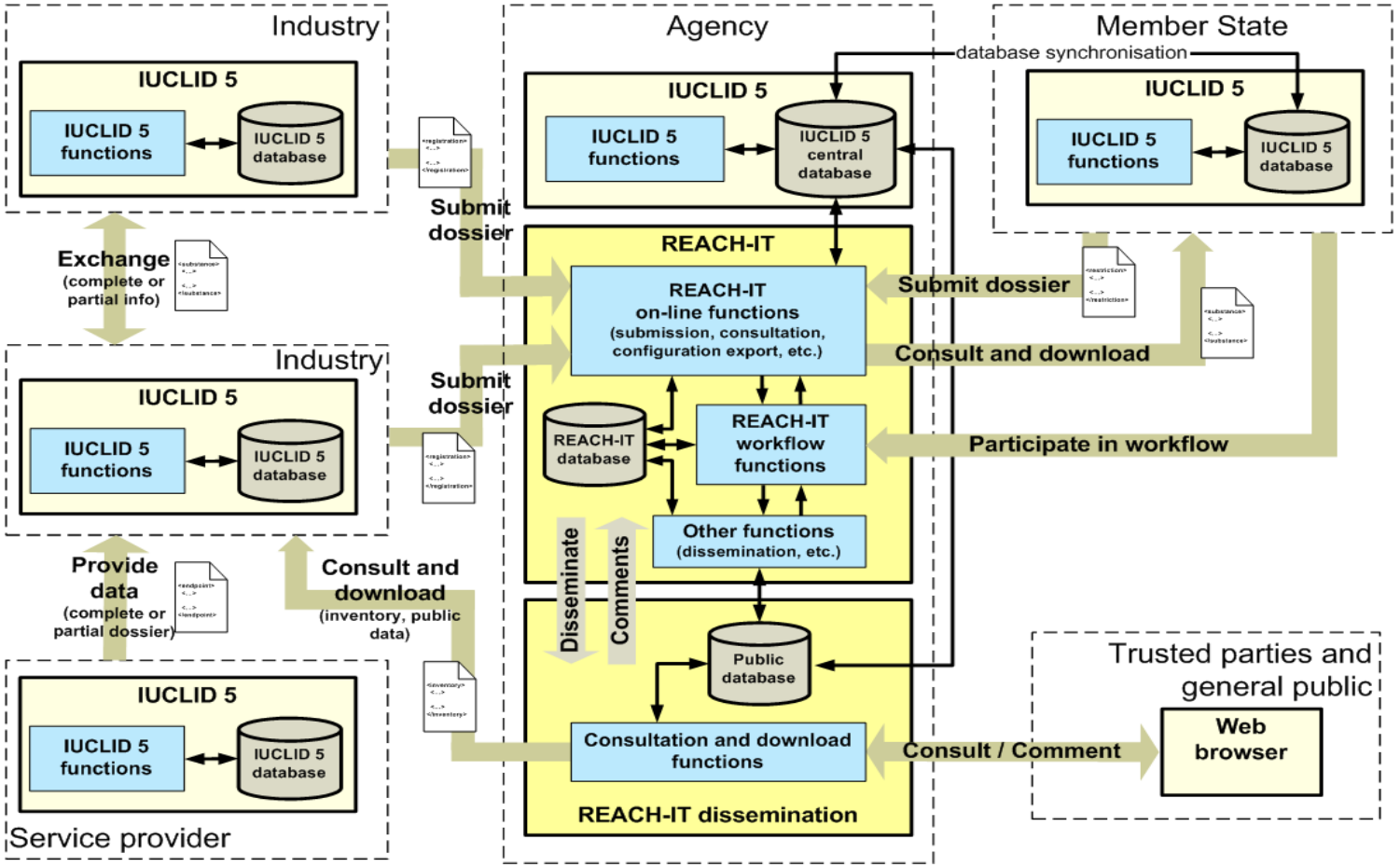
- Never published (Art. 118(2))

  e.g. full composition of a preparation, precise tonnage, etc.

- Potentially published-published *unless claimed confidential (Art. 10(xi) and Art. 119(2))* ***and*** *claim was accepted by ECHA*



e-submission in EU-the complete picture



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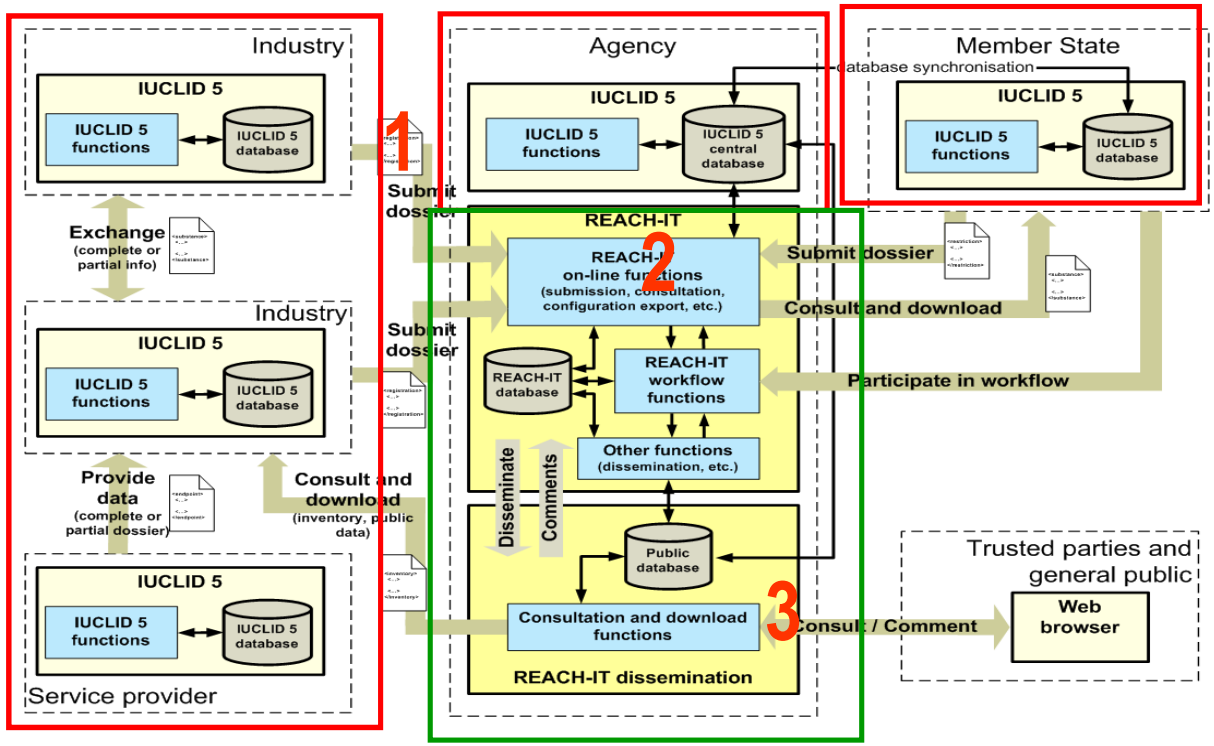
e-submission in EU - step 1



IUCLID

REACH-IT

1: Data are collected and stored by industry in IUCLID 5 local installation; Registration dossier is generated out of pool of collected data and submitted to ECHA information system (REACH-IT)

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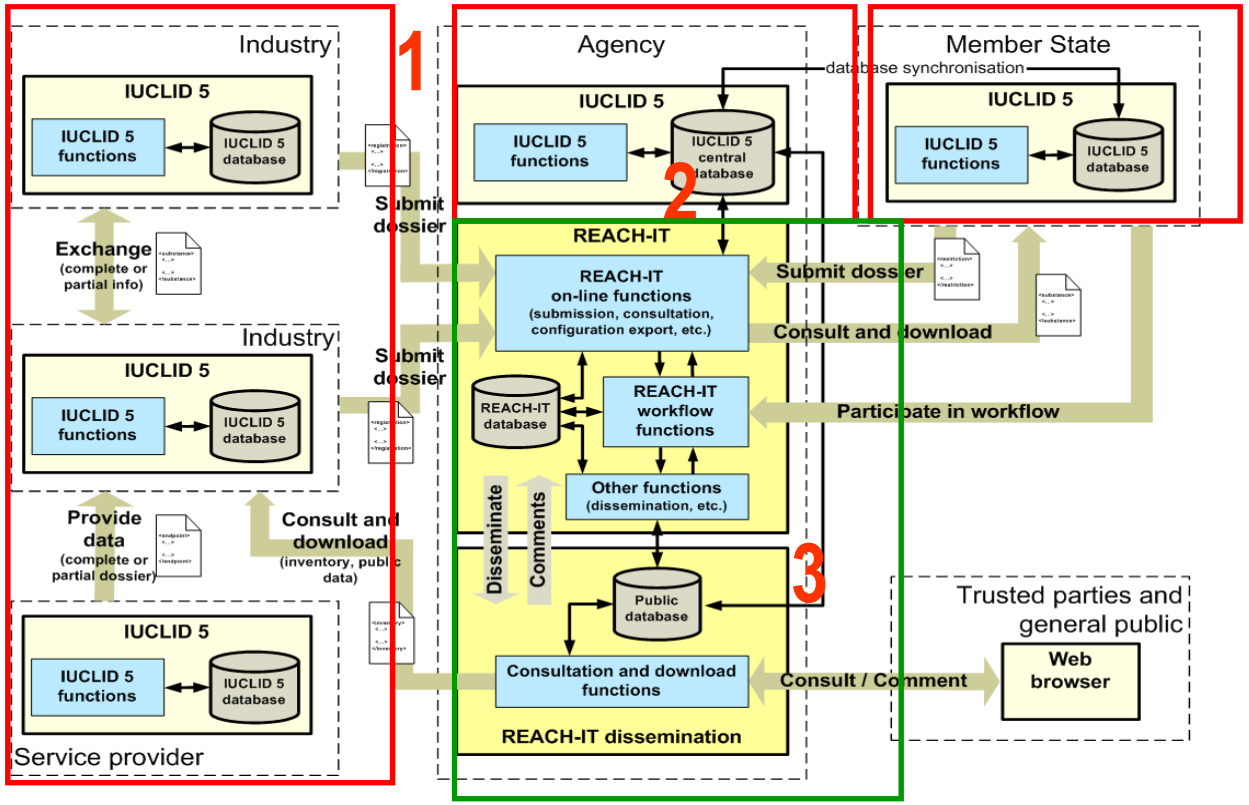
e-submission in EU - step 2



2: Dossier submitted to REACH-IT is uploaded into IUCLID 5 central database, directly accessible by ECHA and EU MSCA

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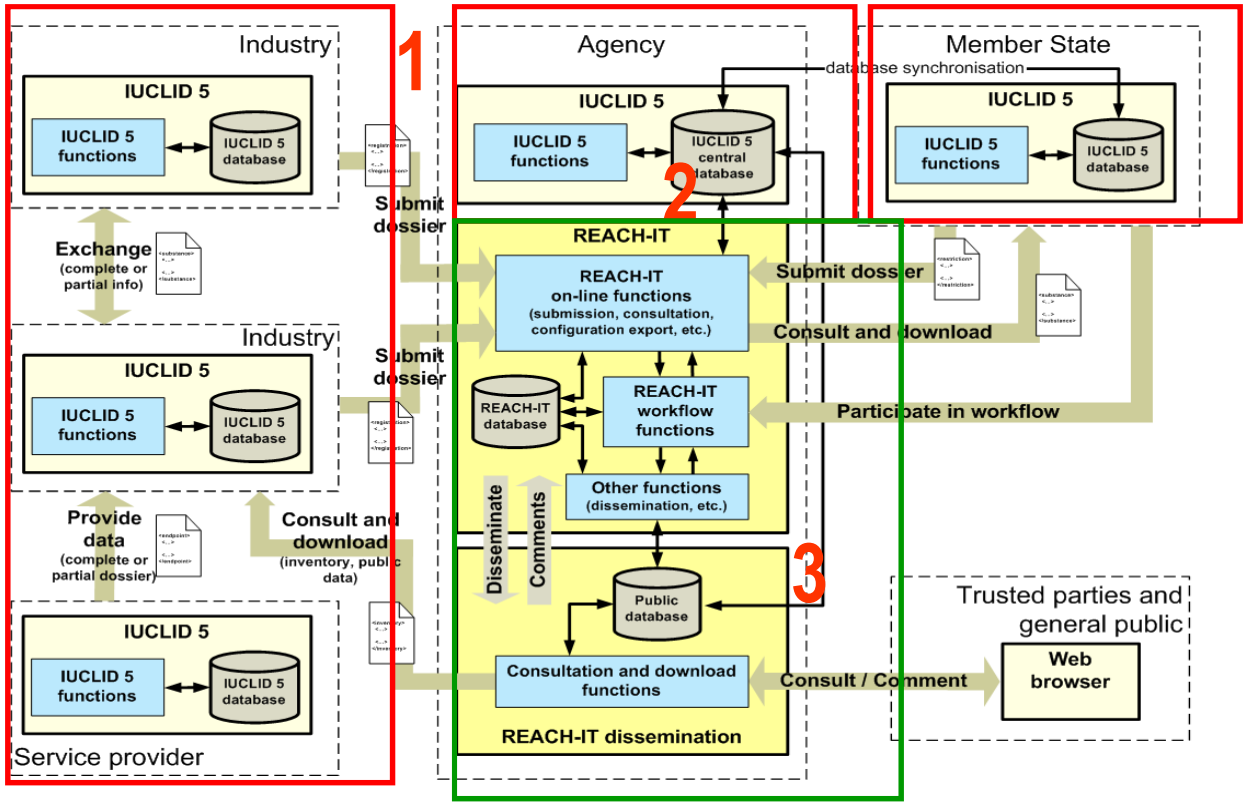
e-submission in EU - step 3



3: Sub-set (non confidential) is sent to the Public database for dissemination

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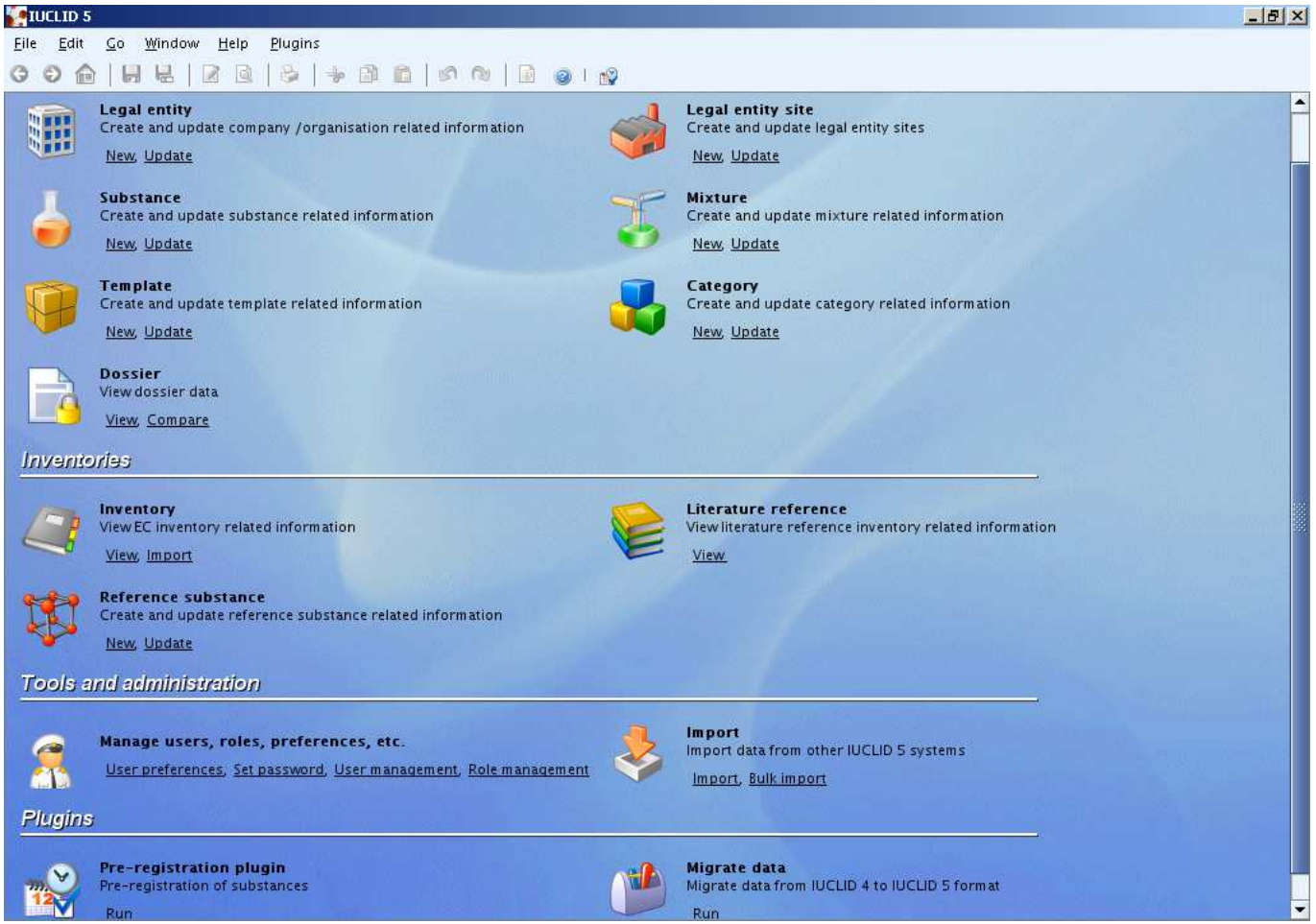
IUCLID Demo



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Environment and Climate Regional Accession Network ECRAN

Capacity building on compliance
with chemicals legislation, with emphasis on REACH/CLP
linked to IED

Consortium and Substance Information Exchange Forum

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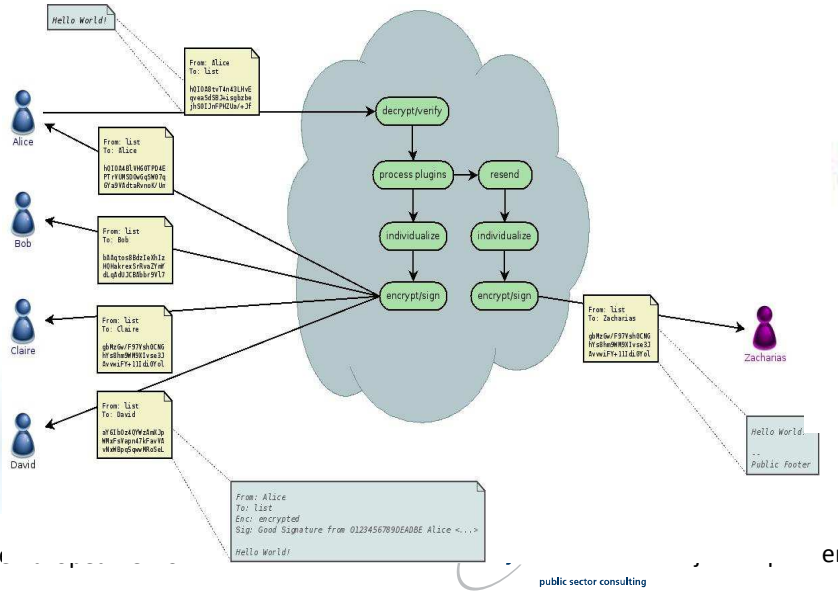
Environment and Climate Regional Accession Network

REACH Registration - SIEF

(54) In order to avoid duplication of work, and in particular to avoid duplication of testing, registrants of phase-in substances should pre-register as early as possible with a database managed by the Agency. A system should be established in order to provide for the establishment of Substance Information Exchange Forums (SIEF) to help exchange of information on the substances that have been registered. SIEF participants should include all relevant actors submitting information to the Agency on the same phase-in substance. They should include both potential registrants, who must provide and be supplied with any information relevant to the registration of their substances, and other participants, who may receive financial compensation for studies they hold but are not entitled to request information. In order to ensure the smooth functioning of that system they should fulfil certain obligations. If a member of a SIEF does not fulfil his obligations, he should be penalised accordingly but other members should be enabled to continue preparing their own registration. In cases where a substance has not been pre-registered, measures should be taken to help downstream users find alternative sources of supply.



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ented by Human Dynamics Consortium

public sector consulting

S.I.E.F. =

SUBSTANCE INFORMATION EXCHANGE FORUM

WHERE SIEF PARTICIPANTS **'SELF-ORGANISE'** TO COMPILE AND SUBMIT THE TECHNICAL DOSSIER REQUIRED FOR COMPLIANCE WITH REACH

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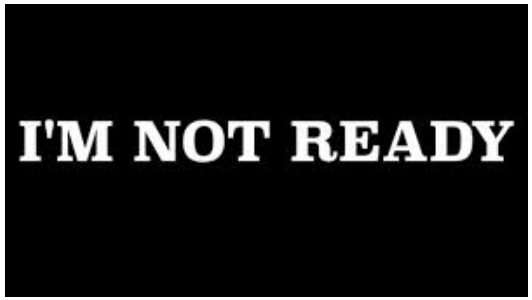
REGISTRATION-SIEFs

- **Participation – active? / dormant?**
  - Consortia? / Licence?
  - Lead? Take part? Wait? No Action???



- Dossiers – joint and individual
- Safety Assessment – e-SDS Exposure scenarios
- Downstream users – communication
  - Identified uses
  - Registration numbers

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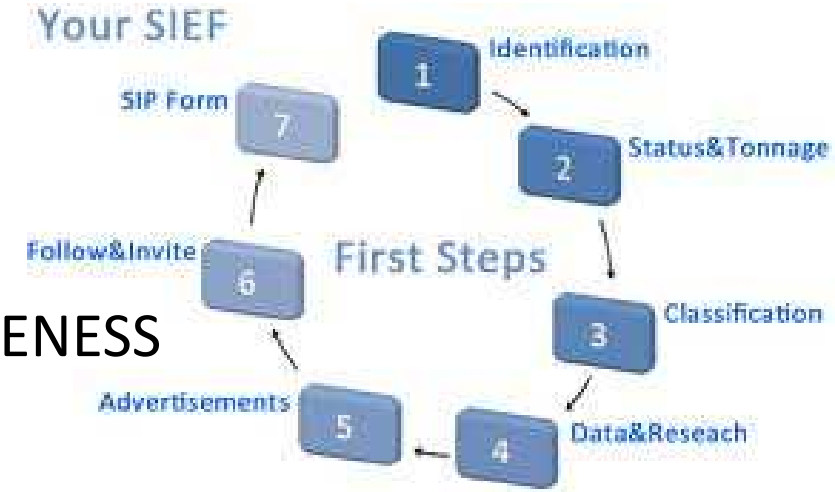
DATA-SHARING LESSONS LEARNED IN THE CONTEXT OF:



1. SIEF COMMUNICATION
2. PRE-SIEF FOR SUBSTANCE SAMENESS
3. STUDIES AND EXPOSURE DATA
4. IDENTIFIED USES
5. LETTERS OF ACCESS / LICENCE TO USE
6. e-SDS
7. UPDATING DOSSIERS / EVALUATION

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Basics of pre-registration

Pre-registration is a duty under REACH for **every potential registrant** of phase-in substances, taking place between **1 June – 1 December 2008**, granting them extended deadlines for registration.

LATE PRE-REGISTRATION

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Pre-registration

The pre-registration period, between 1 June and 1 December 2008, allowed potential registrants of the same phase-in substance to get together and submit a registration dossier jointly. Pre-registration was a requisite to benefit from the extended registration deadlines foreseen for these substances.

Potential registrants who, for the first time after 1 December 2008, manufacture or import a phase-in substance in quantities of one tonne per year or more can still submit certain information to ECHA (late pre-registration) and benefit from the extended deadlines. Producers and importers of articles with an intended release of a substance can also submit a late pre-registration.

Late pre-registrations have to be submitted within six months after the manufacturing or importing of the substance that exceeds the one-tonne threshold and no later than twelve months before the relevant registration deadline. Therefore, the late pre-registration period ends on 31 May 2012 for substances to be registered by 31 May 2013, and 31 May 2017 for substances to be registered by 31 May 2018.

Late Pre-registration is a simple process. You can submit your information directly online using REACH-IT. Please note that the official pre-registration period is over and late pre-registration is only allowed under specific circumstances.

- Potential registrants first need to **sign-up** to **REACH-IT**.
- Each legal entity must sign-up and pre-register separately.
  - an OR must sign-up and pre-register separately for each non-EU manufacturer represented.
- Pre-registration is free of charge.
- 2 ways to pre-register:
  - **on-line**: pre-registrations created one at a time using REACH-IT
  - **bulk pre-registration**: file prepared in a separate system (such as IUCLID) and submitted via REACH-IT

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Sign-up

Signing-up in REACH-IT is considered to be the starting point for any data submission to ECHA. You can refer to the Industry User Manual - Part 1: Getting started with REACH-IT, for a general overview of the system.

Each company and party must create an account in REACH-IT, online, providing the required identification details (i.e. legal entity name, contact details and billing information). The company identification details are contained in the Legal Entity Object (LEO), which also includes a unique identifier (UUID – Universal Unique Identifier) for every company.

› Access to REACH-IT

There are only two accepted methods for creating an official Legal Entity Object (LEO):

- via the official IUCLID 5 website (but not from your IUCLID 5 stand-alone application)
- created directly in REACH-IT

It is important to maintain consistency, between IUCLID 5 and REACH-IT regarding the company UUID. For more detailed information, please refer to the Industry User Manual - Part 2: Sign-up and account management. After signing-up, the Industry User Manual - Part 3: Login and Message Box will help you to familiarise with the system.

Only representatives have to sign-up in REACH-IT for each non-EU manufacturer they represent and submit
(late pre-registrations) using the appropriate accounts. It is not possible to use the same LEO (having the same company UUID) for multiple accounts, but it is possible to use the same company identification information (name, VAT, etc.). Only representatives must indicate, in the "company size", the size of the non-EU manufacturer they are representing.

Related documents

› Industry User Manual - Part 1: Getting started with REACH-IT [PDF]

bg cs da de el en
es et fi fr hr hu
it lt lv mt nl pl
pt ro sk sl sv

› Industry User Manual - Part 2: Sign-up and account management [PDF]

bg cs da de el en
es et fi fr hr hu
it lt lv mt nl pl
pt ro sk sl sv

› Industry User Manual - Part 3: Login and Message Box [PDF]

bg cs da de el en
es et fi fr hr hu
it lt lv mt nl pl
pt ro sk sl sv

› REACH-IT Fact Sheet - Avoid blocking your REACH-IT account [PDF]

Pre-registration - data

- substance identifiers to use:
  - 1. EC number
  - 2. CAS number and CAS name
  - 3. IUPAC name
- chemical name:
  - IUPAC name in **English**,
  - all other available numerical identifiers
  - if regarded necessary, synonyms and/or chemical names in other languages
- company's and contact person's details

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Pre-SIEF

- After pre-registration, a substance pre-SIEF webpage formed for each EINECS n°/ CAS n°/ other identity code
- All potential registrants are able to see:
  - each others contact details + contact details from data holders
  - identified read-across possibilities
  - remarks about the substance
- It is possible to navigate to the pre-SIEF web pages of the substances identified for read-across (to and from)
- concerns on confidentiality - a **third party representative** for pre-registration

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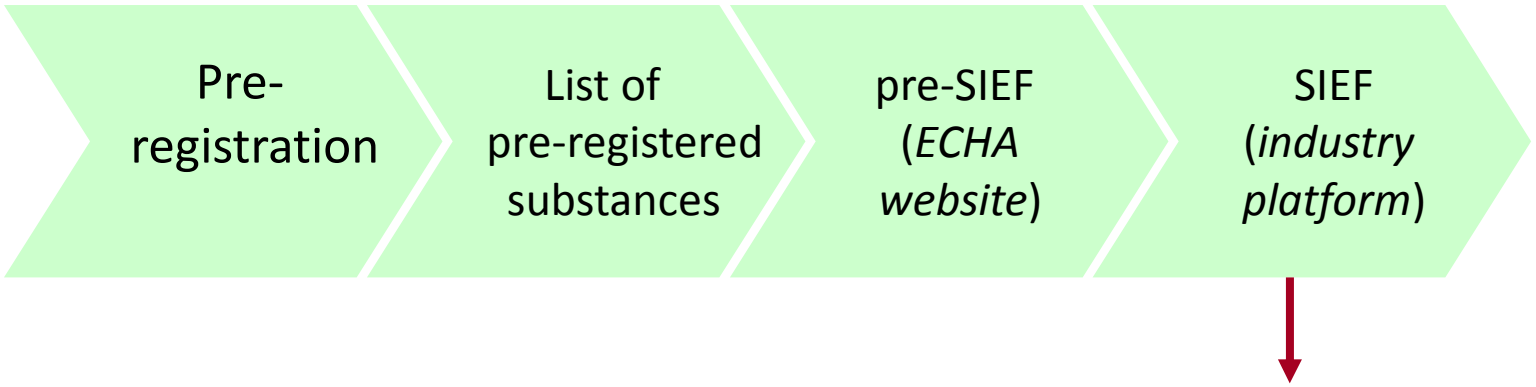
SIEF Formation Facilitator

→ To initiate discussions after pre-registration a “SIEF formation facilitator” can be identified on the pre-SIEF webpage:

- **Only potential registrants can volunteer to become SIEF formation facilitator, on a first-come first-serve basis.**
- Not legally binding, no additional obligations.
- Can post information to the other participants in a separate text box on the pre-SIEF webpage, e.g. on further communication tools to be used.

What Happens after Pre-registration?



- Industry needs to agree on SIEF formation and share data and costs within the SIEF

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Lead registrant nomination

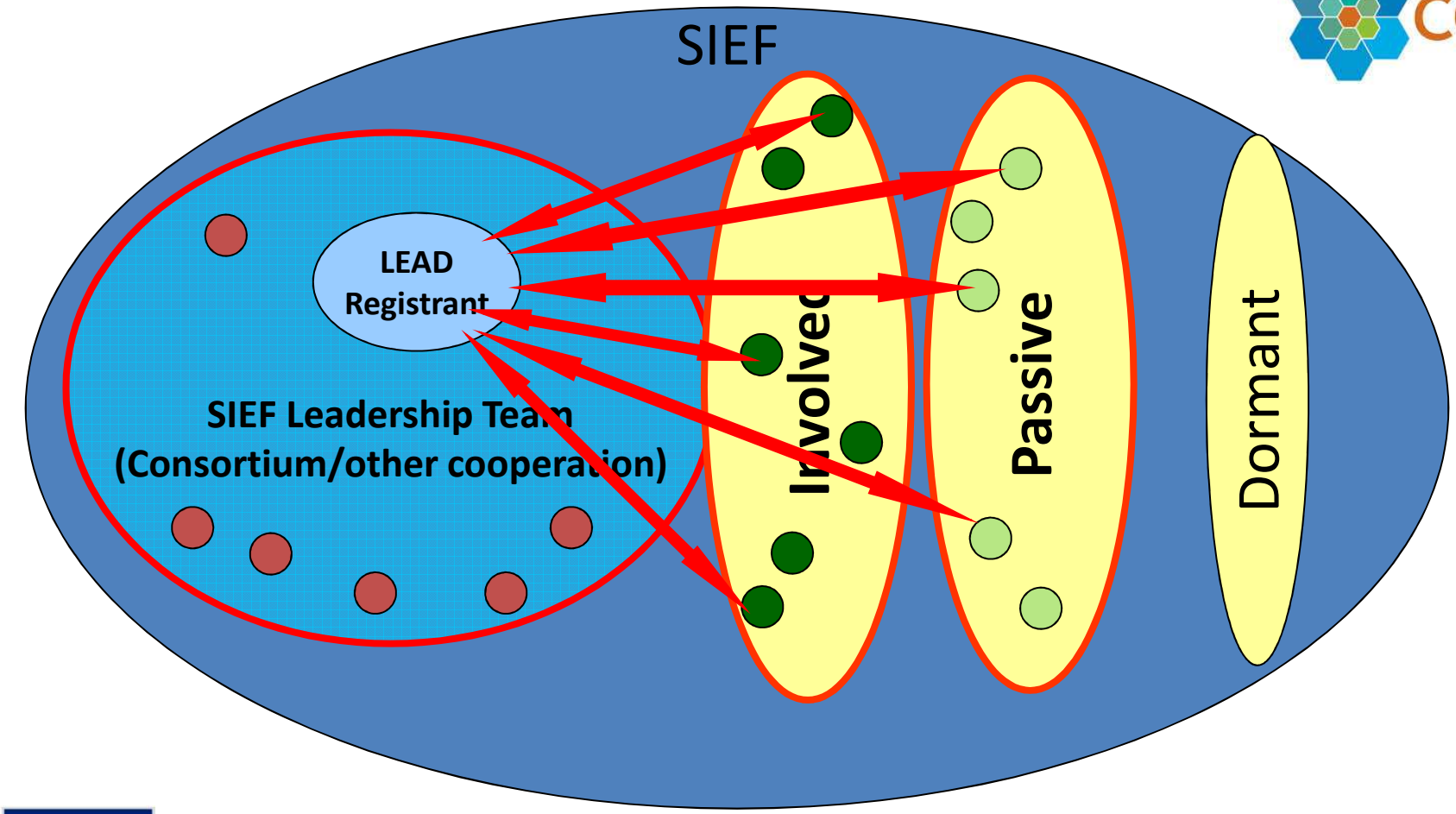
ECHA encourages lead registrants and candidate lead registrants to communicate their role to ECHA. This is to support SIEF activities and to record accurate information regarding SIEF progress.

Lead Registrant notification webform

The data is provided on a voluntary basis. ECHA assumes no responsibility regarding the possible confidentiality on the information. ECHA does not endorse or reject lead registrant nominations. ECHA holds no responsibility for, neither can it guarantee the accuracy or validity of, the information contained in the list. ECHA does not (and will not) edit the content provided.

SIEF agreement: link between SIEF Leadership Team and other SIEF participants (potential registrants)

= SIEF agreement: bilateral agreement between the SLT represented by LR and each SIEF participant.



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CIRCA 55% OF 2009 PRE-SIEF COMMUNICATIONS TO PRE-REGISTRANTS WERE NOT EVEN OPENED!

blue spark *

Overview | Create/Send | Lists & Subscribers | Reports

Sent Campaign Reports

Campaign Name	Sent ▼	Recipients	Opened	Clicked
Ammonium octamolybdate - Substance Sameness Survey - reminder	4 Mar 2009	66	29.23%	57.89%
Pre-SIEF Activity Alert	4 Feb 2009	1,382	40.74%	15.88%
Molybdenum metal - Substance Sameness Survey	23 Jan 2009	1,429	43.59%	43.48%
Sodium molybdate - Substance Sameness Survey	23 Jan 2009	336	47.38%	50%
Ferromolybdenum slags - Substance Sameness Survey	23 Jan 2009	34	34.38%	63.64%
Pure molybdenum trioxide - Substance Sameness Survey	23 Jan 2009	320	49.19%	58.55%
Roasted molybdenite concentrate - Substance Sameness Survey	23 Jan 2009	114	50%	74.55%

IMOA

< 20% SIEF E-MAILS OPENED TOWARDS END 2010 REGISTRATION DEADLINE

blue spark *

Overview | Create/Send | Lists & Subscribers | Reports

Recently Sent Campaign Reports

See all sent campaigns

Campaign Name	Sent	Recipients	Opened	Clicked
CLP-Notification Obligation Reminder	10 Dec 2010	1,966	22.71%	22.85%
Iron Molybdate successfully REACH-registered	24 Nov 2010	29	17.86%	80%
LoA deadline applications - End october 2010	25 Oct 2010	1,880	19.11%	17.46%
OCTA successfully REACH-registered	25 Oct 2010	69	11.76%	25%
HEPTA successfully REACH-registered	25 Oct 2010	171	16.37%	17.86%

IMOA

SIEF solution - CEFIC

- It is highly recommended that the SIEF Leadership Team (the Lead Members) puts a structured SIEF process in place with the other SIEF participants.

- The SIEF agreement comprises :
  - ✓ confidentiality obligations
  - ✓ data sharing and costs compensation arrangement
  - ✓ Arrangement on participation in the Joint Submission of the Dossier

- Quick adoption of the SIEF agreement is possible :
  - Very few options in the SIEF agreement
  - Standardised electronic process of signature (via the relevant SIEF IT-platform)
  - Only to be submitted to the Involved and Passive SIEF Participants (members of category 2 & 3) which reduces the administrative burden

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SIEF

- Obligatory platform to:
  - share data among potential registrants of the same phase-in substances and data holders + avoid unnecessary testing
  - agree on classification and labelling
- Suitable platform to organise the mandatory joint submission of data
- Potential registrants within a pre-SIEF must discuss whether their substances are the same or not.
- **If agreement on the sameness: SIEF is 'born'** (Article 29)

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Active lead registrants

The list of lead registrants provides information concerning the SIEF progress. It shows whether lead registrants have made themselves known to ECHA (SIEF is active).

ECHA publishes also the following information:

- The lead registrant name is disclosed, if the lead registrant has allowed ECHA to do so. As a consequence of agreeing to publish the name, the lead registrant can no longer claim it confidential in the registration dossier.

- ECHA periodically checks the new substance registrations and updates the list to indicate when a dossier has been submitted by a lead registrant. The list also indicates if the dossier was submitted by the same lead registrant (who notified ECHA) or by a different (lead) registrant.

ECHA invites companies to still actively participate in the lead registrant nomination scheme. This way the companies help ensure the administration of the lead registrant list and the update regarding the SIEF formation activities for the 2018 deadline.

Download the list

[PDF] [XLS]

The list reproduces the information filled in by lead registrants in the web form. If the company name is not mentioned for your substance, it means that the lead registrant has not authorised to publish their name.

SIEF Formation – Key Issues

- Industry must assess the sameness (see guidance on substance identity)

  No confirmation by ECHA!

- SIEF participants are free to organize themselves as they see fit
  - Consortium is one possible form of co-operation
  - Co-operation and collective approaches highly encouraged

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SIEF Formation – Key Issues

- In many cases EINECS = SIEF, but:
  - substances within one EINECS number may, after detailed examination, turn out to be so different in terms of composition that data from one substance may not be relevant to describe the profile of the other substance: several SIEFs may be formed.
  - different EINECS numbers may reflect the same substance: one SIEF may be formed.
- Data sharing obligations must be respected! (it is not allowed to form 2 SIEFs for the same substance) …opt-out possibility

SIEF Formation – Key Issues

Cost sharing (see guidance on data sharing)

- Costs must only be shared for information:
  - that a registrant is required to submit
  - at the time when a registrant is required to submit the information
- Costs must be shared in a fair, transparent and non-discriminatory way
- If SIEF participants cannot reach an agreement, costs shall be shared equally

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Data sharing disputes

ECHA can assist in the resolution of data sharing disputes between existing and potential registrants. A claim must only be initiated as a last resort after all possible avenues have been explored between the parties.

Any potential registrant who lodges a data sharing dispute with ECHA must always obtain a decision from ECHA before submitting the registration dossier.

If there is a dispute, ECHA's decision will be based on an assessment of the parties' respective efforts to reach an agreement on the sharing of the data and its costs in a fair, transparent and non-discriminatory way.

A potential registrant initiating a data sharing dispute procedure with ECHA must demonstrate the efforts made by all the parties to reach an agreement and must provide appropriate documentary evidence.

Information to ECHA indicating the failure to reach an agreement on data sharing

Pursuant to Article 27(5) of the REACH Regulation, the European Chemicals Agency (ECHA) provides potential registrants with the opportunity to inform ECHA of the failure to reach an agreement with the previous registrant(s) on the sharing of existing in case of substances registered less than 12 years previously.

The potential registrant submitting this webform shall provide documentary evidence demonstrating the efforts made by **all the parties** compelled to reach an agreement on the sharing.

The documentary evidence may therefore consist in:

- they have made every effort to obtain access to the information and to agree on the sharing of the costs in a fair, transparent and non-discriminatory way;
- they have notified the previous registrant(s) by a **letter** and **a proof of transmission** that ECHA will be informed of their joint failure to reach an agreement.

An objective and contradictory assessment of the case requires the ECHA requests from both parties, any copies of the letters and other documents relating to the negotiation sent to or received from the other party.

The potential registrant will receive from ECHA the permission to refer to the data, if ECHA considers that the request is founded, i.e. if it is demonstrated by documentary evidence that the previous registrant has not met his obligation to make every effort to share the data and its costs in a fair, transparent and non discriminatory way, although the potential registrant has made such efforts.

The previous registrant shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

What do you need to do to submit information to ECHA?

1. **Use a valid REACH-IT user ID** (i.e. your username during sign-up as a company or third party representative (TPR) in REACH-IT). Please note that if you do not provide a valid REACH-IT user ID, ECHA can neither import your information in REACH-IT nor use it. In that case, your claim will not be processed.
2. **Fill in** the web-form below. Please note that, in order to process your request, you must fill in all compulsory fields (*).
3. **Upload all the requested documentation** (.zip file or .pdf document):

   I. **a note** setting out the sequence of all the efforts of all the parties to reach an agreement
   II. **a copy of any correspondence** demonstrating the efforts of all the parties to reach an agreement;
   III. **letter** informing the previous registrant(s) of the failure to reach an agreement under the Article 27(5) of REACH Regulation, together with the **Proof of transmission** of the letter to the previous registrant(s) (pursuant to Article 27(5) of REACH Regulation).

4. Make sure you **type in the word shown** in the CAPTCHA picture at the bottom of the web-form and then submit to ECHA.
5. A new webform shall be filled in and submitted for each previous registrant who refuses to share data; but you can include several studies in one webform, if they are owned by the same company.

Reason(s) for failure to reach an agreement on data sharing – Part 3 * (Please tick at least one of the proposed options)

- ☐ No response at all following my attempts
- ☐ One response and then no response to further attempts
- ☐ No agreement on providing the information
- ☐ No agreement on setting up a joint submission
- ☐ No agreement on the timing for the previous registrant to provide the requested information
- ☐ No agreement on the costs for the vertebrate animals endpoints
- ☐ No agreement on the costs for the non-vertebrate animals endpoints
- ☐ Other (please specify)

Description of efforts made to reach an agreement – Part 4
Enclose ALL documentation as proof of failure (in a zip file or a pdf document) to demonstrate that the requirements of Article 27(5) of the REACH Regulation are met

The fields below require indicating whether the information is enclosed in the zip file/ pdf document.
NB: incomplete information will prevent you from submitting successfully your request to ECHA

Date and content of first attempt to reach agreement with the previous registrant * — Please select ... ▼ are enclosed

Date and content of the last attempt to reach agreement with the previous registrant * — Please select ... ▼ are enclosed

Total number of attempts (only numerical value) *
Number of attempts should be at least 2

Proof of payment (where applicable)
In case failure occurs after payment was made, proof of payment MUST be included in the zip file/ pdf document — Please select ... ▼ is enclosed

Upload **the note** describing all the steps in the negotiation (item 3.a) *:
The only formats accepted are as zip file or as pdf document
Choose File No file chosen
Maximum file size is 10 MB

Upload **a copy of any correspondence** demonstrating the efforts of all the parties to

Legal uncertainty in absence of SIEF legal framework

- ✓ What if a SIEF participant misuses the information he receives from the Lead Members and discloses it to another company?
- ✓ What if a non-consortium member files a claim against the consortium for not being properly informed on the preparatory process of the Dossier ?
- ✓ What is the basis for a Lead Registrant to communicate the completion of the joint registration dossier to the other SIEF members?
- ✓ As a SIEF participant, do I need bilateral data sharing agreements with all data owners ?
- ✓ What are the liabilities of the Lead Registrant if things "go wrong" with the registration?

CEFIC support

- ✓ The SIEF Agreement provides a standardised framework for SIEF discussions and activities

- ✓ It has been developed by the Cefic Legal Aspects of REACH Issue Team where more than 50 legal experts from companies participate

- ✓ It is posted on the Cefic website and can be freely used as of today by SIEF leading companies

http://cefic.org/templates/shwPublications.asp?HID=750&S=33

For Cefic and its members: contact Vincent Navez, vna@cefic.be

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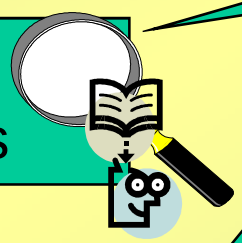
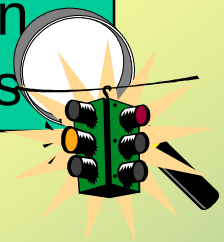
Main elements of REACH

Registration of all substances
> 1 t/yr

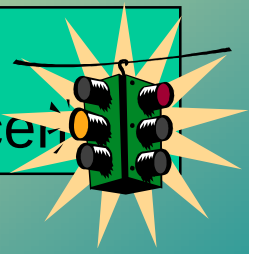
Evaluation by
competent authorities



Authorisation of certain
hazardous substances



Restrictions for
substances of concern



Scope:
- **decisions for additional information**
- **proposal for authorisation**
- **proposal for restriction measures**

The registration process

- Who?
- What?
- When?
- How?

Registration: general

AIM:

- ➔ Manufacturers and importers obtain information on their substances and
- ➔ Use this knowledge to ensure responsible and well-informed management of the risks these substances may present

Registration Dossier = Documentation

- ➔ Technical Dossier: starting at 1 tonnes per year
- ➔ Chemical Safety Report: starting at 10 tonnes per year **and** if classified as hazardous substance!

No formal acceptance - industry retains responsibility

Who Has to Register?

- EU Manufacturers & importers if they manufacture or import > 1 ton/ year of a substance:
  - as defined in Article 3 (1)
  - unless exempted from the registration scope (Article 2, Annexes IV and V)
  - irrespective of whether they are classified as dangerous or not
- Importers and Producers of articles (conditions of Article 7).
  - Intended release of substances only
- Manufactures of substances outside the EU may appoint an “only representative” to fulfil their REACH obligations.
  - “Only representative” relieves importers of their duties.
  - Importers are then considered DUs.

What Must Be Registered?

- Registration only concerns substances (article 3.1)...
- .....on their own, in mixtures (preparations) or in articles
- Mixtures and articles themselves are not registered
- Only substances manufactured/imported over 1 ton/year

Registration

Are substances in articles to be registered?

Only if:

- the substances are intended to be released from the produced or imported article during normal/ reasonable foreseeable conditions of use, AND

- the total amount of the substance present in the articles with intended releases produced and/or imported by that actor exceeds 1 tonne per year per producer or importer

- The substance has not yet been registered for that specific use

Registration

And what if there is no intended release?

In that case there are no registration obligations

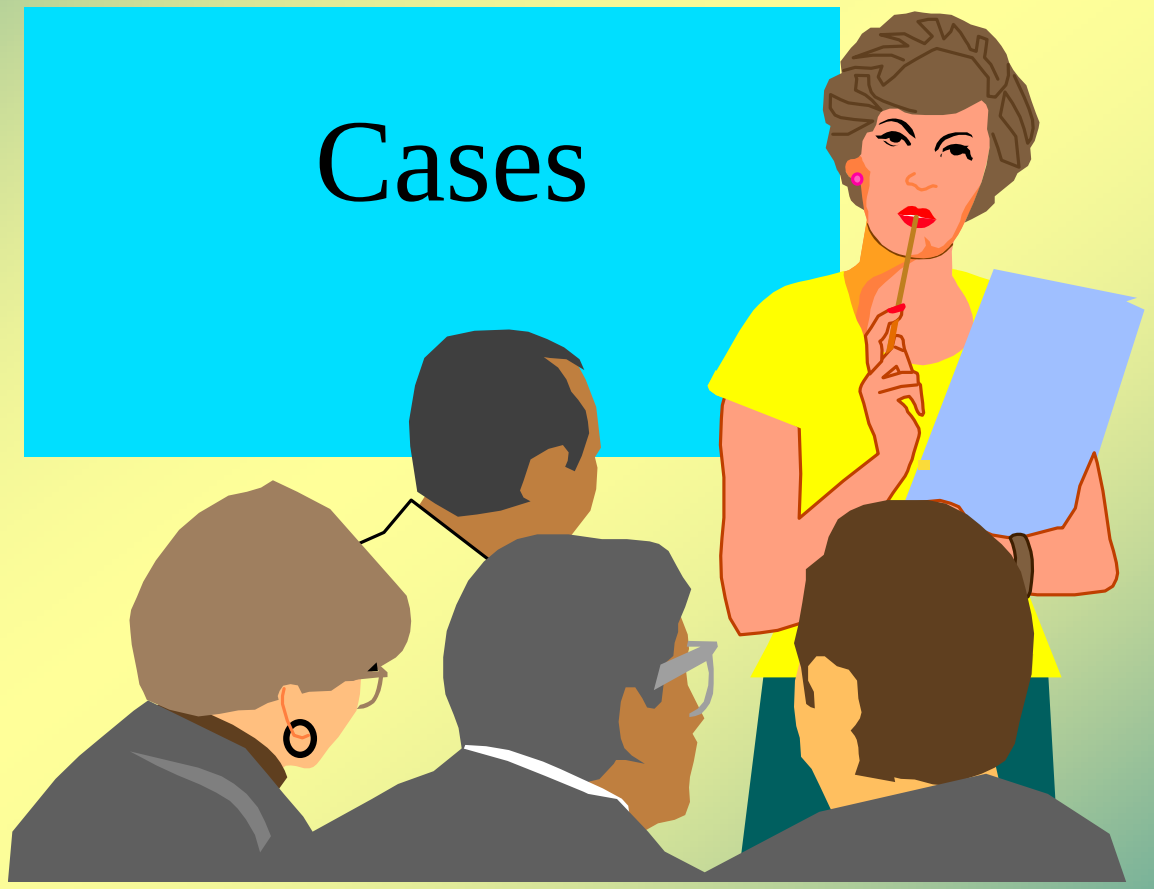
There is a notification obligation for substances in articles if:

- the substance is included in the candidate list for authorisation (Article 59(1)) and
- the substance is present in articles > 0.1% (w/w) and
- the total amount of the substance in all articles produced or imported by one actor > 1 tonne per year

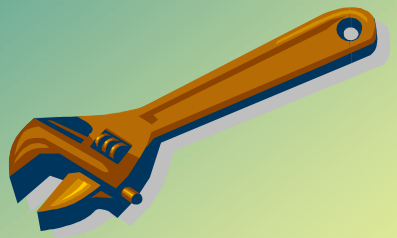
If the first two criteria are met, the manufacturer/ importer has to inform :

- the (professional) recipients without delay about the substance and the safe use
- on request, his customers within 45 working days (free of charge)

Cases



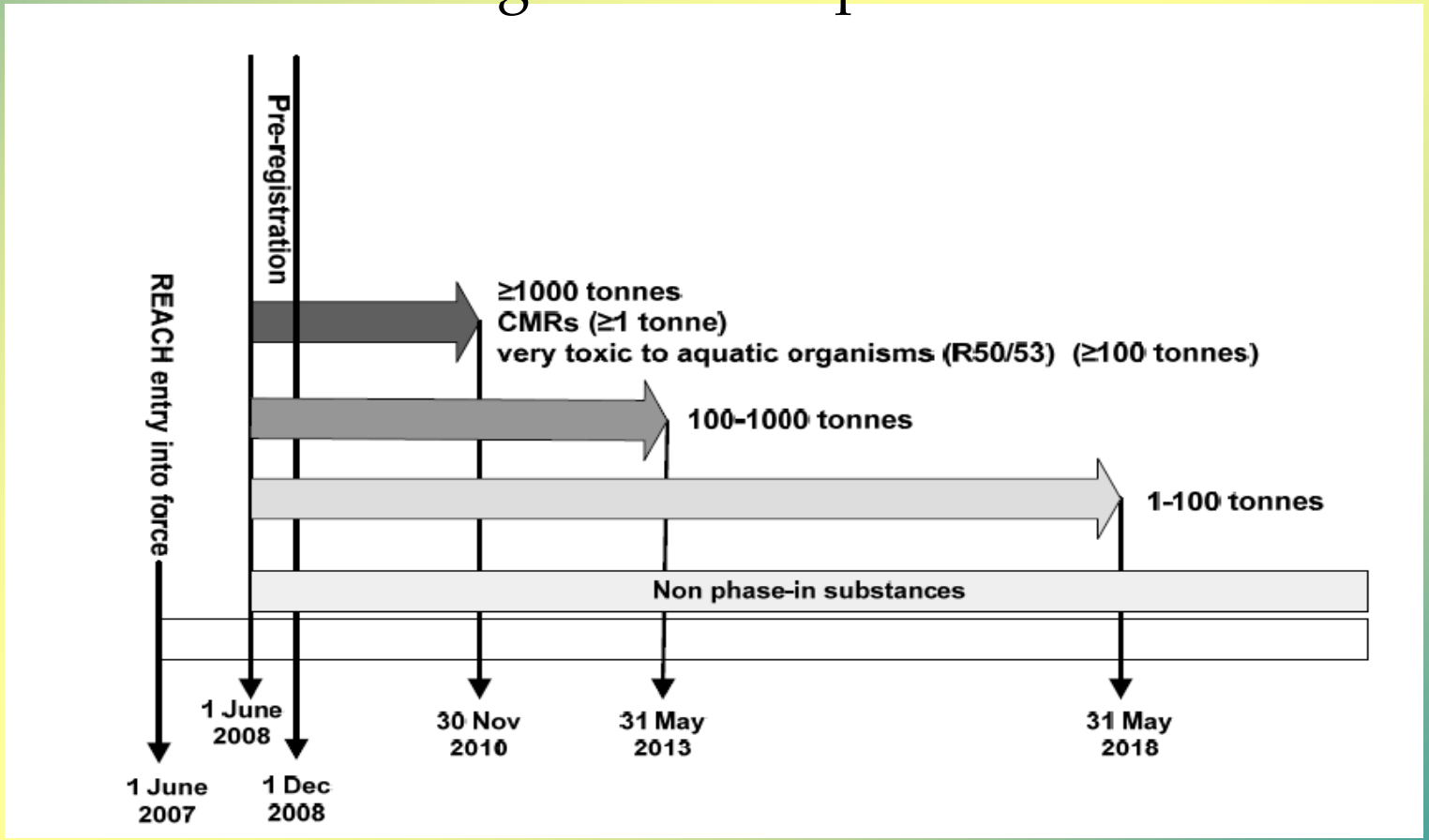
Article or preparation?



Registration – when?

- 1 June 2008

  Deadlines for registration of phase in substances



Registration & ECHA

Registration dossier:

- identity of manufacturer(s)/ importer(s) and substance
- information on manufacturing and use of the substance
- classification and labelling of the substance
- guidance on safe use of the substance
- (robust) study summaries of the information
- submitted info which has been reviewed by an assessor
- test proposals
- exposure info (1 - 10 tpa)
- a request for “confidential” information

Registration dossier & SIEFs

Environment and Climate Regional Accession Network ECRAN

Basic Toxicology and Risk Assessment under REACH

Ike van der Putte/Shufan Qi

Montenegro

13 – 15 May 2014

This Project is funded by the European Union

human dynamics public sector consulting

Project implemented by Human Dynamics Consortium

Basic Toxicology and Risk Assessment

This Project is funded by the European Union

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Chemicals & Hazards

explosive

corrosive

environmental danger

flammable

oxidative

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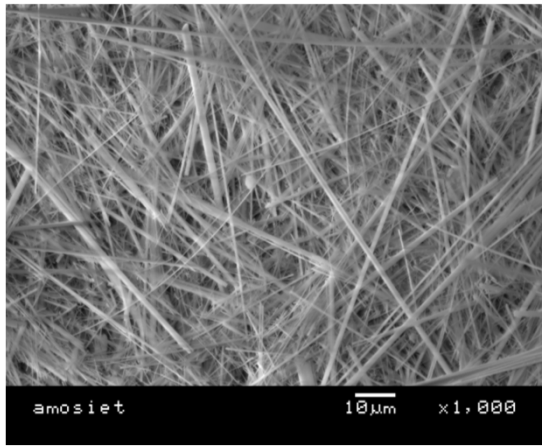
Project implemented by Human Dynamics Consortium

Chemicals and Toxicicity

Paracelsus:"Dosis Sola Facit Venenum"

(it is the dose which makes the poison)

Substance	LD50 (mg/kg bw)
Ethanol	7000
Sodium chloride	3000
Cupric sulphate	1500
DDT	100
Nicotine	60
Tetrodotoxin	0.02
Dioxin (TCDD)	0.02



Asbestos

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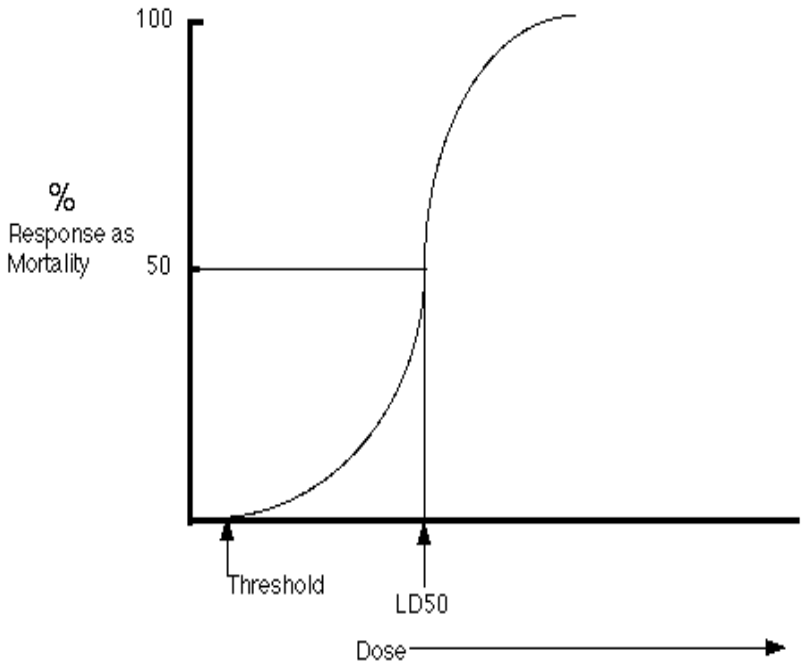
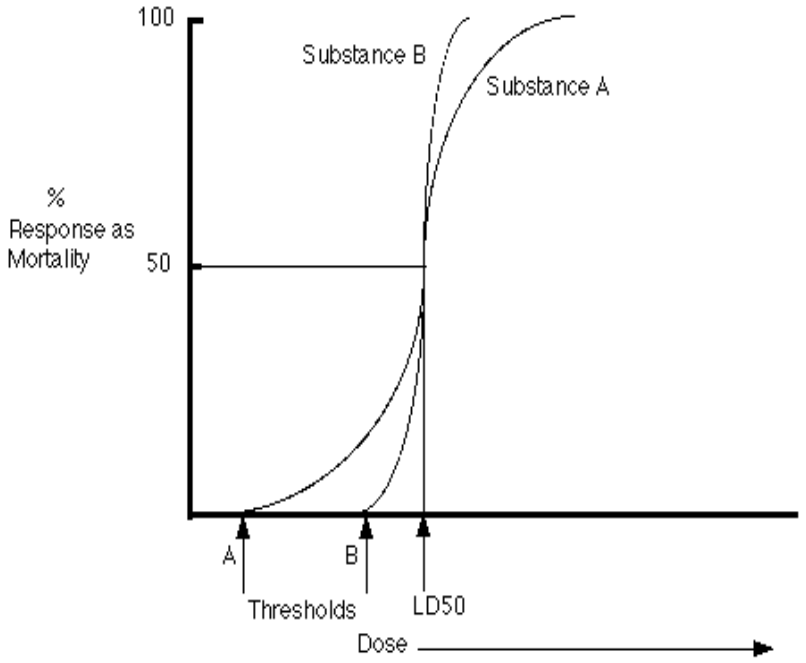
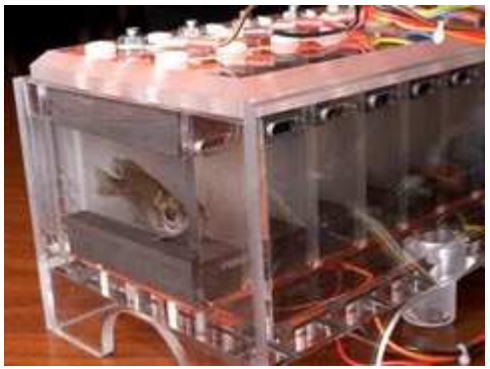
The Relationship of Dose or Concentration of a Toxicant to the Response Produced in Terms of Mortality





VARIOUS TEST SYSTEMS AND ANIMALS



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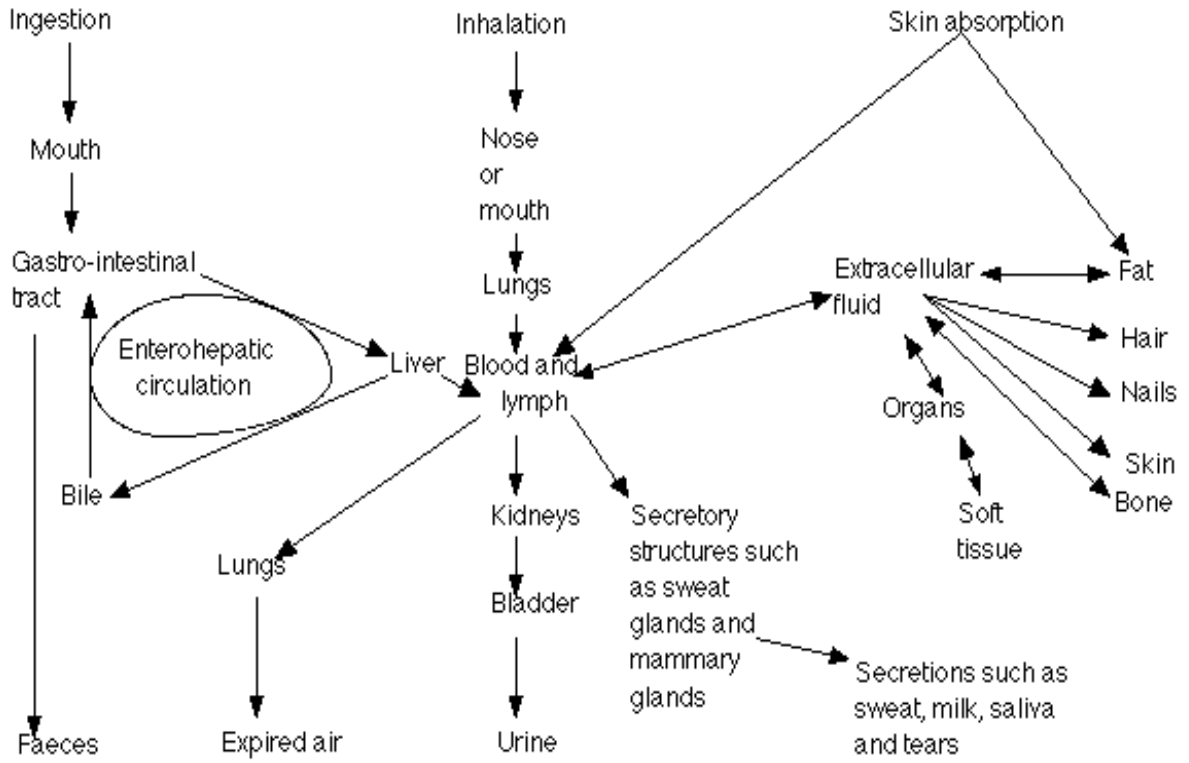
Routes of absorption, distribution and excretion of potentially toxic substances



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Accidents & chemicals

Minamata -MeHg

Bhopal- MIC

Seveso- TCP/Dioxins

Basel (Sandoz)- pesticides

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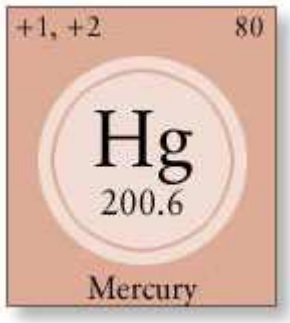
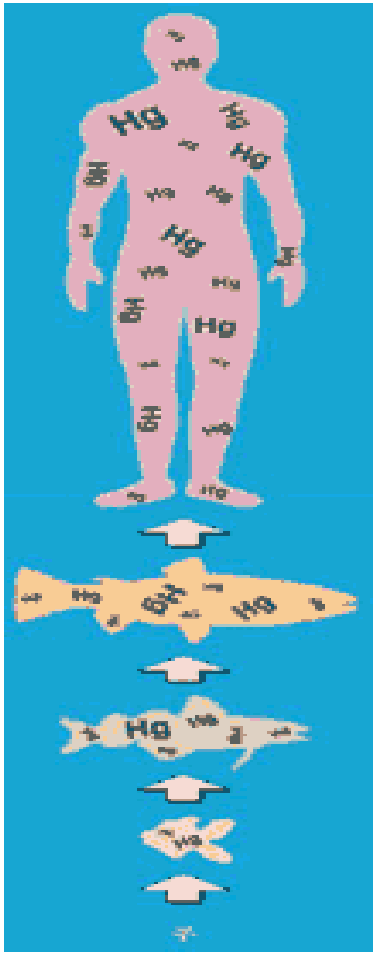
Minamata disease





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In 1971-72, a major epidemic occurred in Iraq in which 6,530 persons were hospitalized and almost 500 died. In a well-intentioned humane response to famine, several nations shipped wheat grain intended for planting to Iraq. The seeds had been treated with a methylmercury-containing fungicide to hold down mold growth and preserve the viability of the seeds
(note: originating from Mexico, warning labels in Spanish)

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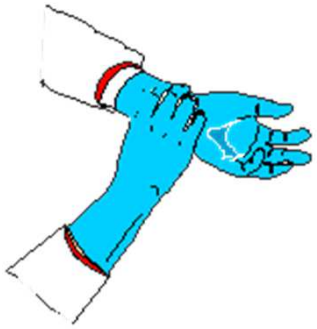
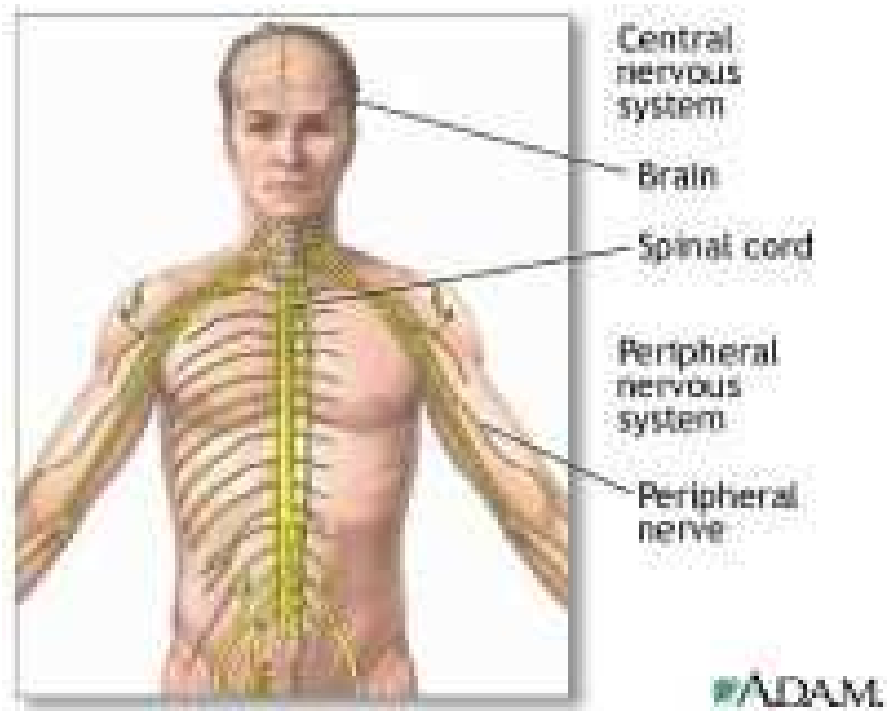
Mercury caused a tragic incident in Hanover, New Hampshire, in 1997.

The story of Dartmouth College Chemistry professor Karen E. Wetterhahn (Di-methylmercury)





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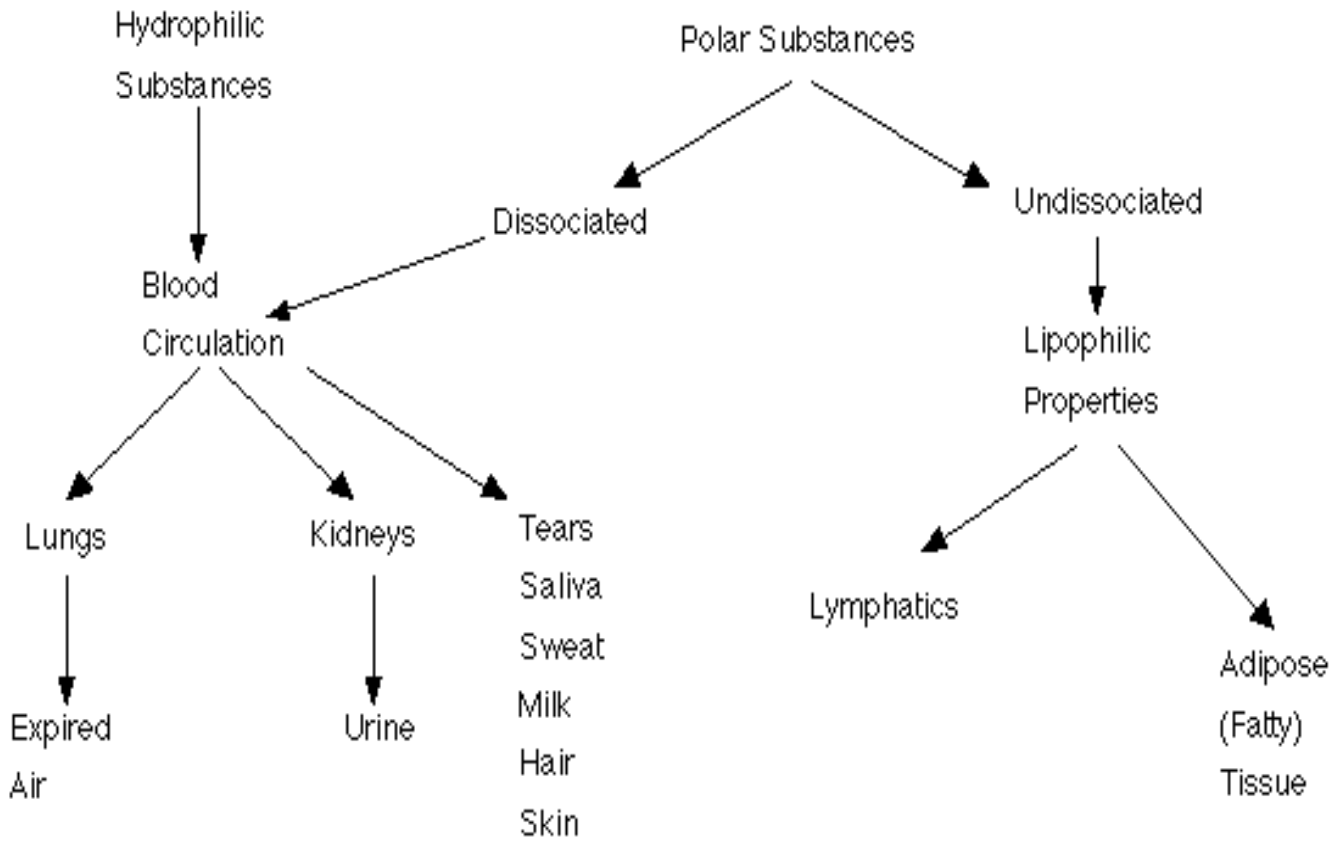
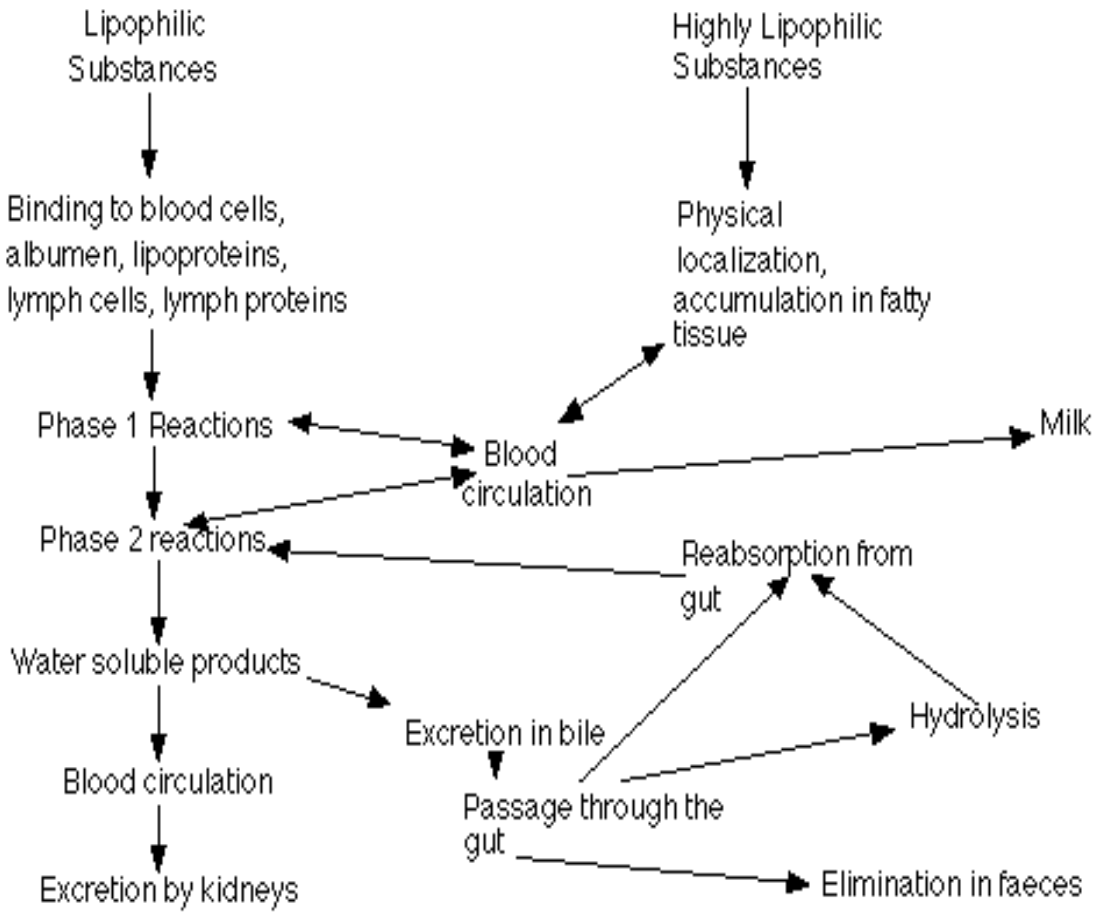
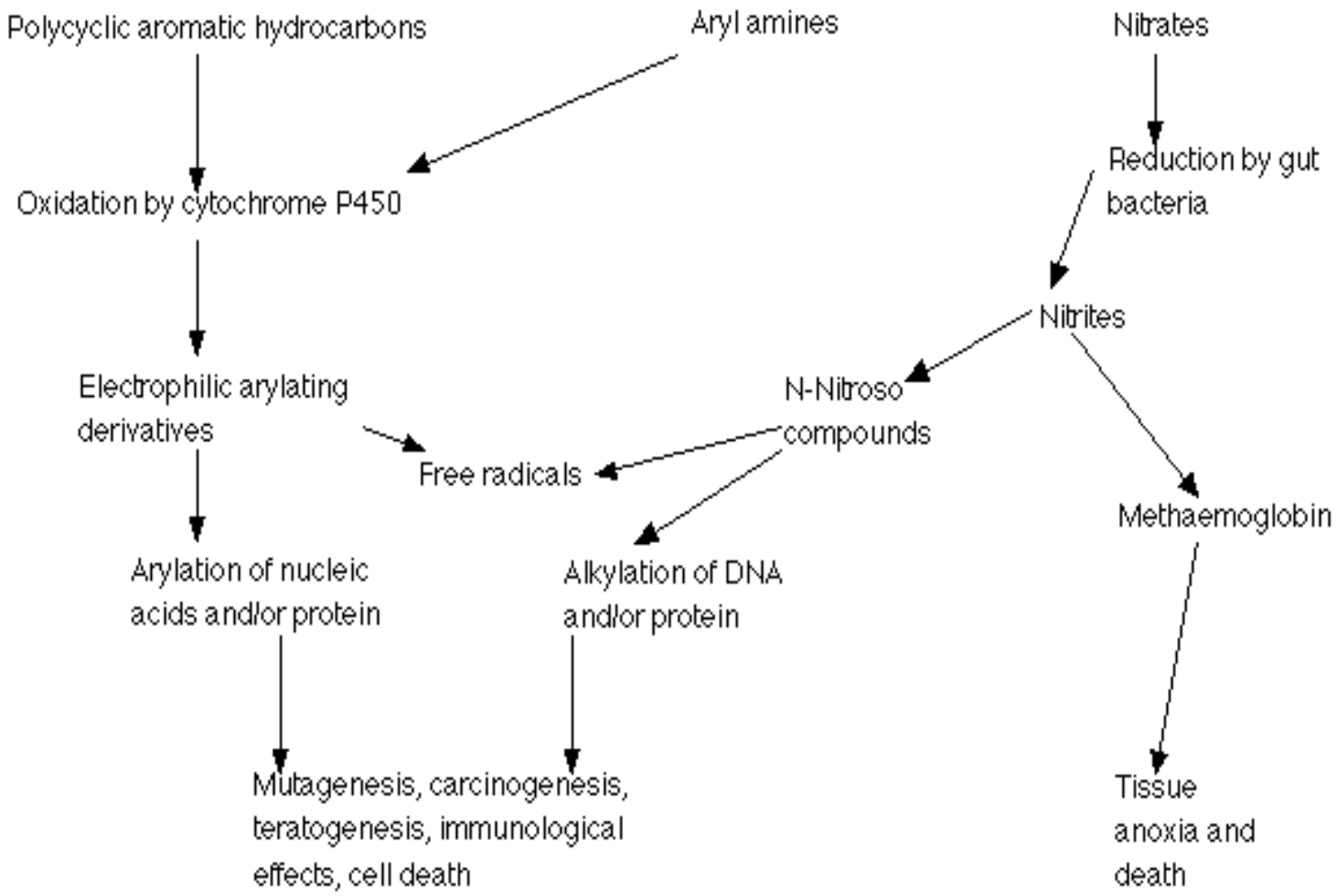
Distribution and excretion of potentially toxic substances which are hydrophilic or polar



Distribution and excretion of potentially toxic substances which are lipophilic



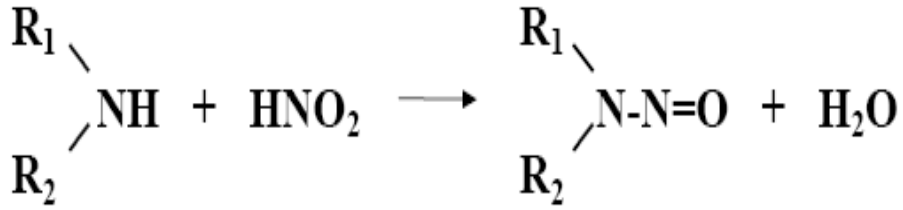
Examples of biotoxification

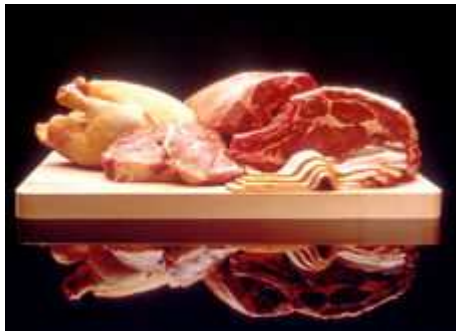


NITRATE/NITRITE/NITROSAMINES

Nitrate ***mouth bacteria*** Nitrite

Stomach





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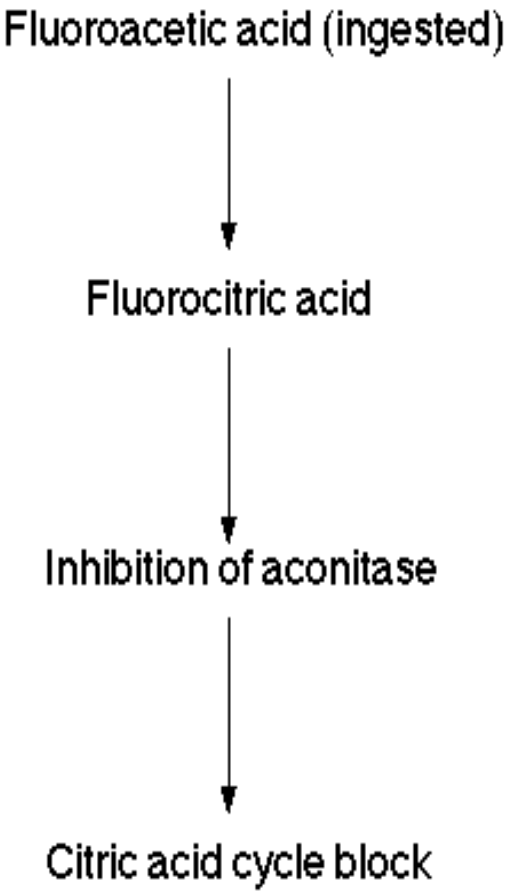
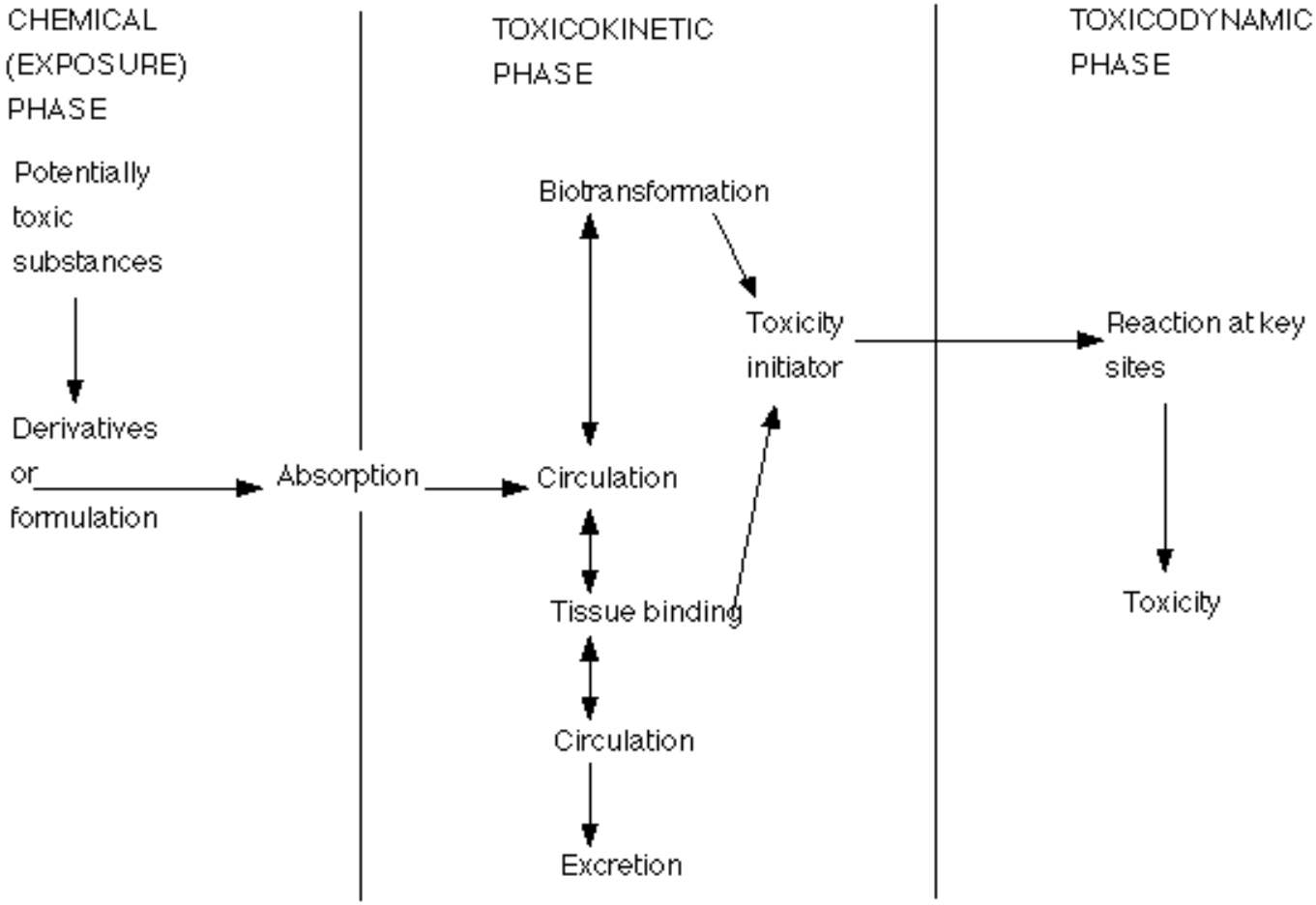
“Lethal Synthesis (rat poison-fluoro-acetic acid)”



Phases in the production of toxicity



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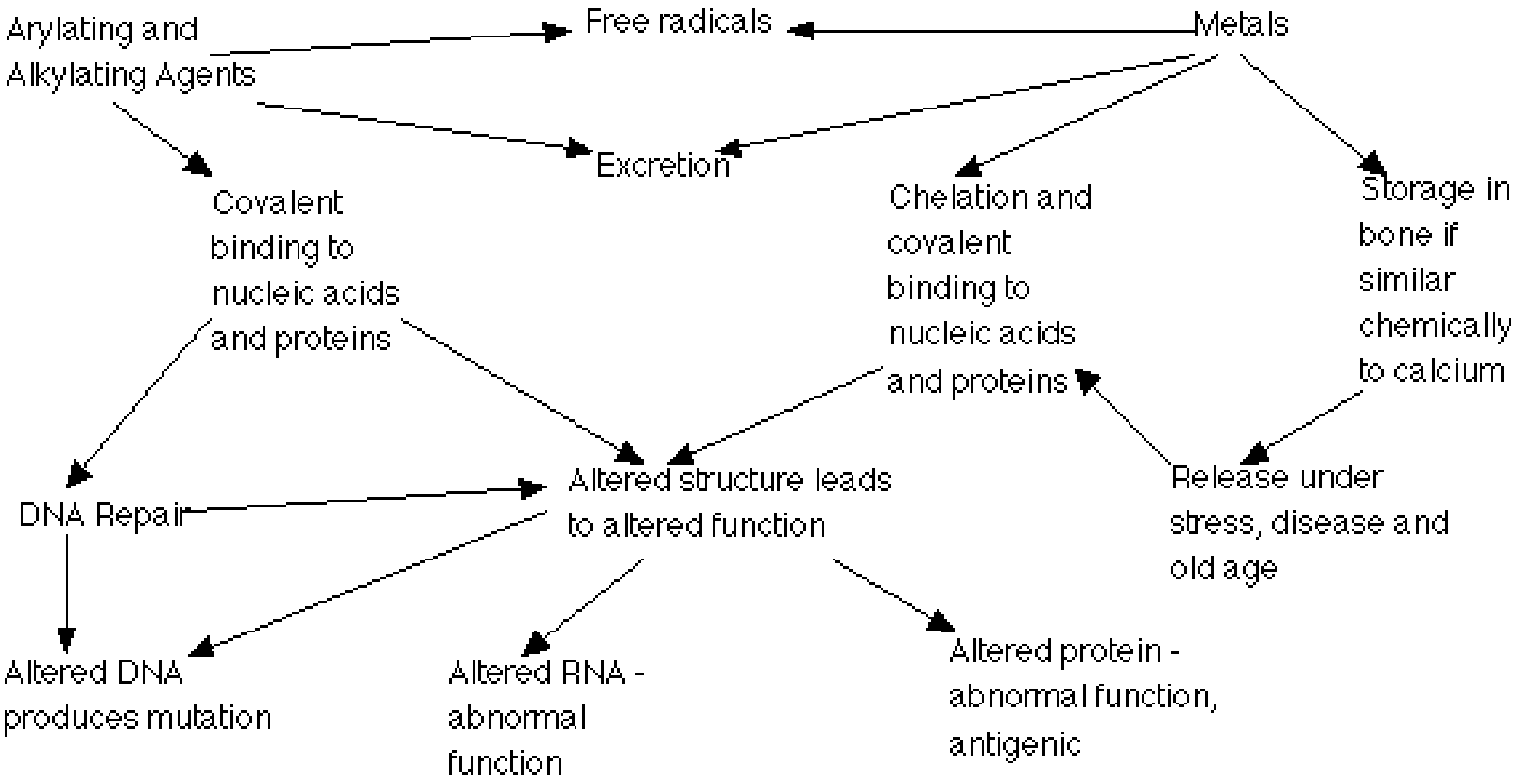
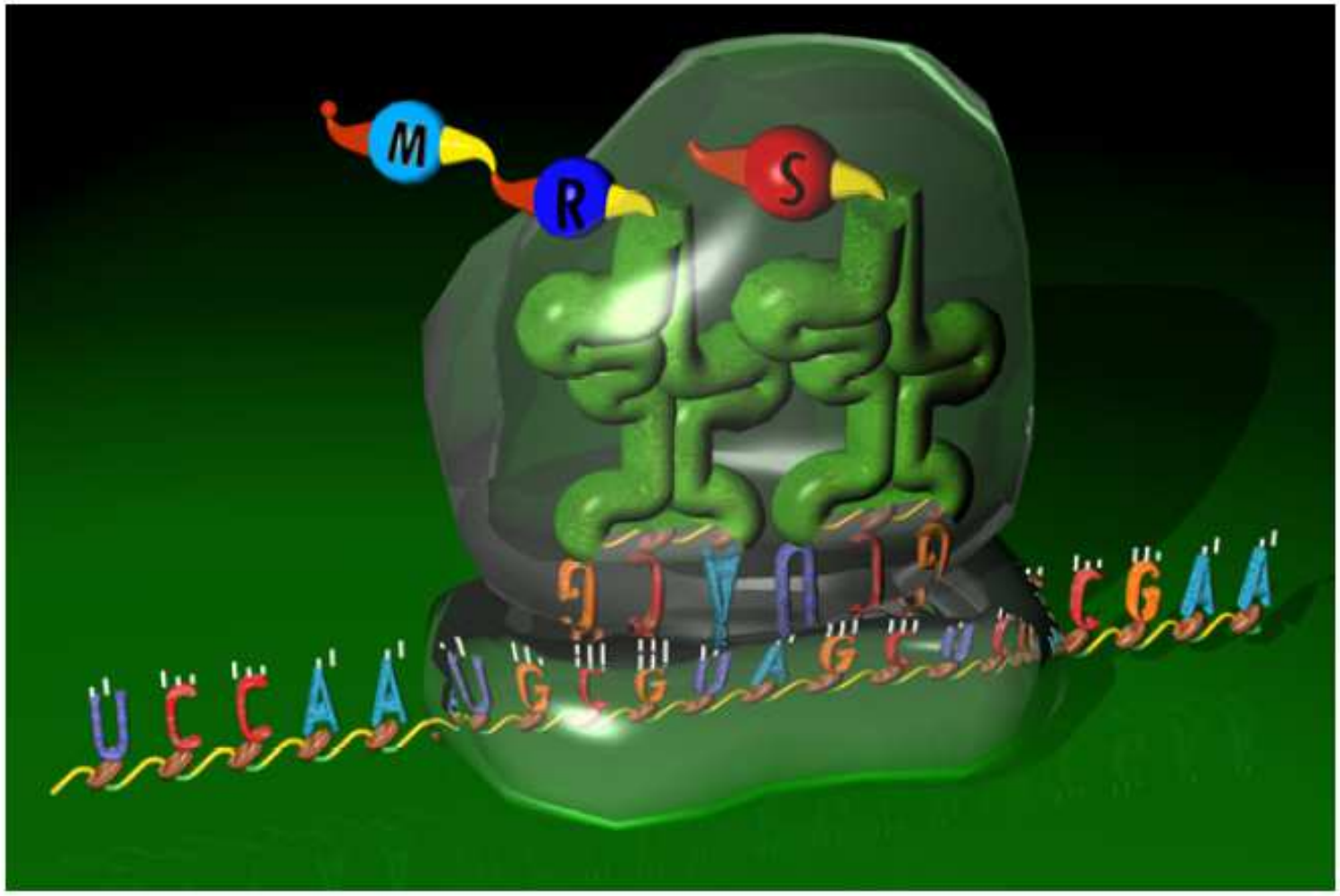
Main steps in biotransformation of potentially toxic substances which are arylating or alkylating agents or metals



DNA → messenger RNA (mRNA) → proteins



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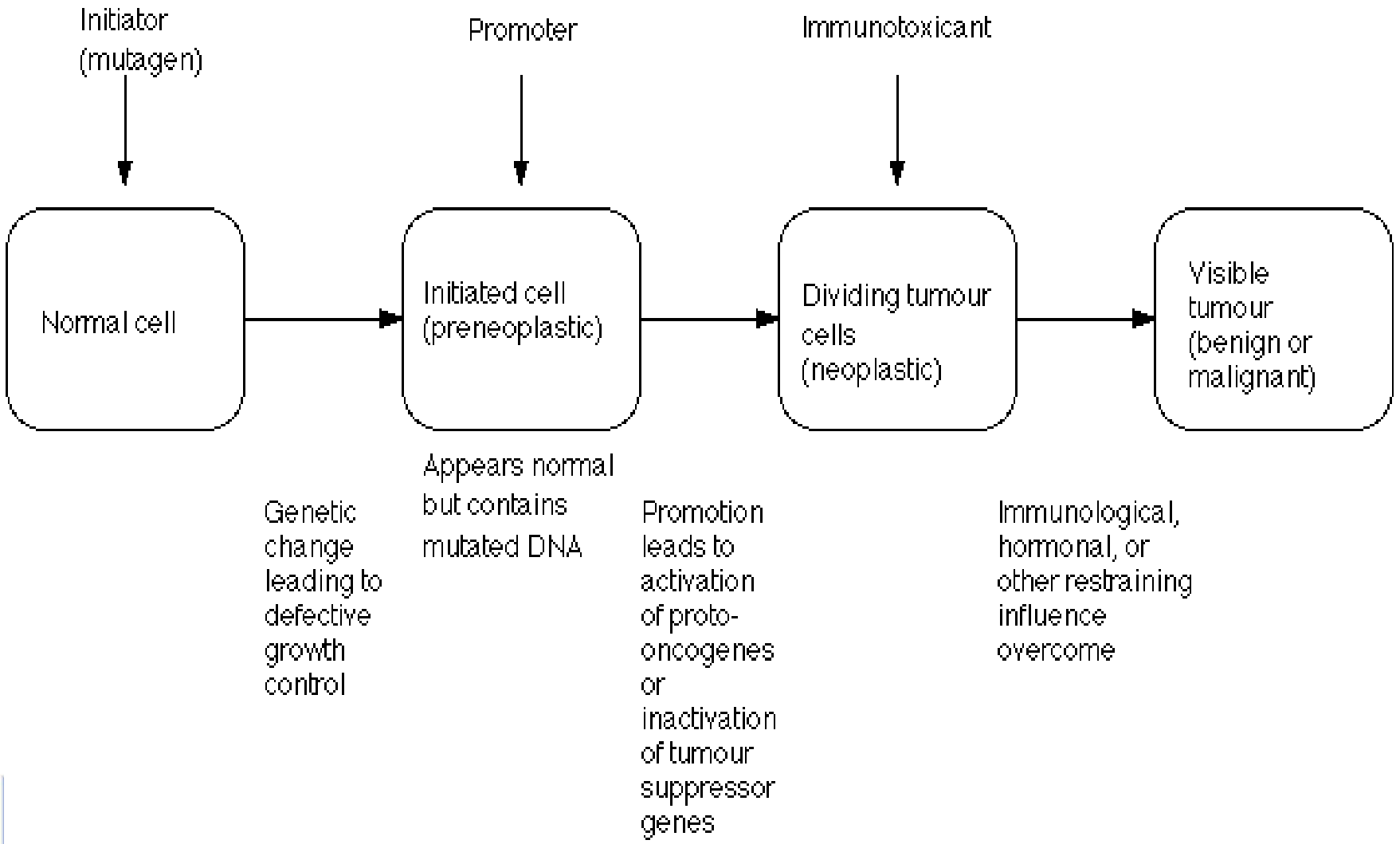
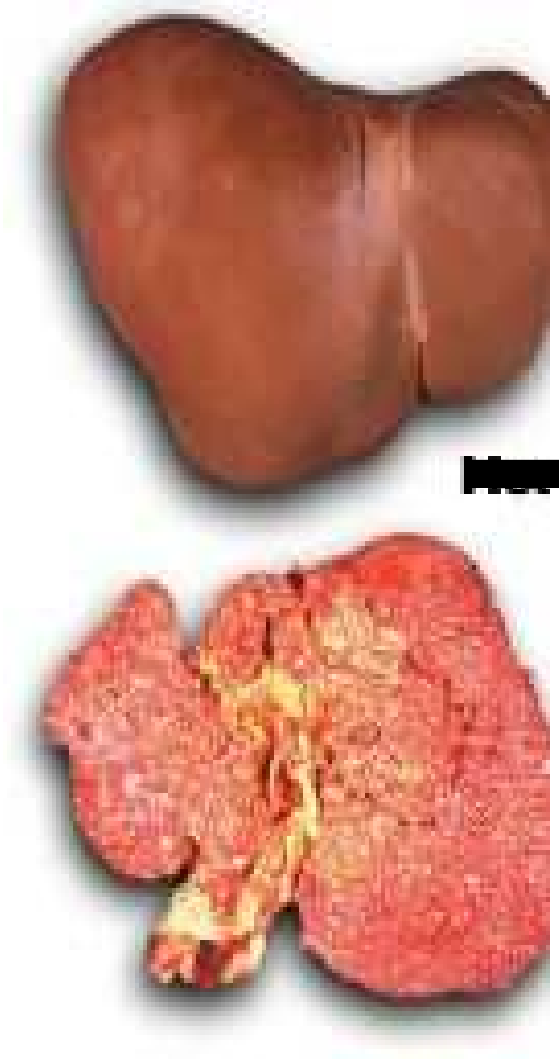
Steps in the development of tumors





LIVER CANCER

PRIMARY (eg.caused by aflatoxine or vinyl chloride)

SECONDARY (spreading of other)

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Cancer - Breast

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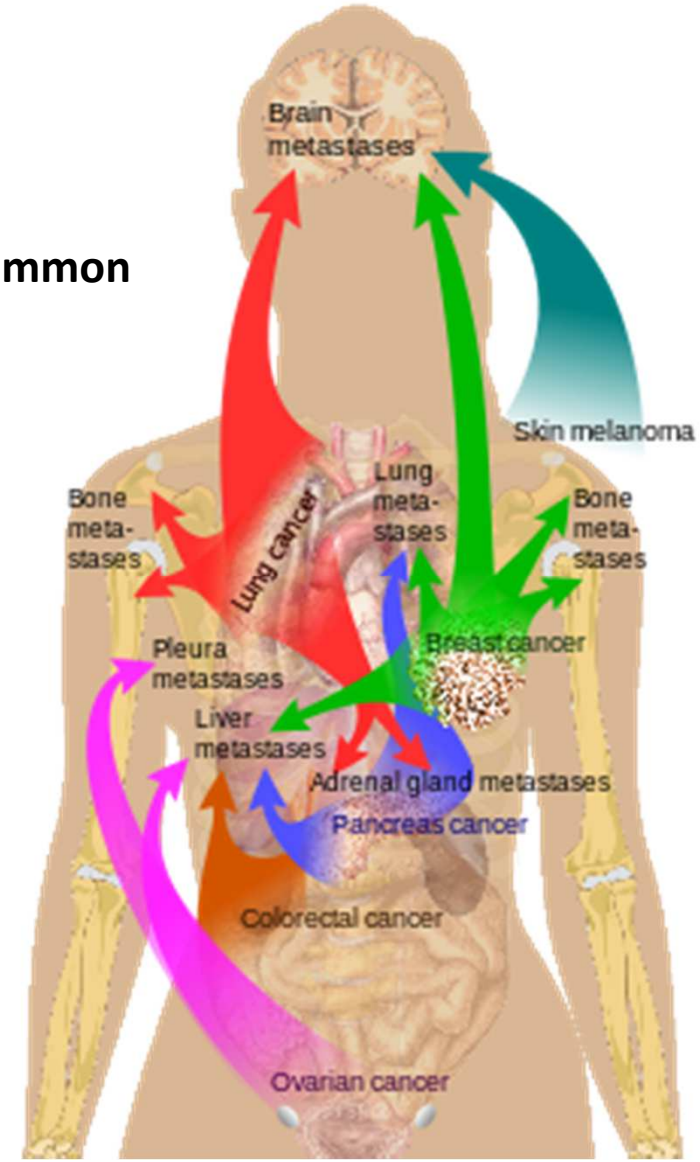
Metastases for common cancer types



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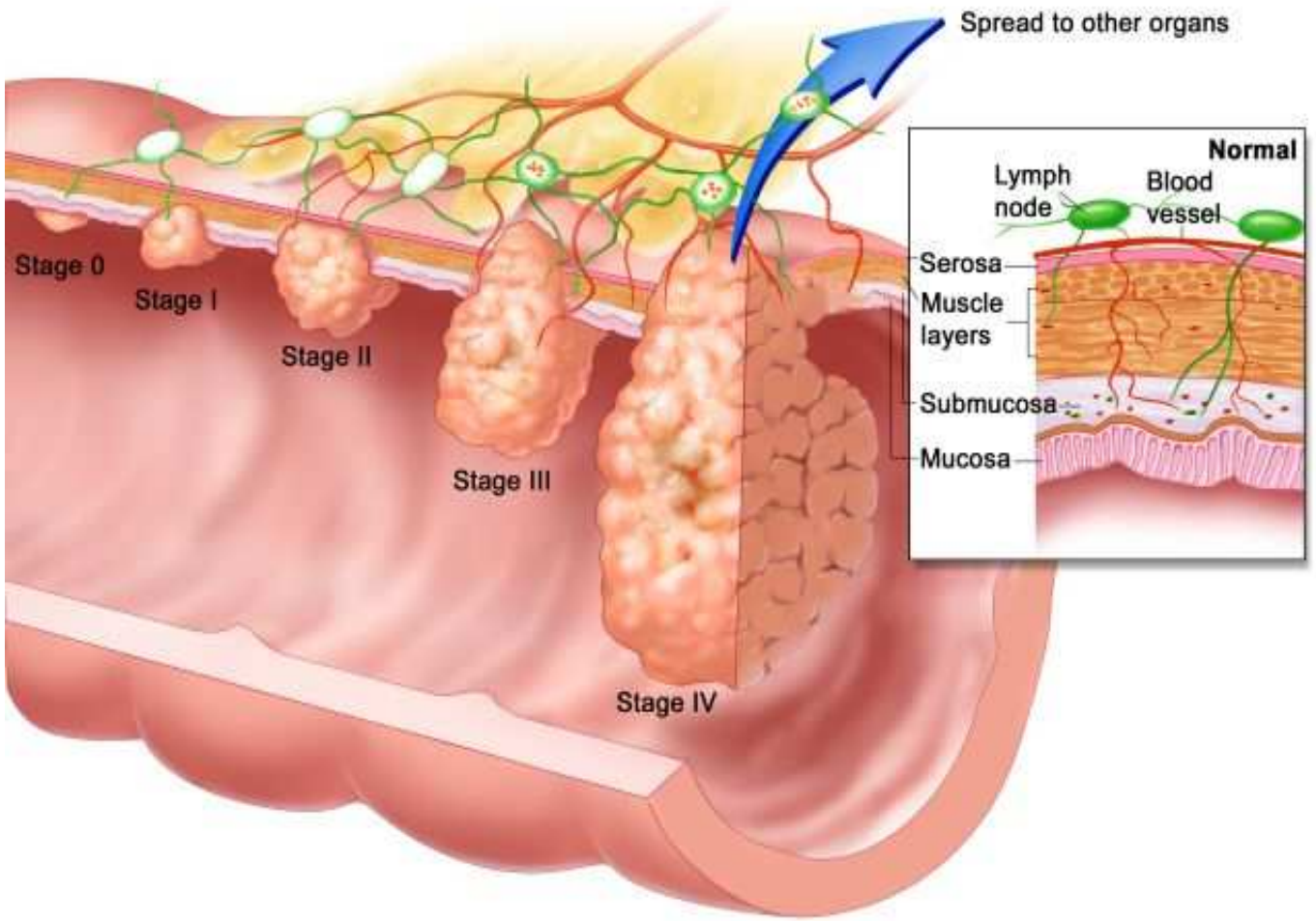
Cancer - Colon



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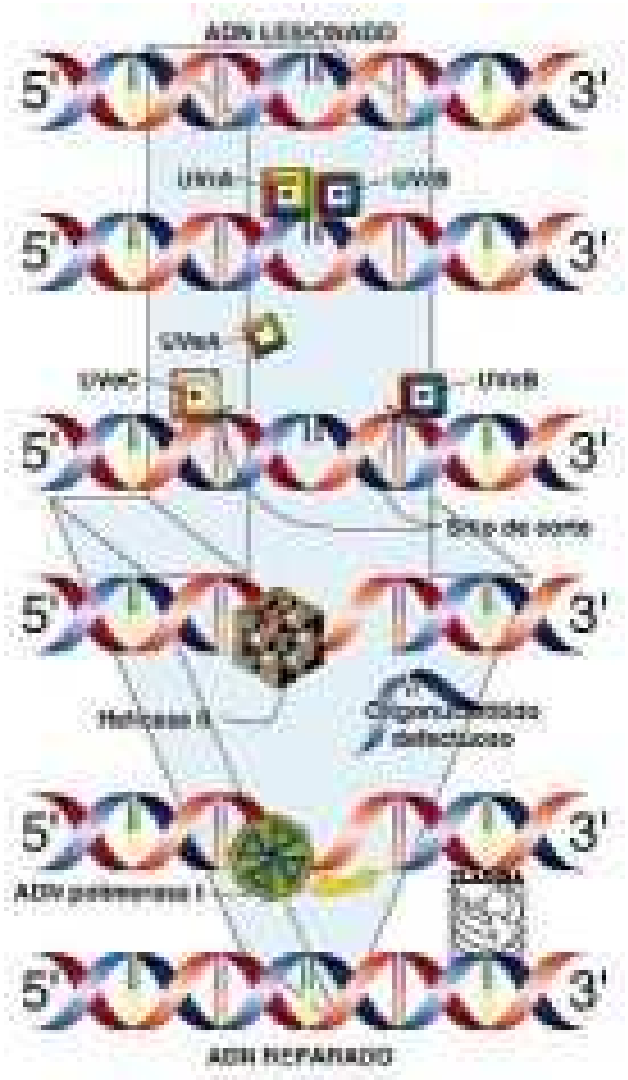
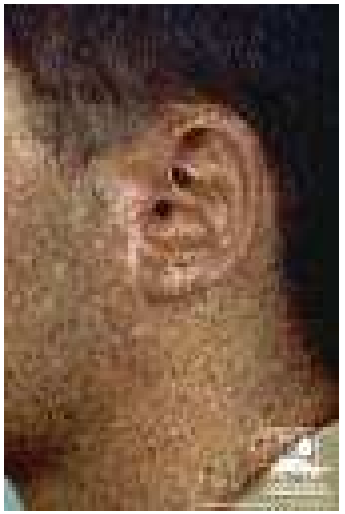


EXCISSION REPAIR MECHANISM

DNA lesions

(missing enzyme:example people sufferingfrom Xeroderma Pigmentosum)



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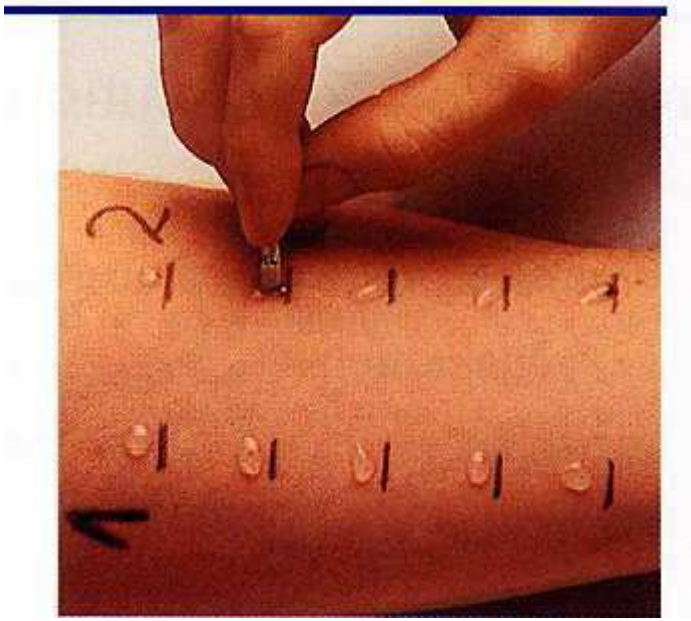
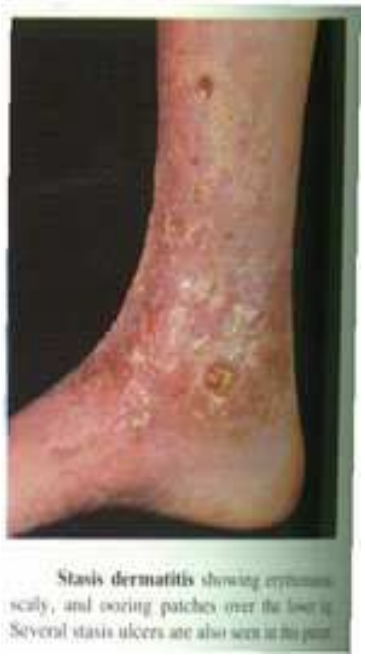
Allergic reactions

chemical → **combine with proteins** → **allergen** → **antibodies**





Stasis dermatitis showing erythema, scaly, and oozing patches over the lower l
Several stasis ulcers are also seen in this pati

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Interactions in toxicity

1 + 1 = 2, 1 + 5 = 6 (additive: eg. organophosphate pesticides)

1+ 1= 4, 1+ 5= 10 (synergistic: eg. asbestos and cigarette smoke increase risk of lung cancer with factor 40)

1+1=0, 1+5= 2 (antagonism: eg. some metals)

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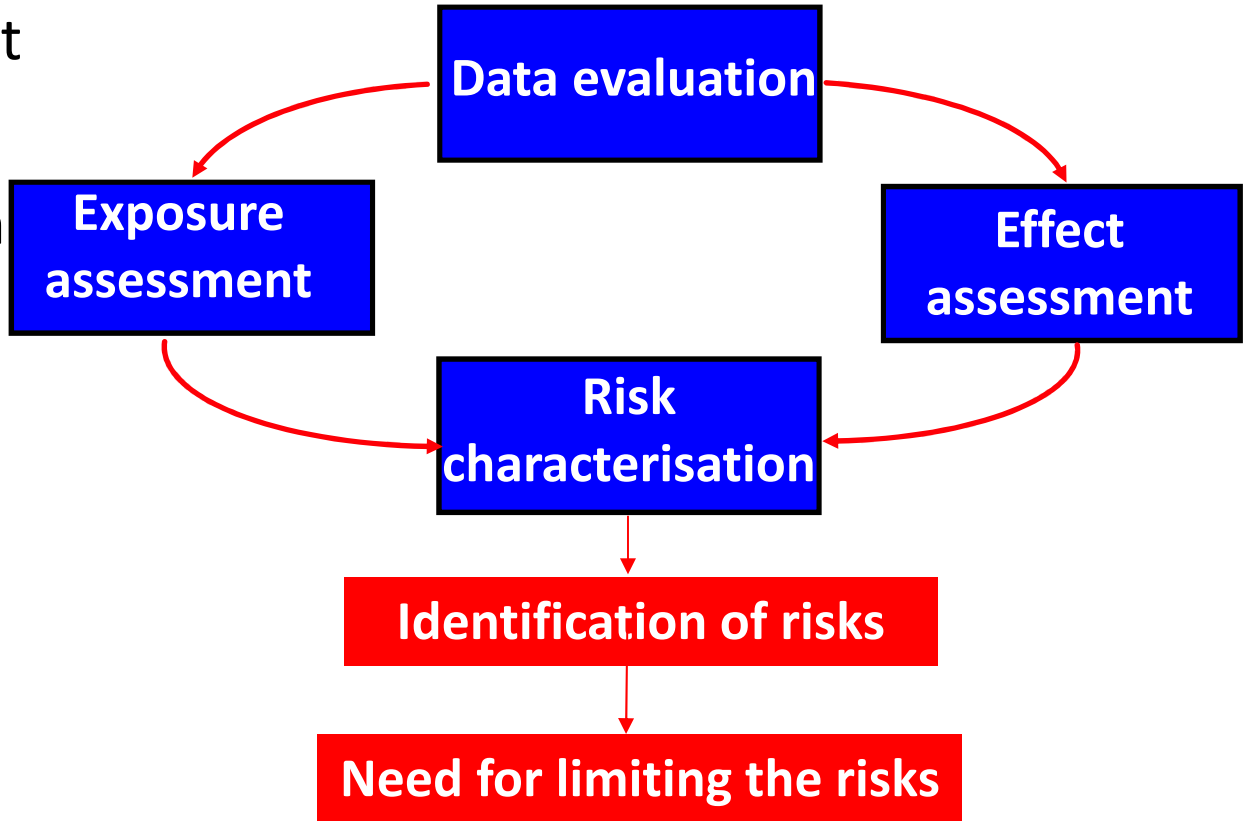
Principles of Health Risk assessment

Data evaluation: hazard indentification

Exposure assessment

Effects assessment

Risk characterisation



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Hazard identification - step 1

Hazards include:

- Physico-chemical hazards (main hazards are fire and explosion in this group)

- Hazards to health (divided in acute and chronic effects; local and systemic effects and; reversible an irreversable effects).

For example, skin irritation is an acute, local, reversible effect, whereas liver cancer is chronic, systemic and irreversible

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Effects Assessment - step 2

Effects human health

- ✓ acute toxicity;
- ✓ irritation;
- ✓ corrosivity;
- ✓ sensitisation;
- ✓ repeated dose toxicity;
- ✓ mutagenicity;
- ✓ carcinogenicity;
- ✓ toxicity for reproduction.

Laboratory NELs converted to DNELs
by applying “uncertainty factors” (range 10 - 10,000)

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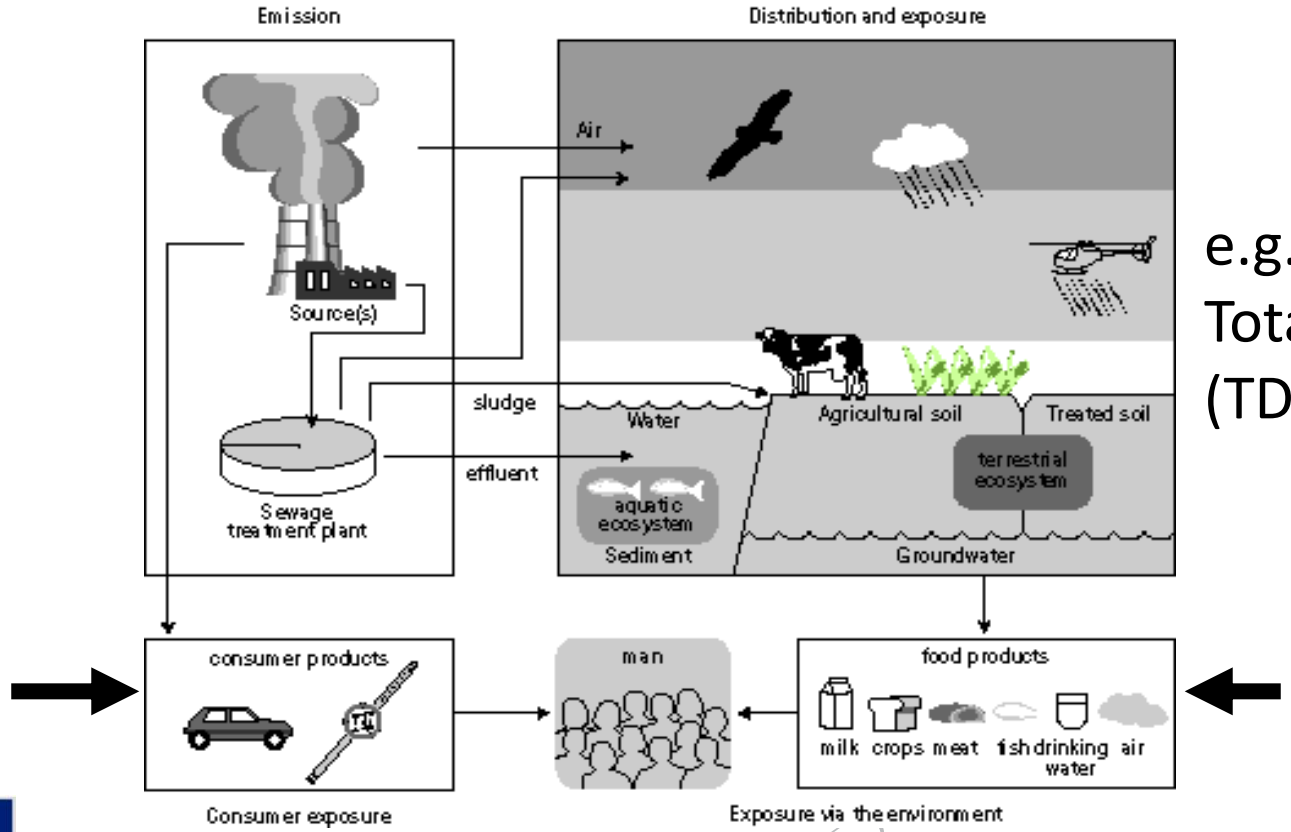
Exposure Assessment - step 3.1

1. Consumers
2. Human exposure via the environment



e.g. what is the Total Daily Intake (TDI)?

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Exposure Assessment - step 3.2

3. Workers (occupational exposure)

e.g. What is the exposure concentration 8-hr TWA in mg/m3 as percentage of the TLV, PEL or MAK)?

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Risk Characterization - step 4

Risk characterization is the estimation of the incidence and severity of the adverse effects likely to occur in the human population due to actual or predicted exposure.

= integration of step 1-3

When risk is not neglegible (eg TDI higher than 0.1(NEL or DNEL))

→ **Acceptable, tolerable or not?**

Is 1 in 50 000 risk of death each year acceptable, or should it be 1 in 100 000, or more?

= Risk Management ←

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Risk Assessment under REACH

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Basic risk assessment principles

Hazard Assessment	Hazard identification	DNEL/DMEL
	Dose - effect assessment	PNEC
Exposure Assessment	Quantification of exposure (direct and indirect)	Upper exposure level
		PEC
Risk Characterisation	Assessment of actual risk	Upper exposure level/DNEL < 1 PEC / PNEC < 1

** DNEL: Derived No Toxic Effect Level*
** DMEL: Derived Minimal Effect Level (for non-threshold Carcinogens)*
** PNEC: Predicted No Effect Concentration (for the environment)*

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Steps in Hazard Assessment

Step 1: Evaluation and integration of available information

Step 2: Classification and Labelling

Step 3: Derivation of the hazard threshold levels for human and the environment (DNEL/DMEL, PNEC)

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Hazard Assessment

- Step 1: Evaluation and integration of available information

- Registration dossier:
  - ≥1 tonne: Technical dossier
  - ≥10 tonnes: with Chemical Safety Report (CSR)

- Information requirements:
  - 1-10 tonnes: available phys-chem, tox and ecotox information + Phys-chem properties in Annex VII (full Annex VII for substances meeting Annex III criteria)
  - 10-100 tonnes: Annex VII & VIII
  - 100-1000 tonnes: Annex VII & VIII; test proposals for information in Annex IX
  - ≥ 1000 tonnes: Annex VII & VIII; test proposals for information in Annex IX & X

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REACH Registration Requirements

Tonnage	Physico-chemical properties
≥ 1 t/y	State of the substance at 20 °C and 101,3 kPa Smelting/freezing point Boiling point Relative density Vapour pressure Surface tension Water solubility Partition coefficient in-octanol/water Flash-point Flammability Explosive properties Self-ignition temperature Oxidising properties Granulometry
≥ 100 t/y	Stability in organic solvents and identity of relevant degradation products Dissociation constant Viscosity

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

Step 1: Evaluation and integration of available information

Information Gathering

1: Gather and share existing information

2: Consider information needs

3: Identify information gaps

4: Generate new information or propose a testing strategy

Information sources

- ✓ *in-house company and trade association files (including test data)*
- ✓ *databanks and databases of compiled data*
- ✓ *agreed data sets such as the OECD HPV Chemicals Program*
- ✓ *published literature*
- ✓ *internet search engines and relevant websites*
- ✓ *(Q)SAR models (Section R.6.1)*
- ✓ *data sharing in the substance information exchange forum (SIEF)*

Step 1: Evaluation and integration of available information

Evaluation of available information

- ✓ Relevance
- ✓ Reliability

Klimisch code (scoring system) for 4 categories

1. Reliable without restrictions
2. Reliable with restrictions
3. Not reliable
4. Not assignable

- ✓ Adequacy
  - ➢ Test data
  - ➢ Non-testing data
  - ➢ Human data

✓*New toxicology and ecotoxicology tests must be based on GLP (OECD and EU protocols)*

✓*Others must be carefully evaluated*

The weight of evidence (WoE) approach

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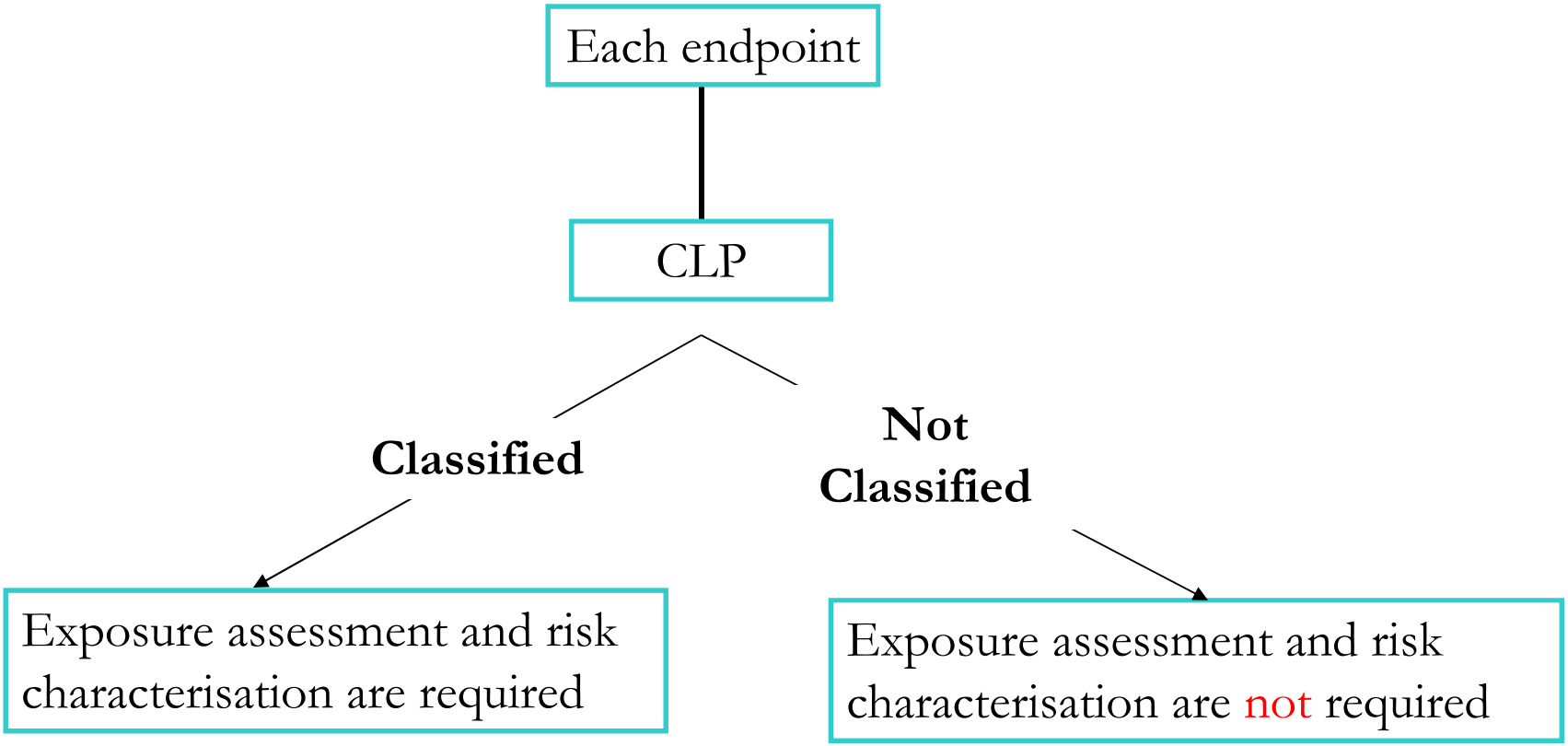
Step 2: Classification and Labelling



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Step 3: Derivation of the hazard threshold levels - DNEL(s)/DMEL

1. Identifying dose descriptors and deciding on mode of action

As part of the evaluation of the toxicity studies, dose descriptors (e.g., NOAEL, NOAEC, BMD, LD50, LC50, T25) should be identified for the endpoint concerned.

→ DMEL derivation

If no treshold mode of action (eg. Geno-toxic carcinogen)

2. Application of Assessment Factors (AFs)

To compensate for uncertainties (intra-/interspecies, Quality, exposure duration etc.)

$$Endpoint-specific \quad DNEL = \frac{NOAEL_{corr}}{AF_1 * AF_2 * \_ * AF_n} = \frac{NOAEL_{corr}}{Overall \quad AF}$$

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Step 3: Derivation of the hazard threshold levels - DNEL(s)/DMEL

Local *vs* Systemic Health Effects

A **Local effect** refers to an adverse health effect that takes place at the point or area of contact. The site may be skin, mucous membranes, the respiratory tract, gastrointestinal system, eyes, etc. Absorption does not necessarily occur.

Examples: strong acids or alkalis.

Systemic effect refers to an adverse health effect that takes place at a location distant from the body's initial point of contact and presupposes absorption has taken place.

Examples: arsenic effects to the blood, nervous system, liver, kidneys and skin; benzene effects to the bone marrow.

Step 3: Derivation of the hazard threshold levels - DNEL(s)/DMEL

3. Select the leading health effect(s) for relevant exposure patterns

The critical DN(M)EL, used for the (semi-)quantitative risk characterisation, should be the lowest DN(M)EL obtained for the relevant combination of population/route/exposure pattern.

For both **acute and long-term local effects**, DNELs may need to be set for workers and the general population exposed via the dermal and inhalation routes (i.e., four local DNELs).

For **systemic, long-term effects**, long-term DNELs are needed for worker dermal and inhalation exposure routes.

Additionally, three long-term DNELs may need to be set for the general population (dermal, oral and/or inhalation) (ref consumer products and environmental contaminants)

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Step 3: Derivation of the hazard threshold levels - PNEC

$$PNEC_{comp} = \frac{\text{Min } \{EC_{comp}\}}{AF}$$

The lowest valid effect concentration for organisms from the compartment i.e. EC50 or LC50, EC10/NOEC

Assessment factor

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Step 3: Derivation of the hazard threshold levels - PNEC

Data set	Assessment factor (AF)
Lowest short-term L(E)C50 from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels	10,000
Lowest short-term L(E)C50 from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels, + two additional marine taxonomic groups (e.g. echinoderms, molluscs)	1000
One long-term result (e.g. EC10 or NOEC) (from freshwater or saltwater crustacean reproduction or fish growth studies)	1000
Two long-term results (e.g. EC10 or NOEC) from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish)	500
Lowest long-term results (e.g. EC10 or NOEC) from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels	100
Two long-term results (e.g. EC10 or NOEC) from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) + one long-term result from an additional marine taxonomic group (e.g. echinoderms, molluscs)	50
Lowest long-term results (e.g. EC10 or NOEC) from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels + two long-term results from additional marine taxonomic groups (e.g. echinoderms, molluscs)	10

Exposure Assessment

- The exposure should, where possible, be described using both **reasonable worst-case** and **typical exposures**
- Actual exposure measurements
- Exposure estimates should be developed by collecting **all necessary information**
- In carrying out the exposure estimation the risk reduction/control measures (RMMs) that are **already** in place **should be taken into account**

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Exposure estimation with measurements and modelling approaches - Occupational Exposure Estimation

Tier 1:

- ✓ ECETOC Targeted Risk Assessment (ECETOC TRA) tool
- ✓ Easy-to-use workplace control scheme for hazardous substances (EMKG/BauA-COSHH) www.baua.de

Higher Tier:

Currently no validated higher Tier exposure tools

- ✓ Stoffenmanager exposure model
- ✓ RISKOFDERM dermal model
- ✓ Advanced tool for occupational exposure assessment

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Exposure estimation with measurements and modelling approaches - Consumer Exposure Estimation

Tier 1:

ECETOC TRA Consumer tool

Lower tier:

ConsExpo computer tool www.consexpo.nl

Higher tier:

Advanced refinements for ECETOC TRA consumer tool

Others:

US EPS E-Fast model

Web-based GExFRAME system
http://gexframe.jrc.ec.europa.eu/Default.aspx

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Exposure estimation with measurements and modelling approaches - Environmental Exposure Estimation

EUSES http://ecb.jrc.it/euses - Tier 1 assessment

TGD excel sheet (EU TGD 2003 Risk Assessment Spreadsheet Model) – Tier 1 and higher Tiers

Others:

- ✓ FOCUS-models (surface water, agricultural soil)
- ✓ CHARM (offshore installation e.g. drilling and production chemicals, or completion/workover)
- ✓ Emission scenario documents for biocides (ESDs) http://ecb.jrc.it/biocides/

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Risk characterisation ratios (RCRs)

Environment Human health

$$RCR = \frac{PEC}{PNEC} \text{ or } \frac{Exposure}{DNEL}$$

If RCR < 1 → Risk is adequately controlled

If RCR > 1 → Risk is NOT controlled

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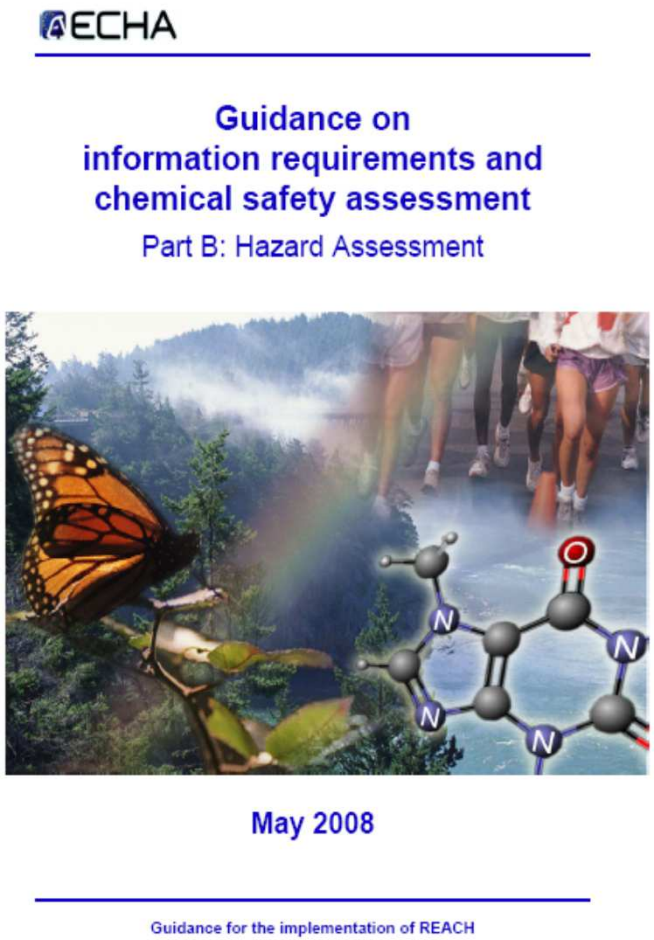
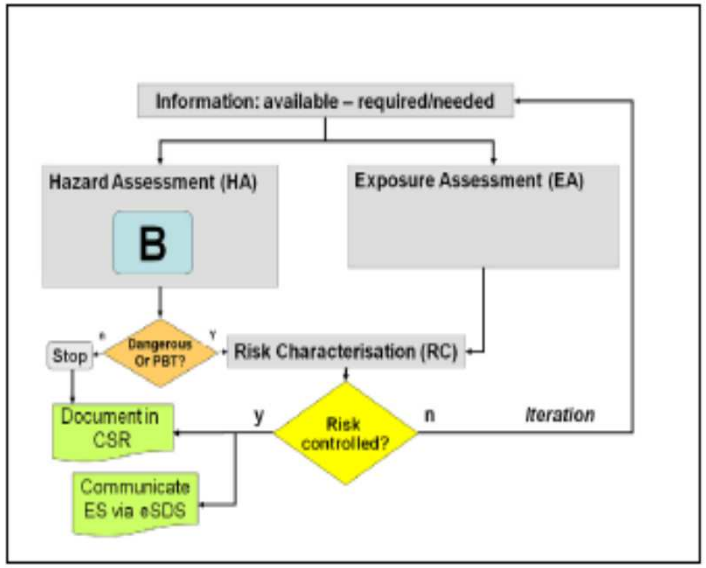
ECHA Guidance - Effect Assessment





R.7: Endpoint specific guidance
R.8: Characterisation of dose [concentration]-response for human health
R.9: Physico-chemical hazards
R.10: Characterisation of dose [concentration]-response for environment
R.11: PBT Assessment

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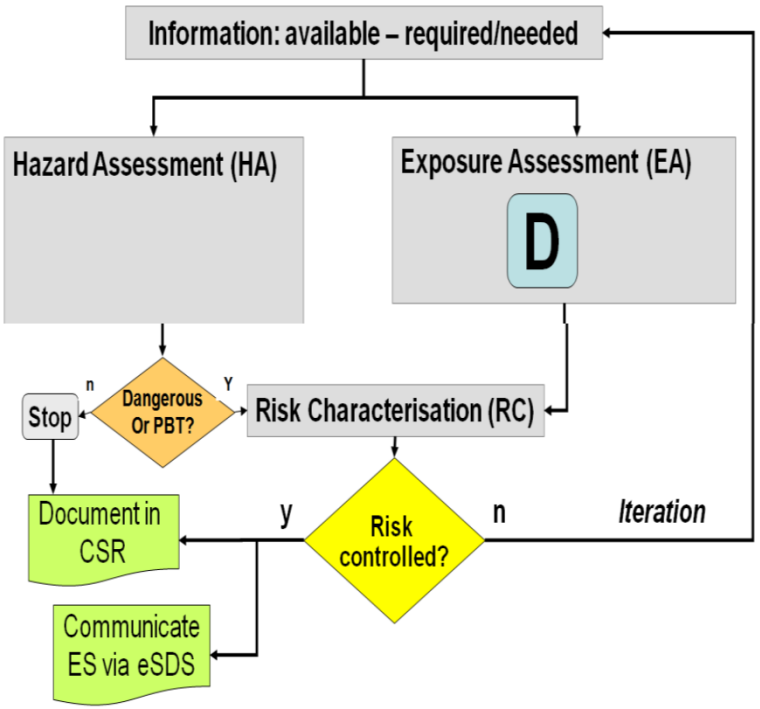
ECHA Guidance – Exposure Assessment



R.12: Use descriptor system

R.13: Risk management measures and operational conditions

R.14: Occupational Exposure Estimation

R.15: Consumer Exposure Estimation

R.16: Environmental Exposure Estimation

R.17: Estimation of exposure from articles

R.18: Estimation of exposure from waste life stage

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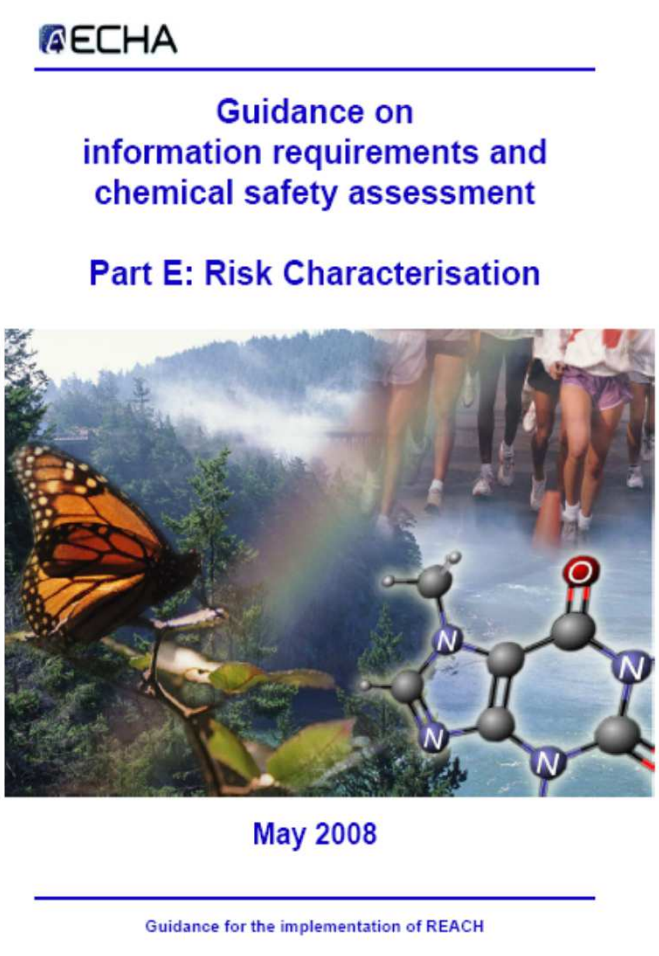
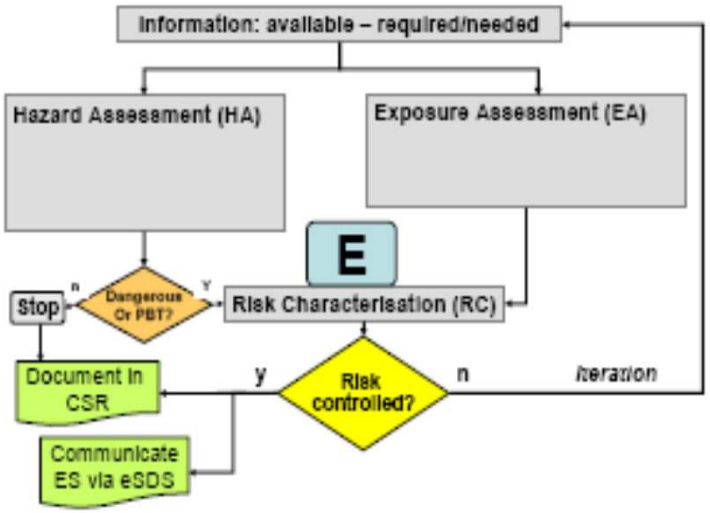
ECHA Guidance – Risk Characterization





R.13: Risk management measures and operational conditions

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Chesar stands for Chemical Safety Assessment and Reporting. The tool has been developed by the European Chemicals Agency (ECHA) for supporting registrants under REACH. It suggests a workflow for carrying out exposure assessments and risk characterisations, thereby facilitating the generation of a Chemical Safety Report (CSR) and exposure scenarios for communication.

website: http://chesar.echa.europa.eu/

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and Climate
on Network ECRAN

Box 1 Manage substance

Box 2 Report uses

Box 3 Manage exposure estimation

Box 4 Build exposure scenarios for the CSR

Box 5 Build exposure scenarios for the extended SDS

Box 6 Library

Box 7 User management

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Environment and Climate Regional Accession Network ECRAN

CLP Specific - Regulation

Ms. Shufan Qi

RPS advies- en ingenieursbureau The Netherlands

Montenegro

13 – 15 May 2014

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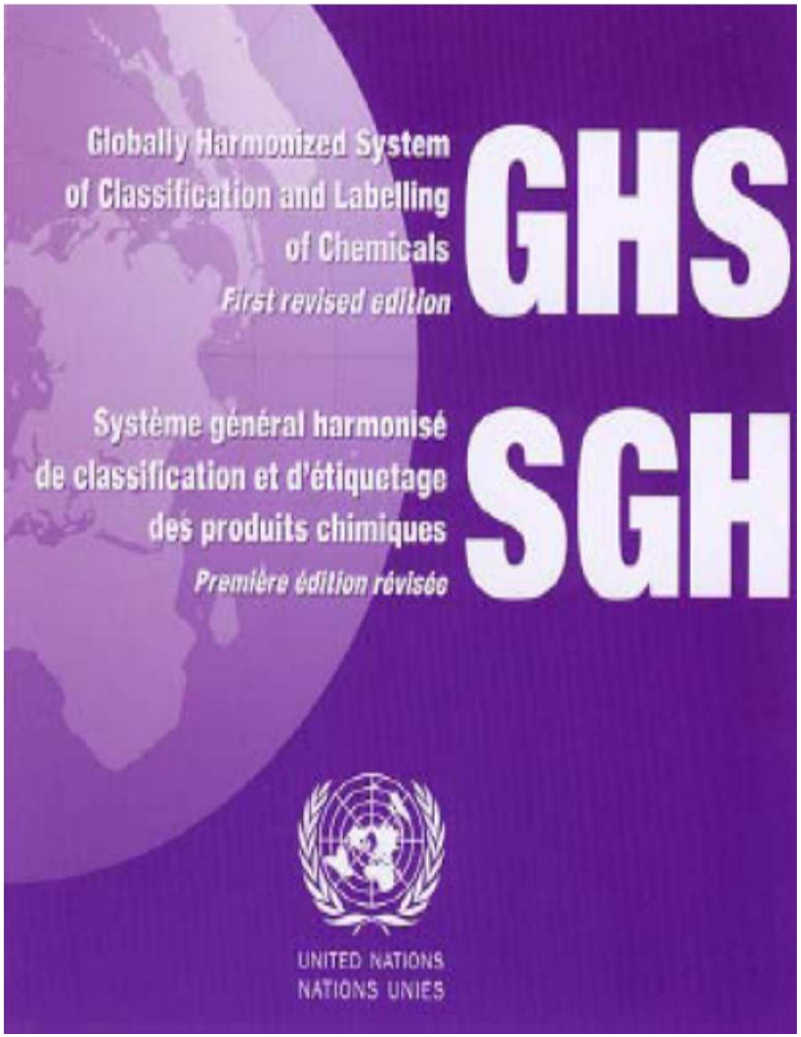

- GSH is **G**lobally **H**armonised **S**ystem of Classification and Labelling of Chemicals
- The United Nations developed GHS to harmonize worldwide how chemicals are classified and how hazards are communicated.
- GHS targets:

✓ *Consumers*

✓ *Workers*

✓ *Emergency responders*

✓ *Transport*

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EU Implementation of GHS

- ✓ The EU has published Regulation No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) on December 31 2008.

- ✓ This legislation lays down the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures.

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Contents of the Regulation

Legal text containing principles and general rules

TITLE I - General Issues

TITLE II – Hazard Classification

- Chapter 1 Identification and Examination of Information
- Chapter 2 Evaluation of Hazard Information and Decision on Classification

TITLE III – Hazard Communication in Form of Labelling

- Chapter 1 Content of the Label
- Chapter 2 Application of Labels

TITLE IV - Packaging

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Contents of the Regulation (Cont.)

TITLE V – Harmonisation of C&L of Substances and the C&L Inventory

- Chapter 1 Establishing Harmonised Classification and Labelling of Substances
- Chapter 2 Classification and Labelling Inventory

TITLE VI – Competent Authorities and Enforcement

TITLE VII – Common and Final Provisions

Contents of the Regulation

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:	Translation Table for classification

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Objectives of CLP Regulation

Replace the Dangerous Substances Directive (DSD) 67/548/EEC and Dangerous Preparations Directive (DPD) 1999/45/EC.

Establish a harmonized list of substances classified at the Community level.

Incorporate Title XI (Classification & Labelling Inventory) from REACH Regulation.

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Scope

CLP does not apply to:

- Radioactive substances and mixtures
- Non-isolated intermediates
- Substances and mixtures under customs supervision
- Waste products
- Medicines and veterinary medicines
- Cosmetics
- Medical devices (e.g. art joints)
- Foods (including additives and aroma substances)
- Animal foods (including additives in cattle and animal foods)
- Substances and mixtures for research and development
- Substances and mixtures exempted by MSs in the interest of defense
- The transport dangerous goods

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Relationship with REACH

CLP	REACH
Transition periods consistent with REACH	Transition periods registration
Provides criteria for C& L	C&L in REACH Registration dossier
C&L of substances	REACH provides information for C&L
C&L of substances	REACH obligations dependent on C&L For example: registration deadline, provisions for substances in articles, authorization

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CLP Timelines

Until December 1, 2010:

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards

Substances

MUST be Classified, labelled packaged under DSD

MAY: Classified, labelled packaged under CLP; No DSD label/package

Mixtures

MUST be: Classified, labelled packaged under DPD

MAY: Classified, labelled packaged under CLP; No DPD label/package

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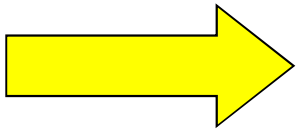
CLP Timelines

FROM 1 December 2010 (CLP replaces DSD substances)

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards



Substances

MUST be Classified in accordance with DSD and CLP, labelled and packaged under CLP

*Note: **substances** already classified, labelled and packaged according to DSD and placed on the market <December 1 2010 will **have to be re-packaged and re-labelled by 1 December 2012***

Mixtures

MUST be Classified, labelled packaged under **DPD**

MAY be Classified, labelled packaged under **CLP**; No DPD label/package

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CLP Timelines

From 1 June 2015 (CLP replaces DPD mixtures)

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards

Substances

MUST be classified, labelled & packaged under CLP

Mixtures

MUST be classified, labelled & packaged under CLP

Note: ***mixtures*** *already classified, labelled and packaged according to DPD and placed* ***on the market <June 1 2015 will have to be repackaged and re-labelled by 1 June 2017***

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Dia 12

SQ1 Need to check
Shufan Qi; 21-3-2014

Roles and obligations

					Downstream user			
	Obligation	Manu facturer	Impor ter	Distri butor	Formu lator	Producer of article	Professional User	Industrial User
1	Classification	X	X	-	X	O	-	-
2	Labelling	X	X	X	X	O	-	-
3	Packaging	X	X	X	X	O	-	-
4	Notification	X	X	-	-	-	-	-
5	Keep Information (10 years)	X	X	X	X	X	-	-

X = always applicable

O = sometimes applicable

- = not applicable

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Obligations

- Classification and labelling according to rules (Article 4)
- Gathering and evaluation of available information (Article 5)
- **Notify classification and labelling at ECHA (Article 40) *As from 1 December 2010***
- Packaging according to rules (Article 35)
- Retention, ten years after last supply (Article 49)

Notification obligation (1)

- Article 40
- Information suppliers: (group of) manufacturers, importers
- Substances placed on the market
- ***Before, and still, or again*** *on 1 December 2010, notification deadline is 3 January 2011*
- ***after*** *1 December 2010, notify at the latest 1 month after the substance has been placed on the market*
- Hazardous substances, irrespective of volume (Article 39b)

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Notification obligation (2)

- All substances subject to REACH registration and placed on the market:
  - *Obligation also applies to certain substances in articles which has to be registered according to article 7 of REACH (Article 39 (a))*
  - *Notification is not necessary when the substance already has been registered in accordance with REACH (Article 40.1)*
- Substances classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC, which results in the classification of the mixture as hazardous, and the mixture is placed on the market (CLP Article 39(b)).
- Notification also obligatory if an other company already has notified the C&L of the same substance

Notification obligation (3)

To provide information:

a. The identity of information supplier who puts the substance on the market, in accordance with point 1 of appendix VI REACH

b. The identity of the substance, in accordance with 2.1 till 2.3.4 appendix VI REACH

c. The classification of the substance

d. If a substance in a number, but not in all hazard classes or subcategories, has been classified, a clear indication of the reason (missing data, data which are not convincing or data which, however, convincing but insufficient to base a classification on)

e. if appraisal, specific concentration borders or M-factors, founded assessment in accordance with chapters 1, 2 and 3 of appendix I (CSR) of REACH

f. specified labelling elements for the substance with additional hazard statements (Article 17, paragraph 1, under d), e) and f), and Article 25, paragraph 1.)

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Overview of changes (1)

67/548/EEG	1272/2008
7 pictograms	9 pictograms
15 danger classes	28 hazard classes including subcategories
R-phrases	**H**-statements
S-phrases	**P**-statements
Additional phrases	EUH-statements
-	Signal words: danger and warning
Annex I	Annex VI
	Annex VII: conversion old to new
Criteria for substances Criteria for mixtures in 1999/45/EG	Criteria for substances and mixtures

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Overview of changes(2)

Classification on Safety Data Sheet for all substances and mixtures classified according to CLP

Definitions:

- Term ‘preparation’ replaced by ‘mixtures’
- Term ‘dangerous’ replaced by ‘hazardous’

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Hazard pictograms CLP

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Transport labelling CLP

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Classification criteria differences

DSD Physical Hazards	CLP Physical Hazards	
Explosives	Corrosive to metals	Pyrophoric liquids
Flammability	Explosives	Pyrophoric solids
Oxidising	Flammable gases	Self-heating su bstances and mixtures
Others	Flammable aerosols	Self-reactive substances and mixtures
	Flammable liquids	Substances and mixtures which in contact with water emit flammable gases
	Flammable solids	
	Gases under pressure	
	Organic peroxides	
	Oxidizing gases	
	Oxidizing liquids	
	Oxidizing solids	

Classification criteria differences

DSD Health Hazards	CLP Health Hazards
Acute lethal	Acute toxicity
Non-lethal irreversible	Aspiration hazard
Severe effects	Carcinogenicity
Corrosive effects	Germ cell mutagenicity
Irritant effects	Reproductive toxicity
Sensitizing effects	Respiratory or skin sensitization
Carcinogens	Serious eye damage/irritation
Mutagens	Skin corrosion/irritation
Toxic for reproduction	Specific target organ toxicity (STOS) – single/repeated exposure

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Classification criteria differences

DSD Environmental Hazards	CLP Environmental Hazards
Aquatic environment Non aquatic environment Dangerous for the ozone layer	Hazardous to the aquatic environment - *Acute aquatic hazard* - *Chronic aquatic hazard* Hazardous to the ozone layer

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EXPLOSIVES & OXIDISING SUBSTANCES			
EU Classification/ R-Phrase		**Physical State**	**GHS Hazard class / category**
R1	Explosive when dry	-	-
E; R2	Risk of explosion by shock, friction, fire or other sources of ignition	-	Explosive Division 1.1
			Explosive Division 1.2
			Explosive Division 1.3
			Self Reactive Substance Type A
			Organic Peroxide Type A
E; R3	Extreme risk of explosion by shock, friction, fire or other sources of ignition.	-	Unstable explosive
R4	Forms very sensitive explosive metallic compounds.	-	Not applied
R5	Heating may cause an explosion.	-	
R6	Explosive with or without contact with air.	-	
O; R7	May cause fire.	-	Organic Peroxides Type C to F
R7	May cause fire.	-	Not applied
O; R8	Contact with combustible material may cause fire.	solid	Oxidizing solid Cat. 2
		liquid	Oxidizing liquid Cat. 2
		gas	Oxidizing gas Cat. 1

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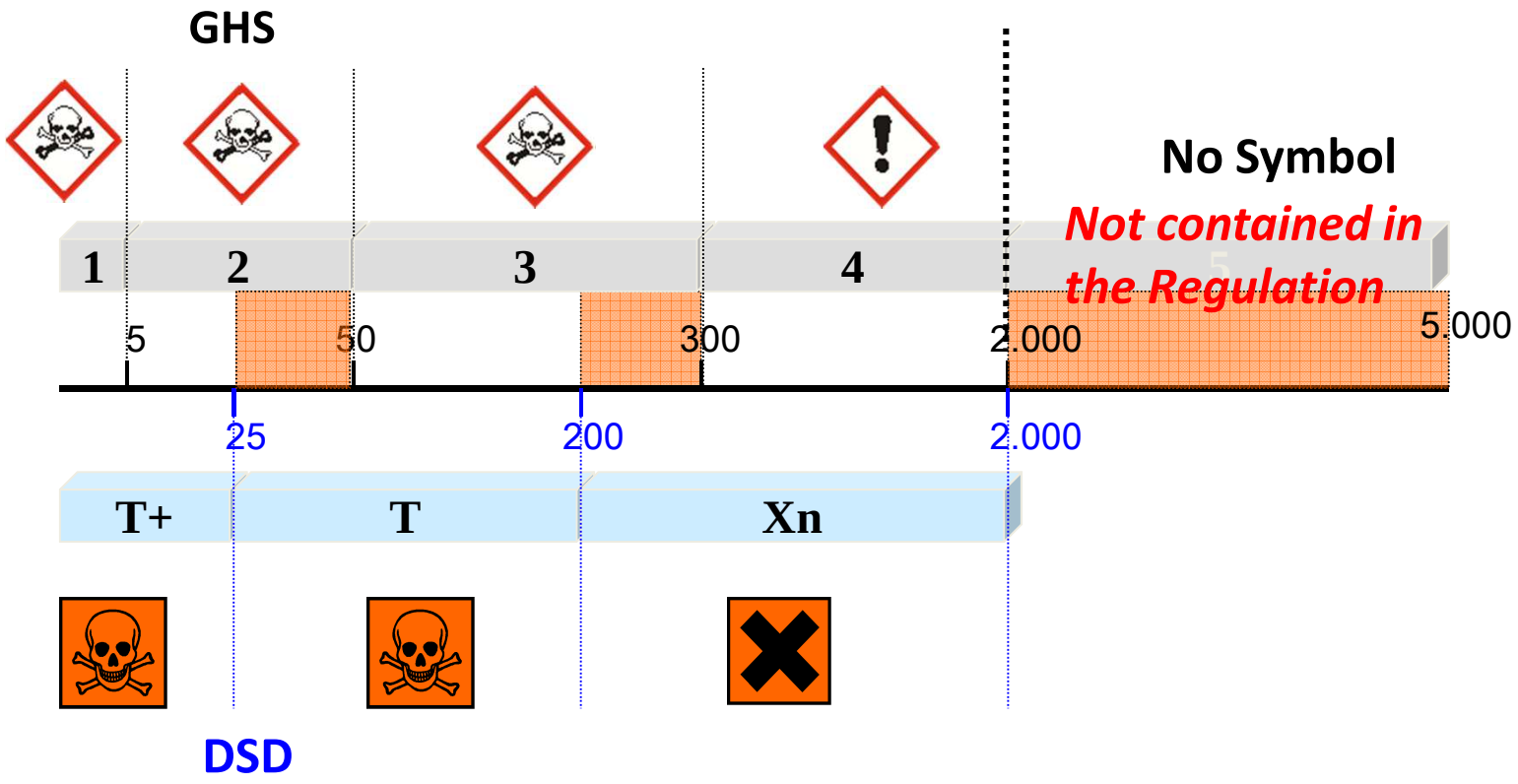

Health Hazards: e.g. acute oral toxicity (mg / kg)

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EU	N, R50 + R53	N, R51 + R53	N, R52 + R53	R53
96h LC_{50} fish or 48h EC_{50} Daphnia or 72h or 96h ER_{50} algae	≤ 1 mg/L	1<C≤10 mg/L	10<C≤100 mg/L	Poorly soluble-no acute toxicity recorded-evidence of persistency and potential to bioaccumulate
· Readily degradable or · Potential to bioaccumulate: ' log P_{OW} unless ' BCF	No ≥ 3 ≤ 100	No ≥ 3 ≤ 100	No	No

CLP	CHRONIC 1	CHRONIC 2	CHRONIC 3	CHRONIC 4
96h LC_{50} fish and/or 48h EC_{50} Crustacea and/or 72h or 96h ER_{50} algae	≤ 1 mg/L	1<C≤10 mg/L	10<C≤100 mg/L	Poorly soluble-no acute toxicity recorded- lack of potential to rapidly biodegrade and have the potential to bioaccumulate
· Rapidly degradable and/or · Potential to bioaccumulate: ' BCF or ' if absent log K_{OW} · Unless chronic toxicity NOEC	No ≥ 500 ≥ 4 -	No ≥ 500 ≥ 4 > 1 mg/L	No ≥ 500 ≥ 4 > 1 mg/L	No ≥ 500 ≥ 4 > water sol. or > 1 mg/L

Implementation in practice (1)

REACH Implementation Project 3.6 (RIP 3.6) develops guidance on application of the proposed Regulation under development

Four working groups: general issues, physical, health and environmental hazards drafting specific guidance (module 2)

In addition, a short and industry-oriented guidance on basic features and procedures was prepared by RPA (module 1)

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Implementation in practice (2)

Basic guidance to CLP

Table 2.2 – Table 2.5

Obligations of the diffent roles under CLP

Table 2.2: Obligations of a manufacturer or importer (cont.)

	Obligations under CLP	Key Sections
8	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance *(part 3 of Annex VI to CLP)* you should submit a proposal to the competent authority in one of the Member States in which the substance is placed on the market *(CLP Article 37(6))*	22
9	You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you have last supplied a substance or mixture. This information should be kept together with the information required in Article 36 of REACH *(CLP Article 49)*	21

Note: Importers and downstream users placing mixtures on the market should be prepared to provide certain information relating to mixtures to those Member State bodies which are responsible for receiving such information in order to formulate preventative and curative measures, in particular in the event of emergency health response *(CLP Article 45)*.

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Implementation in practice (3)

Addressed to suppliers (M/I, DU including formulators, distributors including retailers and producers/importers of certain specific articles*)

Easily digestible text to allow quick and effective orientation on the obligations under CLP

Highlight of relevant obligations and links to REACH, Directive1998/8/EC on biocidal products, Directive 1991/414/EEC on plant production products

**: producers/importers of an explosive article as described in section 2.1 or where REACH Art 7,9 provide for registration/notification of a substance contained in an article*

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Implementation in practice (4)

Table 2.1
Identifying your role under CLP

Table 2.1: Identifying your role under CLP (cont.)

Descriptions		Your role under CLP
3	A natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities	**Downstream User (2) (including formulator / re-importer)**
4	A natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties	**Distributor (including retailer)**
5	A natural or legal person who makes or assembles an article within the Community; where an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition	**Producer of articles (3)**

Notes:
(1) In everyday language the term "manufacturer" can cover both the (natural/legal) person making substances and the (natural/legal) person making mixtures (formulator). In contrast to this everyday language, the term "manufacturer" in REACH and CLP only covers the person making substances. The formulator is a "downstream user" under REACH and CLP.
(2) A distributor or consumer is not a downstream user.
(3) As a producer or importer of an article you are only affected by CLP if you produce or import an explosive article as described in section 2.1 of Annex I to CLP or where REACH Article 7 or 9 provide for registration or notification of a substance contained in an article.

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Implementation in practice (5)

Step 1: is your substance on the harmonised classification list?

If no, go to step 2

If yes, classify accordingly or justify new classifcation based on new evidence and submit Annex XV (REACH)

Step 2: you have data and self classification under old system

If yes: use translation tables

If no: go to step 3

Step 3: conduct base testing under REACH and gather additional relevant information and classify accordingly to Annex I

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CLP Specific – Implementation

Ms. Shufan Qi
RPS advies- en ingenieursbureau The Netherlands

Montenegro
13 – 15 May 2014

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Classification of substances and mixtures

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Rules for classification

- ✓ Starting-point are the intrinsic hazards
- ✓ Intrinsic hazard of substances and mixtures are described by standardized:
  - ➢ hazard classes and hazard category (*e.g. Acute Tox. 1*)
  - ➢ Hazard statement (*e.g. H300: Fatal if swallowed*)
  - ➢ Signal word (*e.g. Danger or Warning*)
- ✓ Criteria in Annex I
- ✓ Hazard classification in three groups:
  - ➢ Physical/chemical hazard
  - ➢ Health hazard
  - ➢ Environment hazard

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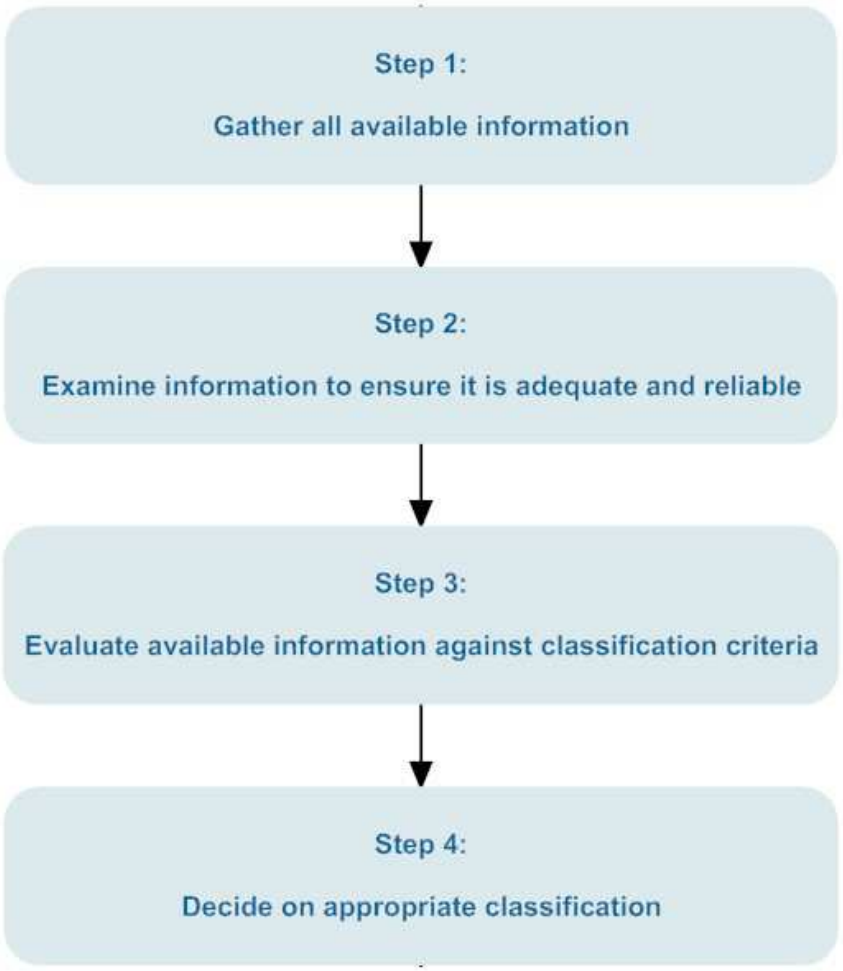
Four basic steps for classifying substance



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General principles classification mixtures (1)

- ✓ Available test data of the complete mixture or substances in the mixture
- ✓ Not for some endpoint (CMR, environment chronically)
- ✓ Bridging principles are applicable if data is available for other similar mixtures:
  - ➢ Dilution
  - ➢ "Batching" (production parties)
  - ➢ Concentration of very hazardous mixtures
  - ➢ Interpolation within one toxicity category
  - ➢ Substantially similar mixtures

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General principles classification mixtures (2)

- ✓ Data separate for all components available, classifies by calculation methods (by endpoints)

- ✓ Not for all components data available: conversion applies, e.g.:
  - ➢ Extrapolation between routes (oral, dermal,…)
  - ➢ Use case study of human exposure, if available
  - ➢ Use data of structure analogues

- ✓ No useful information on one or more components:

  Calculation method + additional statement at classification “x percent of the mixture exists from (an) component(s) of which the toxicity is are not known”.

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General principles classification mixtures (3)

✓ Every endpoint general concentration limits:

concentration of component with a certain classification determines the classification of the mixture

e.g. sum of ingredients classified as skin corrosive Cat. 1 ≥ 5%

⟶ Mixture is classified as skin corrosive Cat. 1

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General principles classification mixtures (4)

- ✓ Maximum variation (%) permitted (bridging principle)
  - ➢ depending on the initial concentration of a component in a classified mixture
  - ➢ supplier (with change of the composition of a mixture) can apprehend the old classification (art 15 (2) (a), annexed I, section 1.1.3.6).

Bridging Principle for changes in the composition of a mixture

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	± 30 %
2,5 < C ≤ 10 %	± 20 %
10 < C ≤ 25 %	± 10 %
25 < C ≤ 100 %	± 5 %

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Classification of substances and mixtures

Hazard category in three groups:

- Physical/chemical hazards
- Health hazards
- Environmental hazards

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Hazard classes	Categories							
Explosive substances	unstable explosives	Sub. cat.1.1	Sub. cat.1.2	Sub. cat.1.3	Sub. cat.1.4	Sub. cat.1.5	Sub. cat.1.6	Sub. cat.1.7
Flammable gases	CAT 1	CAT 2						
Flammable aerosols	CAT 1	CAT 2						
Oxidizing gases	CAT 1							
Gases under pressure	Compressed gas	Liquefied gas	Refrigerated liquefied gas	Dissolved gas				
Flammable liquids	CAT 1	CAT 2	CAT 3	CAT 4	CAT 4			
Flammable solids	CAT 1	CAT 2						
Self-reactive substances or mixtures	Type A	Type B	Type C & D	Type E & F	Type G			
Pyrophoric liquids	CAT 1							
Pyrophoric solids	CAT 1							
Self-heating substances or mixtures	CAT 1	CAT 2						
Substances and mixtures which, in contact with water, emit flammable gases	CAT 1	CAT 2	CAT 3					
Oxidising liquids	CAT 1	CAT 2	CAT 3					
Oxidising solids	CAT 1	CAT 2	CAT 3					
Organic peroxides	Type A	Type B	Type C & D	Type E & F	Type G			
Corrosive for metals	CAT 1							

Category included by EU

Category not included by EU (however, stated worldwide)

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GHS 01

Unstable explosives

Self reactive substances and mixtures, organic peroxides (Types A & B)

GHS 02

Flammable gases, aerosols, liquids and solids, Self-reactive substances and mixtures, Pyrophoric liquids, and solids, Self-heating substances and mixtures

Substances and mixtures, which in contact with water, emit flammable gases, Organic peroxides (Types B, C, D, E, F)

GHS 03

Oxidising gases, liquids and solids

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Gases under pressure

GHS 04

Corrosive to metals

GHS 05

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Hazard classes	Categories				
Acute toxicity	CAT1	CAT2	CAT3	CAT4	CAT5
Skin irritation/corrosion	CAT1 (corrosive)	CAT2 (irritating)	CAT3		
Eye irritation	CAT1	CAT2A	CAT2B		
Sensitization (respiratory, skin)	CAT1 (respiratory)	CAT2 (skin)			
Germ cell mutagenicity	CAT1A	CAT1B	CAT2		
Carcinogenicity	CAT1A	CAT1B	CAT2		
STOT (single exposure)	CAT1	CAT2	CAT3		
STOT (repeated exposure)	CAT1	CAT2	CAT3		
Aspiration hazard	CAT1	CAT2			

Category included by EU

Category not included by EU (however, stated worldwide)

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GHS 07

Acute toxicity (Cat. 4), Skin irritation, Eye irritation, Skin sensitization, Specific Target Organ Toxicity — Single exposure (Cat. 3)

GHS 05

Skin corrosion, Serious eye damage

GHS 06

Acute toxicity (Cat. 1,2, 3)

GHS 08

Respiratory sensitization, CMR, Specific Target Organ Toxicity — Single exposure and Repeated exposure (Cat. 1, 2), Aspiration hazard

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Environmental hazards

Hazard classes	Categories						
Hazardous to the aquatic environment	Acute 1	Acute 2	Acute 3	Chronic 1	Chronic 2	Chronic 3	Chronic 4
Hazardous for the ozone layer	Hazardous						

Category included by EU

Category additional in EU (not stated worldwide)

Category not included by EU (however, stated worldwide)

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Pictogram environmental hazard

Hazardous to the aquatic environment, acute and chronic (cat. 1, 2)

GHS 09

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The label

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Rules for labelling

- ✓ Title III and appendix I, section 1.3 up to 1.5
- ✓ Label in official language of the Member State where the substance or mixture is placed on the market
- ✓ Elements of label (art 17 and 18).
- ✓ NEW data of supplier of substance or mixture
- ✓ Nominal quantity of substance or mixture in offered packaging
- ✓ Product identifications (name, identification number)
- ✓ Hazard pictograms (if of application)
- ✓ Signal words (danger or warning) (if of application)
- ✓ Hazards statements (H- statements) (if of application)
- ✓ Precautionary statements (P- statements) (if of application)
- ✓ Additional information
- ✓ Special rules for small packing (art. 29)

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Labelling Elements

Signal word Danger **OR** Warning

Hazard pictogram

- ✓ Diamond-shaped
- ✓ Red edge
- ✓ White background
- ✓ Black symbol
- ✓ 1/15 parts of the label
- ✓ Surface minimum 1 cm^2

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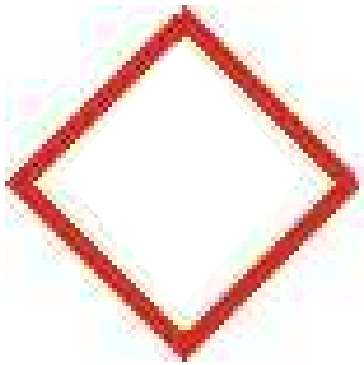
Labelling Elements



Not permitted

Indication as “not toxic”. “Harmless”, “environmental friendly” or similar

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Precedence rules for labelling (1)

For physical hazards

If the substance or mixture is classified with GHS01 (exploding bomb), then GHS02 (flame) and GHS03 (flame over circle) are optional, except in cases where more than one pictogram is compulsory (Annex I to CLP, section 2.8 self-reactive substances and mixtures Type B and section 2.15, organic peroxides Type B)…

Optional

Optional

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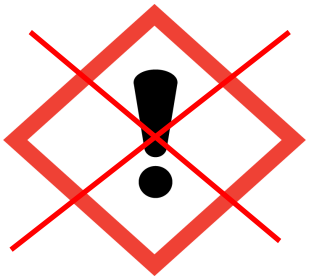
Precedence rules for labelling (2)

For health hazards:

If GHS06 (skull and crossbones) applies, then GHS07 (exclamation mark) shall not appear…



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Precedence rules for labelling (3)

If GHS05 (corrosion) applies, then GHS07 (exclamation mark) shall not be used for skin or eye irritation …

……..but may still be used for other hazards

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Precedence rules for labelling (4)

If GHS08 (health hazard) appears for respiratory sensitisation, then GHS07(exclamation mark) shall not be used for skin sensitisation or for skin or eye irritation

…… but may still be used for other hazards

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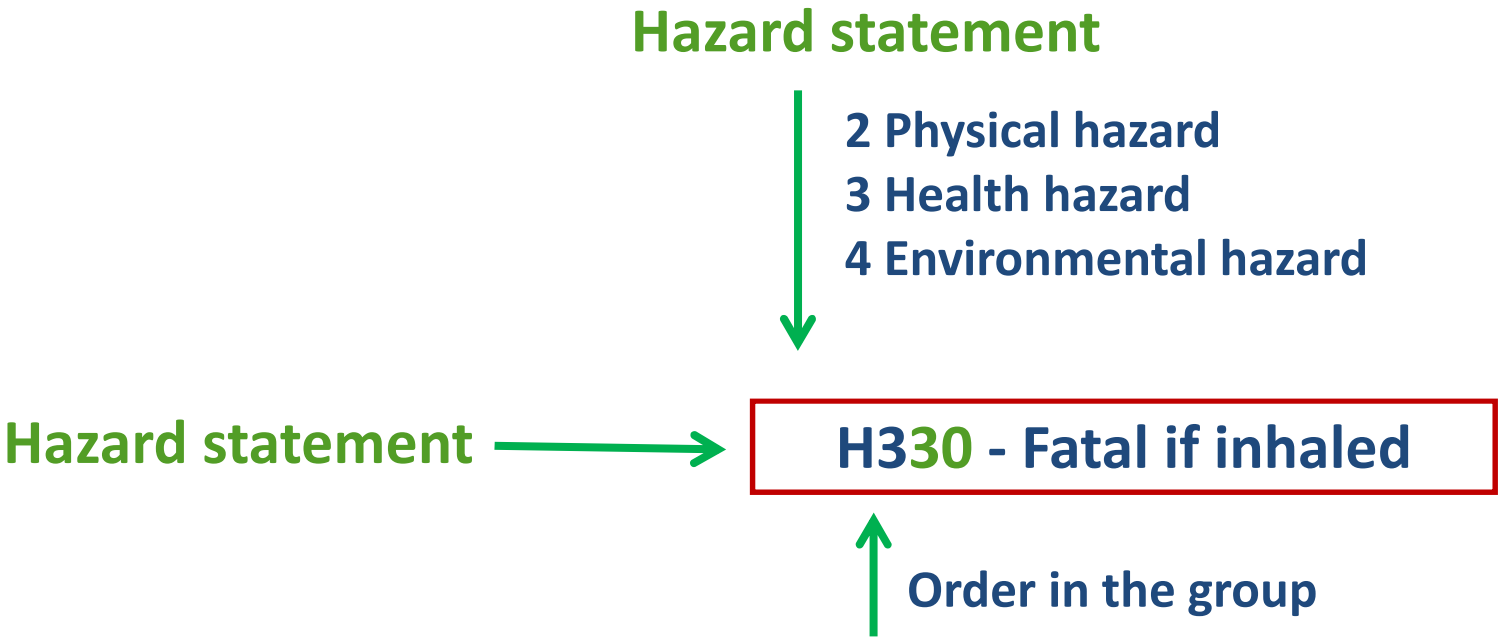
Dimension of label

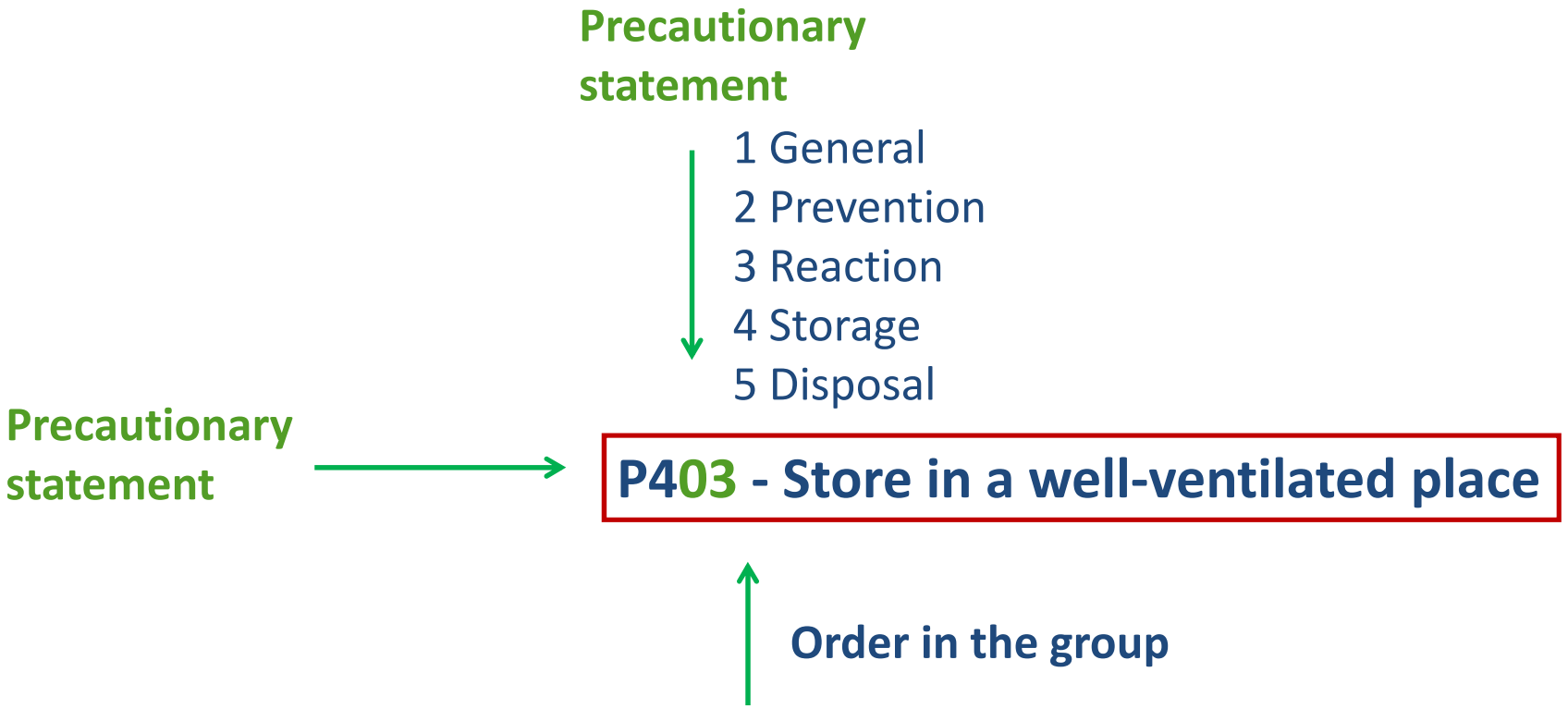
Content of packaging	Dimensions (in mm)
Not more than 3 litre:	possibly at least 52 x 74
More than 3 litre, but not more than 50 litre:	At least 74 x 105
More than 50 litre, but not more than 500 litre:	At least 105 x 148
More than 500 litre:	At least 148 x 210

Hazard statements



Precautionary statements

P-Statements: write to recommended precautionary statements to prevent/minimize adverse effects



Pictograms

Signal word

H- and P-statements

Charge/Lot

CH_3OH
1 l = 0.79 kg
M = 32.04 g/mol

Specification:

Purity (GC)	≥	99.9	%
Identity (IR)			conforms
residue on evaporation	≤	2.0	mg/l
Water	≤	0.02	%
Colour	≤	10	Hazen
Density (d 20 °C/20 °C)		0.791 - 0.793	
Boiling point		64 - 65	°C
Acidity	≤	0.0002	meq/g
Alkalinity	≤	0.0002	meq/g
Gradient grade (at 235 nm)	≤	2.0	mAU
Gradient grade (at 254 nm)	≤	1.0	mAU
Fluorescence (as quinine at 254 nm)	≤	1.0	ppb
Fluorescence (as quinine at 365 nm)	≤	0.5	ppb
Transmission (at 220 nm)	≥	55	%
Transmission (at 235 nm)	≥	83	%
Transmission (from 280 nm)	≥	98	%
Absorbance (at 225 nm)	≤	0.17	

Filtered by 0.2 µm filter
Suitable for UPLC / UHPLC / Ultra HPLC - instruments

?PHOSTNAME:???STM/P

XXXXXXXXXX

Reag. Ph Eur

Methanol

gradient grade for liquid chromatography

Méthanol
Alcole metilico
Metanol

Product identification

Index-No: 603-001-00-X

Mustermann GmbH
98765 Sampleshausen, Germany
Tel. +49(0)2345 67 89 01
www.mustermann.de

IMO: METHANOL
ICAO: METHANOL

UN 1230

Danger. Highly flammable liquid and vapour. Toxic if inhaled. Toxic in contact with skin. Toxic if swallowed. Causes damage to organs. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. IF exposed: Immediately call a POISON CENTER or doctor/physician.

Gefahr. Flüssigkeit und Dampf leicht entzündbar. Giftig bei Einatmen. Giftig bei Hautkontakt. Giftig bei Verschlucken. Schädigt die Organe. Von Hitze/Funken/offener Flamme/heißen Oberflächen fernhalten. Nicht rauchen. Behälter dicht verschlossen halten. Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. BEI KONTAKT MIT DER HAUT: Mit viel Wasser und Seife waschen. BEI Exposition: Sofort GIFTINFORMATIONS-ZENTRUM oder Arzt anrufen.

Danger. Liquide et vapeurs très inflammables. Toxique par inhalation. Toxique par contact cutané. Toxique en cas d'ingestion. Risque avéré d'effets graves pour les organes. Tenir à l'écart de la chaleur/des étincelles/des flammes nues/des surfaces chaudes. - Ne pas fumer. Maintenir le récipient fermé de manière étanche. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon. EN CAS d'exposition: Appeler immédiatement un CENTRE ANTIPOISON ou un médecin.

Pericolo. Liquido e vapori facilmente infiammabili. Tossico se inalato. Tossico per contatto con la pelle. Tossico se ingerito. Provoca danni agli organi. Tenere lontano da fonti di calore/scintille/fiamme libere/superfici riscaldate. - Non fumare. Tenere il recipiente ben chiuso. Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso. IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua e sapone. IN CASO di esposizione, contattare immediatamente un CENTRO ANTIVELENI o un medico.

Peligro. Líquido y vapores muy inflamables. Tóxico en caso de inhalación. Tóxico en contacto con la piel. Tóxico en caso de ingestión. Provoca daños en los órganos. Mantener alejado de fuentes de calor, chispas, llama abierta o superficies calientes. - No fumar. Mantener el recipiente herméticamente cerrado. Llevar guantes/prendas/gafas/máscara de protección. EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes. EN CASO DE exposición: Llamar inmediatamente a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico.

Perigo. Líquido e vapor facilmente inflamáveis. Tóxico por inalação. Tóxico em contacto com a pele. Tóxico por ingestão. Afecta os órgãos. Manter afastado do calor/faísca/chama aberta/superfícies quentes. - Não fumar. Manter o recipiente bem fechado. Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM A PELE: lavar com sabonete e água abundantes. EM CASO DE exposição: contacte imediatamente um CENTRO DE INFORMAÇÃO ANTIVENENOS ou um médico.

Gevaar. Licht ontvlambare vloeistof en damp. Giftig bij inademing. Giftig bij contact met de huid. Giftig bij inslikken. Veroorzaakt schade aan organen. Verwijderd houden van warmte/vonken/open vuur/hete oppervlakken. - Niet roken. In goed gesloten verpakking bewaren. Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. BIJ CONTACT MET DE HUID: met veel water en zeep wassen. NA blootstelling: onmiddellijk een ANTIGIFCENTRUM of een arts raadplegen.

1 litres

Supplier identification

Nominal quantities

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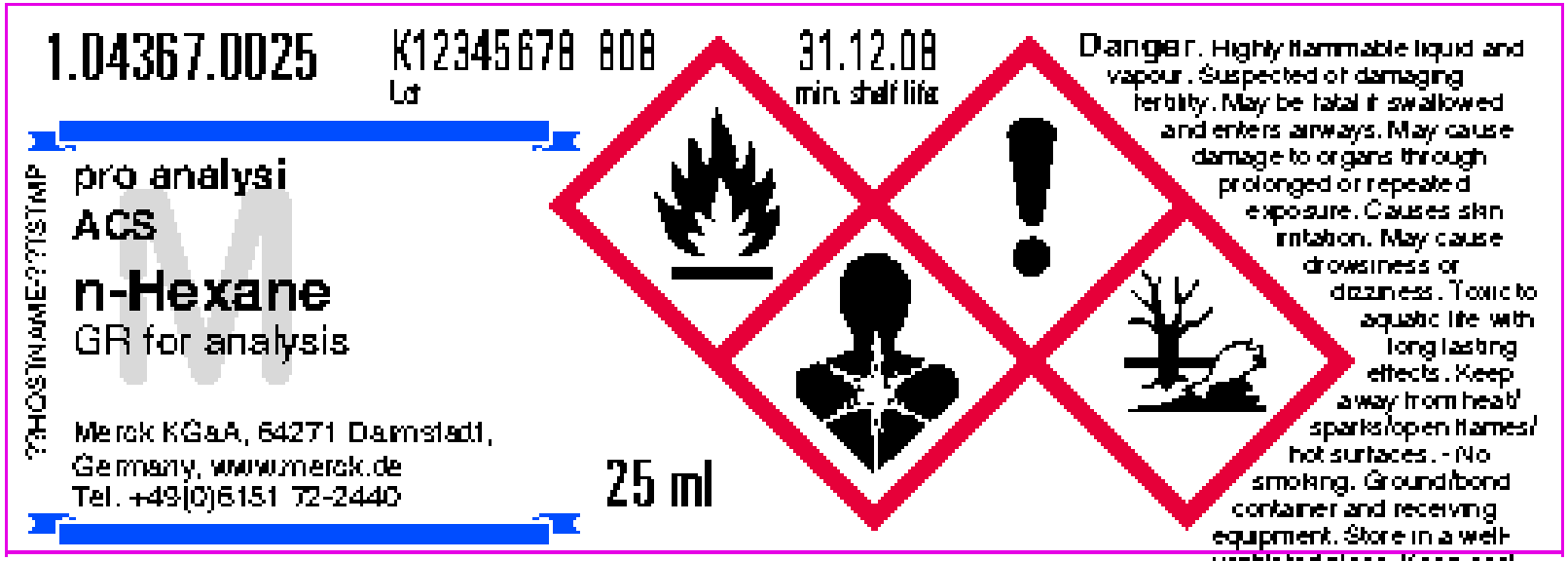
Example label small packaging



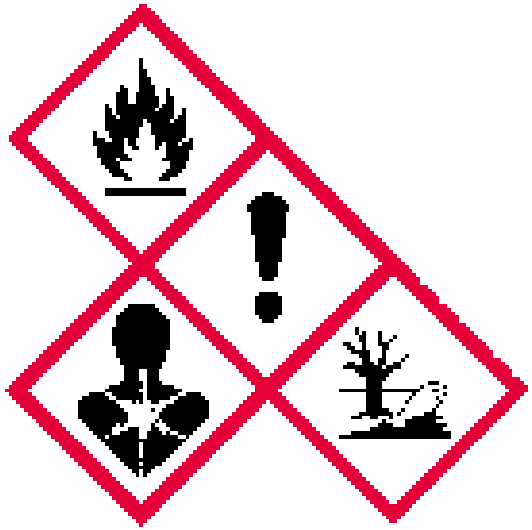
65x23

Pantone 286 merckblau

Example label small packaging

1000000025 K12345678 808 25 ml
Lot
min. shelflife: 31.12.08

pro analysi
ACS
n-Hexane
GR for analysis
n-Hexan
Index-No: 601-037-00-0
Fa. Muster KG, Musterdorf,
Germany, www.mcwustermann.de
Tel. +49(0)1234 56-7890

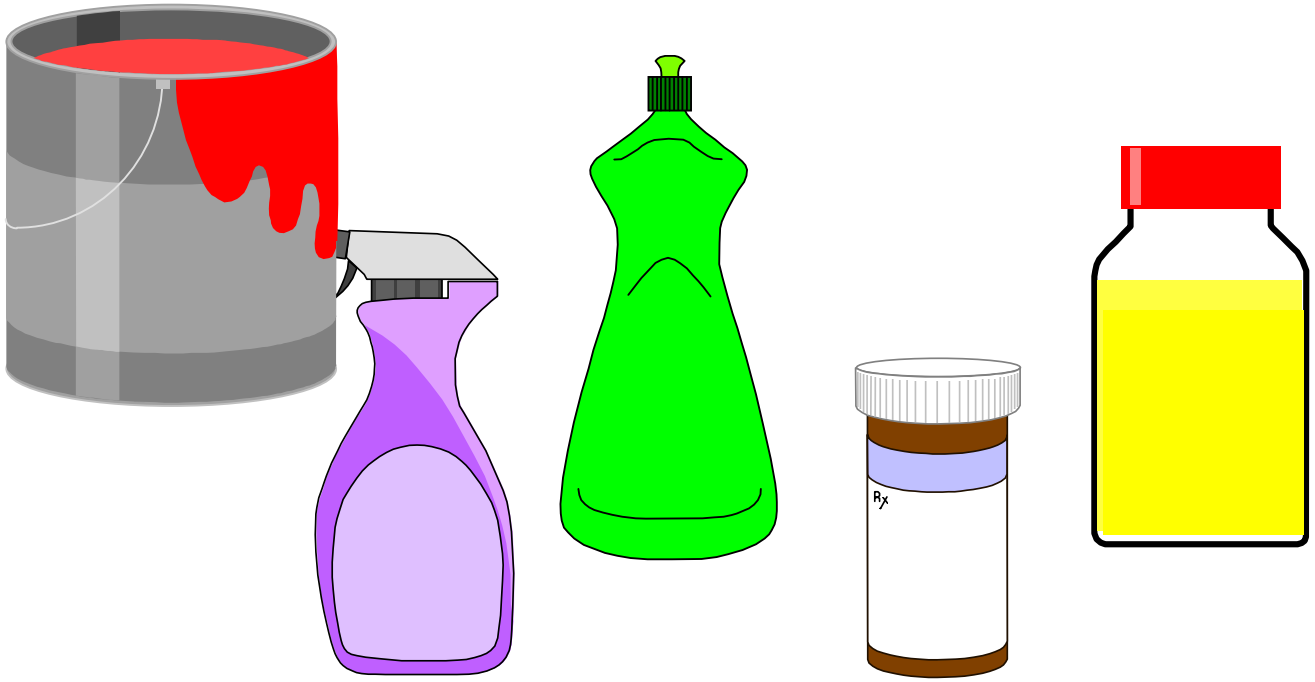


Danger. Suspected of damaging fertility. May be fatal if swallowed and enters airways. Use personal protective equipment as required. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting.

Gefahr. Kann vermutlich die Fruchtbarkeit beeinträchtigen. Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein. Vorgeschriebene persönliche Schutzausrüstung verwenden. BEI VERSCHLUCKEN: Sofort GIFTINFORMATIONSZENTRUM oder Arzt anrufen. KEIN Erbrechen herbeiführen.

Special rules for small packing (appendix 1, section 1.5)

Packaging Rules



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Rules for packaging

- ✓ Similar requirements as under old legislation
- ✓ Article 35
- ✓ Appendix II: Special rules for the certain substances and mixtures
- ✓ Packaging meets that transport requirements meets requirements of CLP

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Classification and labelling

Annex II SPECIAL RULES FOR LABELLING AND PACKAGING OF CERTAIN SUBSTANCES AND MIXTURES

Part 1: contains special rules for the labelling of certain classified substances and mixtures.

Part 2: sets out rules for additional hazard statements to be included on the label of certain mixtures.

Part 3: Prescriptions on child-resistant fastening and tactile warning

Part 4: Prescriptions especially for plant protection products and biocides

Part 5: sets up a list of hazardous substances and mixtures to which Article 29(3) applies.

Part 1

Special rules for the labelling of certain classified substances and mixtures.

Additional awards of the following EUH-statements (under preconditions)

- EUH001 – "Explosive when dry."
- EUH006 – "Explosive with or without contact with air"
- EUH014 – "Reacts violently with water"
- EUH018 – "In use may form flammable/explosive vapour-air mixture"
- EUH019 – "May form explosive peroxides"
- EUH044 – "Risk of explosion if heated under confinement"
- EUH029 – "Contact with water liberates toxic gas"
- EUH031 – "Contact with acids liberates toxic gas"
- EUH032 – "Contact with acids liberates very toxic gas"
- EUH066 – "Repeated exposure may cause skin dryness or cracking"
- EUH070 – "Toxic by eye contact"
- EUH071 – "Corrosive to the respiratory tract"

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Part 2

Rules for additional hazard statements to be included on the label of certain mixtures:

- Plumbiferous mixtures
- Mixtures which contain cyanoacrylate
- Cement and cement mixtures
- Mixtures which contain isocyanates
- Mixtures which contain epoxybridges with average molecule weight of highly 700
- Mixtures sold to the general public which contain active chlorine
- Mixtures which contain cadmium (alloys) and that are intended to be used for welding and soldering
- Not as sensitization classified mixtures which contain at least a sensitizing substance
- Liquid mixtures which contain halogenated hydrocarbons
- Not for the general public intended mixtures
- Aerosols

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Part 3
Child-resistant fastening

Packing of substances and mixtures (if intended for the general public) classified as:

- Acute toxicity category 1 till 3
- Specific target organ toxicity (STOT) single exposure of category 1,
- STOT - repeated exposure of category 1
- Skin corrosion of category 1

And:

- Substances and mixtures which cause aspiration hazard (under conditions)
- Substances and mixtures which contain ≥ 3% methanol or ≥ 1% dichloromethane

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Part 3
Tactile warning

Packaging of substances and mixtures classified as:

- Acute toxicity
- Skin corrosion
- Germ cell mutagenicity, category 2
- Carcinogenicity, category 2
- Reproductive toxicity, category 2
- Respiratory sensitisation
- Specific Target Organ Toxicity (STOT), categories 1 and 2
- Aspiration hazard
- Flammable gases, liquids or solids, categories 1 and 2

If intended for general public

Does not apply for “very light flammable aerosol" of “Light flammable aerosol"

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Part 4
Plant protection products and biocides

In the labelling of plant protection products subject of directive 91/414. /EG the following sentence must be incorporated:

EUH401 – "To avoid risks to human health and the environment, comply with the instructions for use".

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Relation with transport

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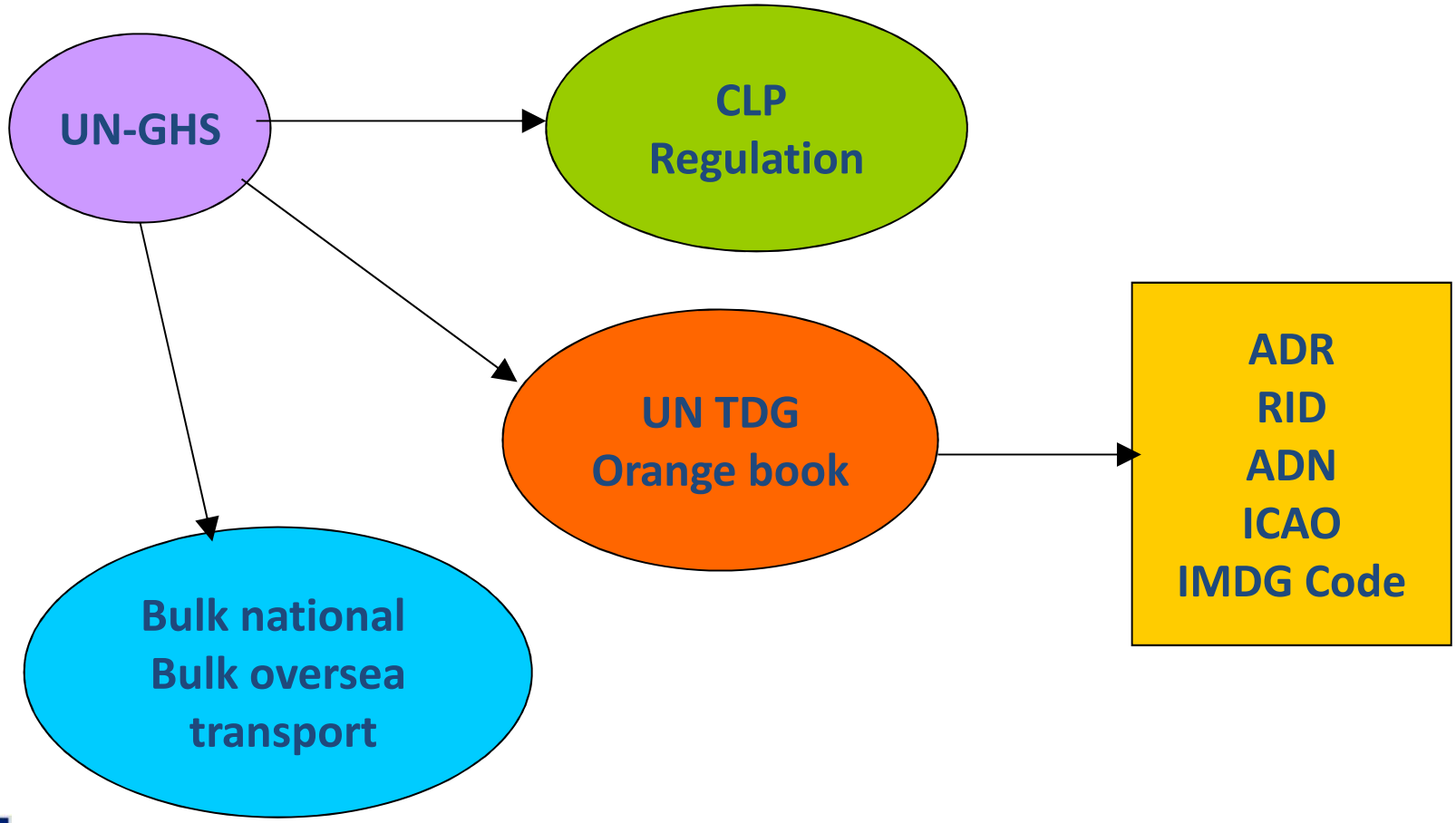
UN-GHS, CLP and transport



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Relation with transport regulation

Physico-chemical hazards: Same criteria, other labels/pictograms

Health hazards (as far as included)

- Same criteria, other labels/pictograms
- Not included:
  - toxic cat.4,
  - irritating,
  - CMR
  - aquatic toxicity (acute cat 2 and 3 only for tankships)
  - aquatic toxicity (chronically)

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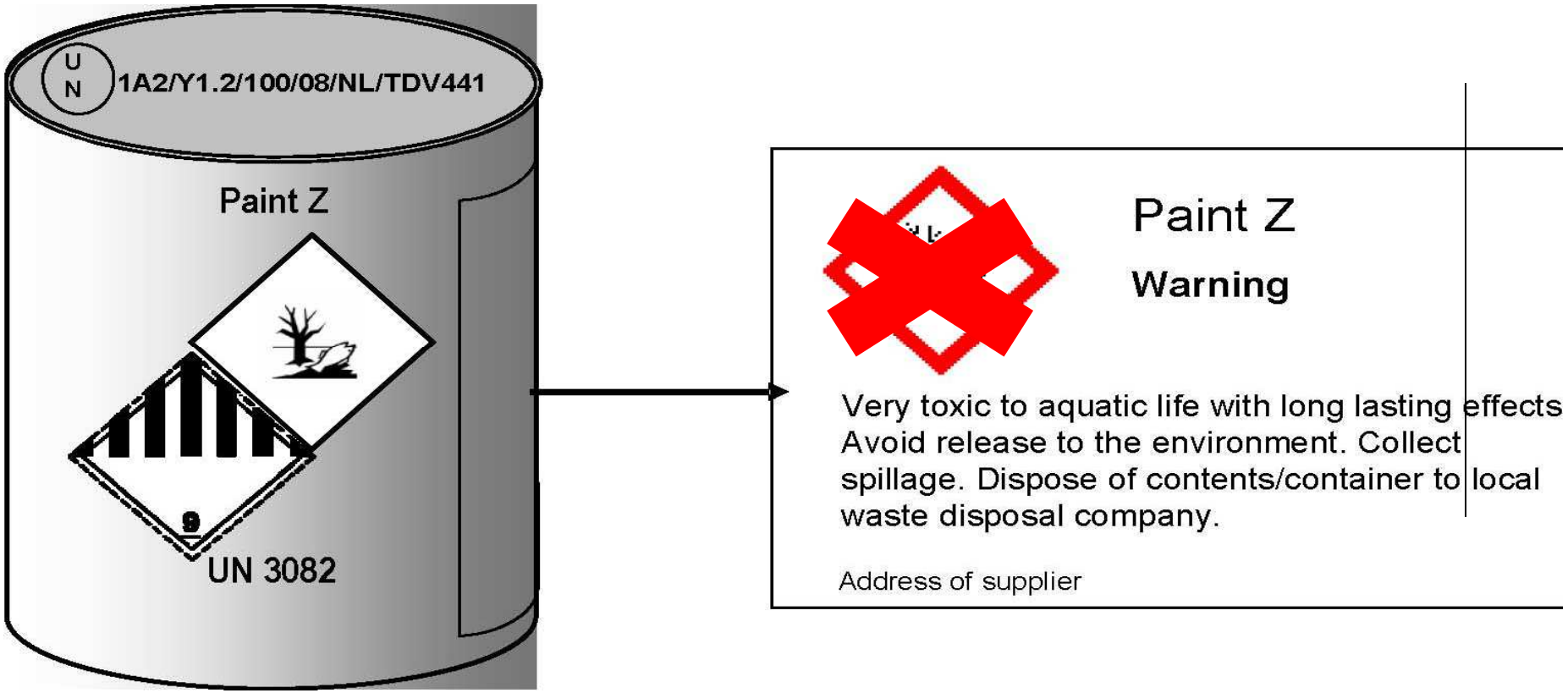
Specific rules for packing (Art. 33, CLP)

As a general rule, where the labelling of an outer packaging is subject to both the transport and the CLP rules, the labelling or marking in accordance with transport legislation is sufficient, and the CLP labelling need not appear.

- ✓ Combination packaging:
  - where a hazard pictogram required by CLP relates to the same hazard as in the rules for the transport of dangerous goods, the hazard pictogram required by the CLP need not appear on the outer packaging, however CLP is allowed
  - If for transport no label on outer packaging is required and a substances is classified according to CLP. CLP pictograms are required on packaging

- ✓ Single packaging:
  - Labelling Rules according to transport legislation and CLP
  - If a hazard pictogram required by CLP relates to the same hazard as in the rules for the transport of dangerous goods, ⇒ no CLP pictogram required

Labelling single packaging from 1-1-2010 also environmental label



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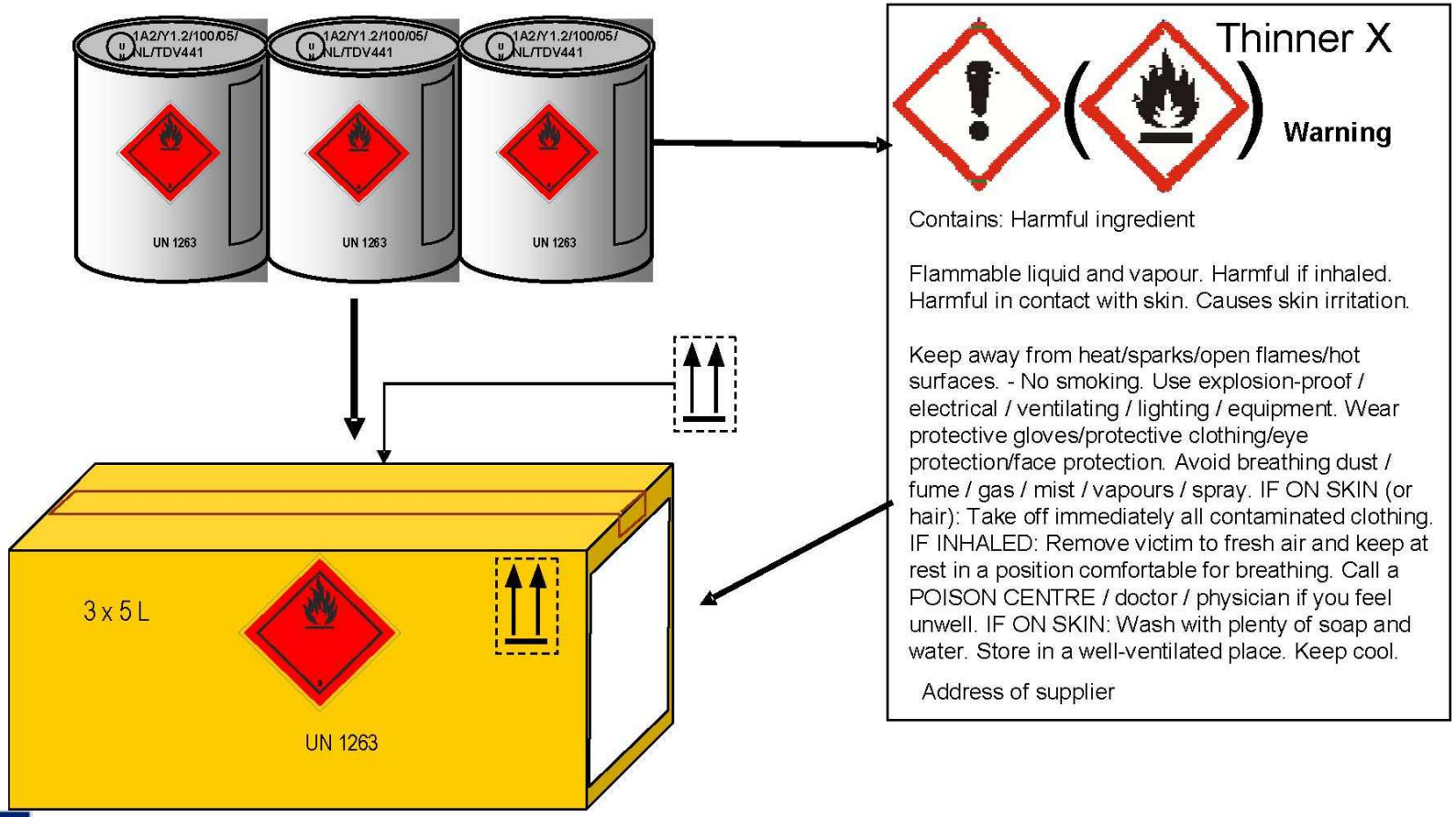
Example labelling in combination packaging



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Hazard Communication:
Safety Data Sheets (SDS)
Title IV, Art. 31 of REACH

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Communication with SDS

Suppliers have to provide their customers with a SDS in the language of the MS where placed on the market:

- For substances/ mixtures classified as dangerous/ (v)P(v)BT/ substances included in the "candidate list"
- (on request) For not classified mixtures containing:
  - > 1% dangerous substance/ > 0,1% (v)P(v)BT
  - a substance in the "candidate list"/ substances with an EU workplace exposure limit
- In case of an CSR, should contain CSR info & ES (Extended SDS)

Communication for substances/mixtures for which a safety data sheet is not required:

- the registration number(s) if available, for any substances
- if the substance is subject to authorisation and details of any authorisation granted or denied
- details of any restriction imposed under Title VIII

Legal requirements

- ✓ Article 31 of REACH
- ✓ Annex II of REACH
  - ➢ Annex II of REACH has been replaced by Annex I of Regulation (EU) 453/2010 from **1 December 2010**
  - ➢ Annex II of REACH will be replaced by Annex II of Regulation (EU) 453/2010 from **1 June 2011**

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General Requirements

- ✓ enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment
- ✓ enable employers to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use
- ✓ shall be written in a clear and concise manner by a competent person
- ✓ language used shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations
- ✓ date of compilation sheet shall be given on the first page.

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Content of SDS – 16 headings

1. identification of the substance/preparation and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

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1. Identification of the substance/mixture

1.1 Product identifier

- Mention the trade name and chemical name of the substance or mixture.
- For substances: mention the REACH registration number if applicable and any other identification (e.g. CAS number, EINECS, ELINCS number).

1.2 Relevant identified uses of the substance or mixture and uses advised against

- Mention the recommended (intended) use of the chemical. If it can be used for different purposes, mention only the use that is most applicable for the customer (and is supported by your company).
- If a REACH Chemical Safety Report is required, the SDS must include information about each intended use that is applicable for the recipient. This information must correspond to the intended use and the exposure scenario as described in the appendix to the SDS.

1.3 Details of the supplier of the substance or mixture

- Identify who is responsible for placing the chemical on the market (this can be the manufacturer, importer or distributor). Mention the following details:
  - *Name of supplier*
  - *Full address*
  - *Telephone number*
  - *E-Mail of the person responsible for SDS*

- If the supplier is not located in the Member State, give a full address and telephone number for the person who is responsible for that Member State.

1.4 Emergency telephone number

Mention in the number of the advisory office in case of poisoning (24 hour emergency phone number).

2. Hazards identification

2.1. Classification of the substance or mixture

- The classification of the substance or mixture which arises from the application of the classification rules in Regulation (EC) No 1272/2008 shall be given.
- The information (hazard statements and R-phrases) mentioned here must be detailed under heading 16 of the SDS.

2.2. Label elements

Based on the classification, at least the following label elements appearing on the label in accordance with Regulation (EC) No 1272/2008 shall be provided:

- *Hazard pictogram(s),*
- *Signal word(s),*
- *Hazard statement(s),*
- *Precautionary statement(s).*

2.3. Other hazards

Information whether the substance or mixture meets the criteria for PBT or vPvB

Information shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture

3. Composition/information on ingredients

3.1. Substances

The chemical identity of the main constituent of the substance and the chemical identity of any impurities, stabilizing additive, or individual constituent, which themselves meet the criteria for classification and which contribute to the classification of the substance.

3.2. Mixtures

Describe all substances, that are classified as hazardous under EU legislation, in a mixture of chemicals.

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4. First aid measures

4.1. Description of first aid measures

- Describe the first-aid measures. Specify whether:
  - *immediate medical attention is required;*
  - *movement of the exposed individual is recommended;*
  - *removal and handling of clothing and shoes from the individual is recommended;*
  - *personal protective equipment for first aid responders is recommended.*

- Subdivide the information according to the different routes of exposure.

4.2. Most important symptoms and effects, both acute and delayed

Briefly summarised information shall be provided on the most important symptoms and effects, both acute and delayed, from exposure.

4.3. Indication of the immediate medical attention and special treatment needed

Where appropriate, information shall be provided on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications.

5. Fire-fighting measures

5.1. Extinguishing media

Describe suitable or unsuitable fire fighting equipment (e.g. water (spray or hose), foam, sand).

5.2. Special hazards arising from the substance or mixture

Give a description of possible dangerous decomposition products when the chemical is exposed to fire (e.g. toxic gases, soot, reaction products, combustion products etc.)

5.3. Special protective actions for fire-fighters

- Advice shall be provided on any protective actions to be taken during fire-fighting
- Advice protection gear (e.g. respirator, flame resistant clothing, etc).

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Describe measures to avoid adverse health effects.

6.2. Environmental precautions

Describe measures to avoid environmental contamination (e.g. keep away from drains, surface- and ground-water, soil)

6.3. Methods and material for containment and cleaning up

Describe removal/cleaning methods after spillage of the chemical (i.e. use of absorbent material (e.g. sand, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution).

6.4. Reference to other sections, if appropriate

7. Handling and storage

7.1. Handling

How to handle the chemical safely (e.g technical measures but also good occupational hygiene (e.g. no smoking, eating and drinking when using the chemical); more details can be mentioned in section 8)

7.2. Storage

Proper and safe storage conditions (e.g. specific design for storage rooms or vessels; temperature, humidity, ventilation, keep away from ignition sources etc.)

7.3. Specific use(s)

Describe conditions for handling and storage for specific uses (i.e. bulk use, laboratory use etc.). If possible make reference to industry- or sector-specific approved guidance.

8. Exposure controls/personal protection

8.1. Exposure limit values

- Describe the occupational exposure limit. This limit ensures that exposure to this chemical will not lead to health problems during a working life.
- Where a CSR is required, the relevant DNELs and PNECs shall be given for the exposure scenarios from the CSR set out in the annex to the SDS.

8.2. Exposure controls

Describe all specific protection and prevention measures that must be taken during the use of the substance or preparation to reduce the exposure to workers and environment.

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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

a. Appearance
b. Odour
c. Odour threshold
d. acidity/pH
e. Melting point / freezing point
f. Initial boiling point/boiling range
g. Flash point
h. Evaporation rate
i. Flammability (solid, gas)
j. Upper/lower flammability or explosive limits
k. Vapour pressure
l. Vapour density
m. Relative density
n. Solubility
o. Partition coefficient:n-octanol/water
p. Auto-ignition temperature
q. Decomposition temprature
r. Viscosity
s. Explosive properties
t. Oxidising properties

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9.2 Other information

Describe other important safety information such as miscibility, melting point, gas group, fat solubility, etc.

10. Stability and reactivity

10.1 Reactivity

The reactivity hazards of the substance or mixture shall be described.

10.2 Chemical stability

It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reaction

If relevant, it shall be stated if the substance or mixture will react or polymerise, releasing excess pressure or heat, or creating other hazardous conditions.

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10.4 Conditions to avoid

List conditions (e.g. temperature, pressure, light, shock, etc.) which may cause a dangerous reaction

10.5 Incompatible materials

List materials (e.g. water, air, acids, bases oxidising agents, other specific substance, etc.) which may cause a dangerous reaction

10.6 Hazardous decomposition products

List hazardous materials produced in dangerous amounts upon decomposition (see also section 5)

11. Toxicological information

11.1 Information on toxicological effects

- Description of the various acute (e.g. burns, allergy) and chronic (e.g. cancer, infertility) health effects, which can arise if workers come into contact with the chemical after long term and short term exposure.

- If a CSR is required, the information in this section should to correspond with the information in the CSR and the information in the Annex of this SDS.

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12. Ecological information

12.1. Ecotoxicity

Chronic and acute toxicity data on aquatic (water) and soil organisms (e.g. fish, algae, water fleas) and micro-organisms (e.g. bacteria)

12.2. Mobility

Description of possibilities to move to groundwater or to parts far from the emission site.

12.3. Persistence and degradability

Description of the breakdown of the chemical in the environment

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12.4. Bio accumulative potential

Description of the accumulation of the chemical in the food chain

12.5. Results of PBT assessment

Summary of the results of the PBT assessment from the CSR

12.6. Other adverse effects

If available, include information on any other effects on the environment. For example: ozone depletion potential or endocrine disrupting potential.

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13. Disposal considerations

13.1 Waste treatment methods

- Mention how get rid of chemical in a safe way, according to national and EU laws.

- If a CSR is required, the information in this section should to correspond with the information in the CSR and the information in the Annex of the SDS.

14. Transport information

Describe transport conditions and all applicable requirements according to international regulations (IMDG (sea transport), ADR (road transport), RID (rail transport) and/or ICAO/IATA (air transport) to list as mentioned below.

14.1 UN number,

14.2 UN transport hazard class(es),

14.3 UN proper shipping name,

14.4 packing group,

14.5 Environmental hazard (marine pollutant, if applicable),

14.6 Special precautions for user,

14.7 Transport in bulk according to Annex II of MARPOL73/8 and the IBC Code

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15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet

15.2 Chemical Safety Assessment

It shall be indicated if a chemical safety assessment has been carried out for the substance or the mixture by the supplier.

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16. Other information

Indicate any other important information which for the health and safety of the workers and for the protection of the environment, for example:

- list of all relevant R phrases. Write out the full text of any risk phrases (coded as R-phrases in European legislation on classification and labelling) mentioned in section 3 of the Safety Data Sheet
- sources of key data used to compile the Safety Data Sheet.

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Also information regarding training advice and any further information regarding written references and/or technical contact point can be placed in this section.

For a revised Safety Data Sheet, indicate clearly the information, which has been added, deleted or revised (unless this has been indicated elsewhere).

E-SDS – Exposure Scenario

The Exposure Scenario describes, for each use:

- ✓ The Operational Conditions (OC)
- ✓ The risk management measures (RMM)

that need to be applied

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The Exposure Scenario (ES) – 4 Sections

Section 1: Title: Description of uses and activities covered by the ES

Section 2: Operational conditions (OCs) and risk management measures (RMMs): Description of how to ensure safe use of the chemicals.

- ✓ Protection of workers
- ✓ Protection of the environment (if relevant for the uses covered by the ES)

Section 3: Exposure estimation and reference to its source

Section 4: Guidance to downstream user to evaluate whether he works inside the boundaries set by the ES

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Chemical Safety Assessment and Extended Safety Data sheet

Arnold van der Wielen

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Core issue is responsible risk management

"Employees & Public"

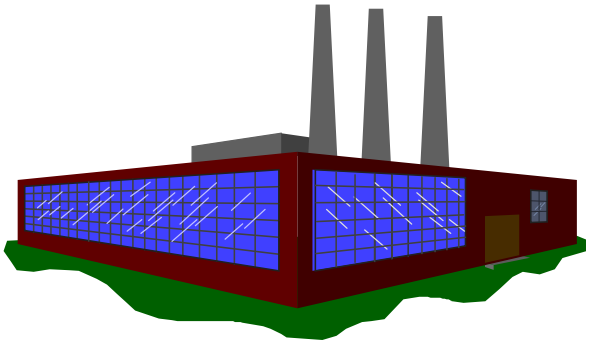
Data collection

Evaluation of hazardous properties

Evaluation of exposure / emission

Risk assessment

Risk reduction measures



Chemical industry

Chemical Safety Assessment:

Belongs to responsibility of industry

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Core tools of REACH

- The Chemical Safety Assessment is the tool used to ***determine*** the safety of the chemical
- The Chemical Safety Report is the tool used to ***record/document*** the assessment to ECHA
- The Safety Data Sheet is the tool used to c***ommunicate*** safe use to downstream users

Aim of Chemical Safety Assessment

To establish the safe conditions of manufacture and use of a substance (on their own or in preparations or in articles) for all life-cycle stages.

Manufacturers/Importers/Downstream Users have to ensure that the manufacture and use is in such a way that human health and the environment are not adversely affected.

Results of a CSA should be documented in a Chemical Safety Report being part of a registration dossier of a substance

CSA should describe

1. **The intrinsic properties of the substance**
   - Human Health (Physico-chemical) hazards
   - Environmental Health hazards
   - PBT & vPvB properties
2. **Exposure assessment**
   - All manufacturing and use scenarios
   - Set of exposure scenarios adressing all identified uses
   - Corresponding release and exposure estimates
3. **If applicable, risk characterisation**
   - Quantitative: compare estimated exposure with PNEC/DNEL
   - Qualitative: compare estimated exposure and risk management
   - Conditions of safe use (operational conditions and risk management measures)

PBT = Persistent, Bioaccumulating and Toxic,
vPvB = very Persistent, and very Bioaccumulating

Note

If

the substance meets the criteria for classification as dangerous* or is assessed to be PBT or vPvB,

then

the Chemical Safety Assessment has to include an exposure assessment for one or more exposure scenario(s), exposure estimation and risk characterisation.

*** i.e. labeled with any R or H sentence**

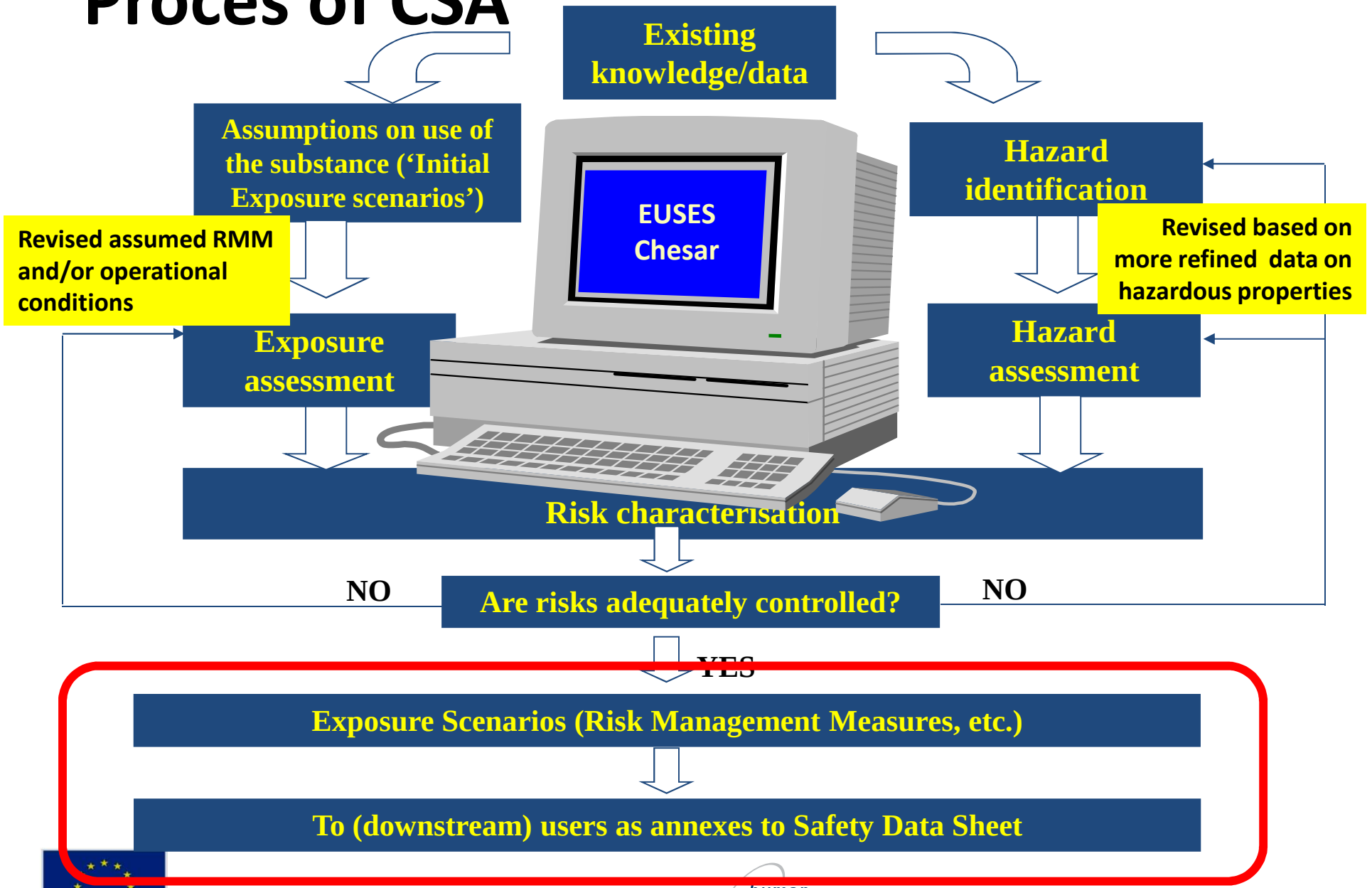
CSA: objectives of hazards to be assessed

1. **Human health hazard assessment**
    1. determine **Classification & Labelling** (CLP criteria)
    2. derive Derived No Effect Level(s) or Derived Minimal Effect Level(s): **DNEL(s) / DMEL(s)**
2. **Human health hazard assessment of phys-chem properties**
    1. determine **Classification & Labelling** (CLP criteria)
3. **Environmental hazard assessment**
    1. determine **Classification & Labelling** (CLP criteria)
    2. derive Predicted No Effect Concentration: **PNEC**
4. **PBT and vPvB assessment**
    1. determine if criteria **Annex XIII** are fulfilled

CSA is based on risk

RISK = HAZARD x EXPOSURE

Proces of CSA



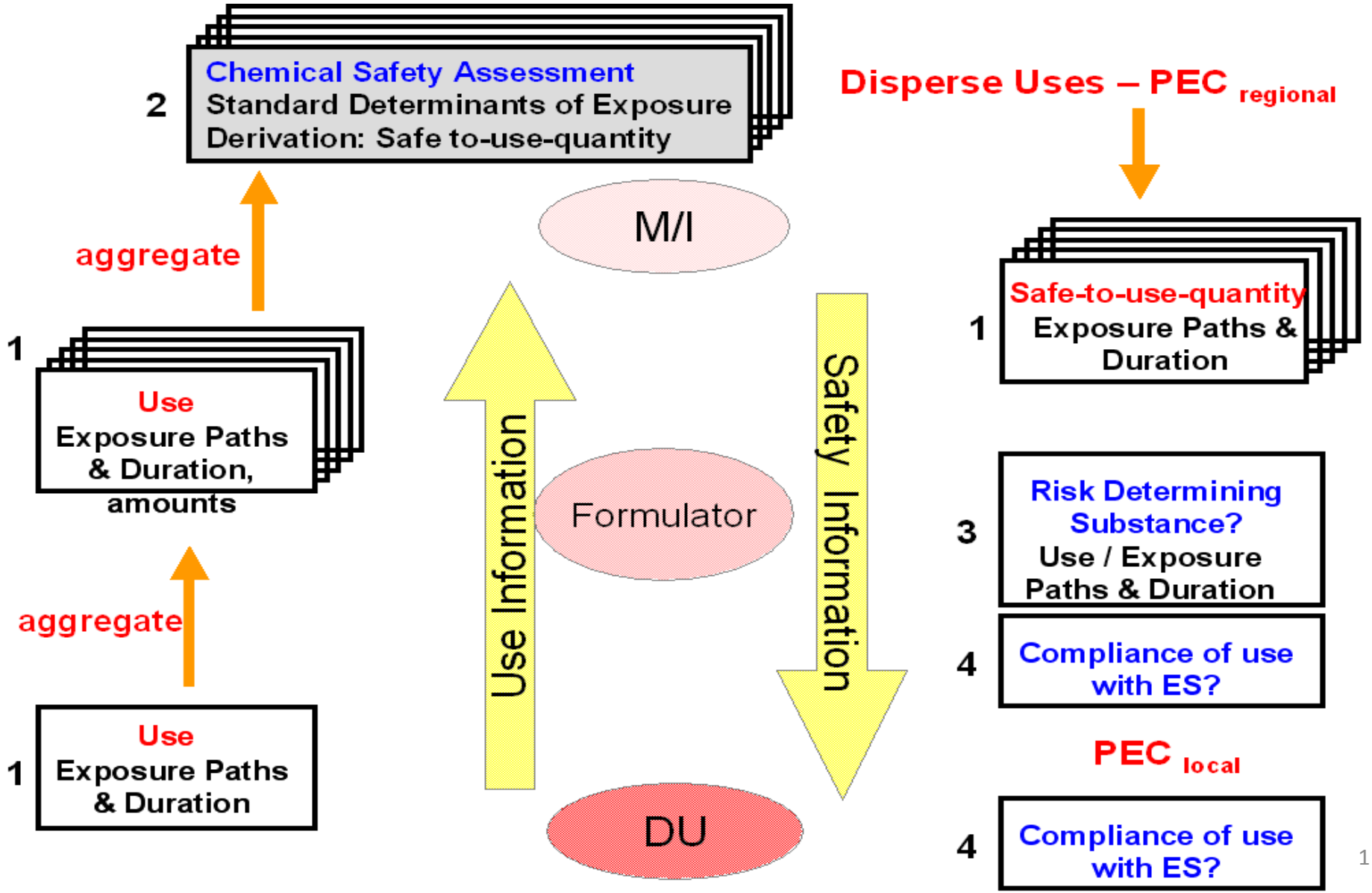
Exposure Scenario

Exposure scenario: means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate. (REACH Article 3(37))

REACH requires

- Description of ES for hazardous substances.
- Communication of ES in the annex of the SDS of hazardous substances and preparations.

Two-way communication (up- and downstream)



Communication obligation

- REACH requires manufacturers and importers of a substance on its own or in a preparation to communicate how their substances or preparations can be used safely for humans and environment.

- Safety Data Sheet

- Prepare the SDS according to a similar principle as he did before REACH came into force. The main difference is that when required, the SDS will also have an annex including exposure scenarios

Obligation to Downstream Users

- **Downstream users in principle do not have to register substances or make Chemical Safety Report.**

- **Downstream users are obliged to use dangerous substance in accordance with Exposure Scenario(s) provided by registrants as an annex to the Safety Data Sheet or in adapted form, if motivated.**

Safety Data Sheets – new style (e-SDS)

- **SDS already required since1993 (SDS Directive)**
- **Integrated in REACH, since 1 June 2007**
- **Practical transition period until 1 December 2010**
  - Since1 December 2010 SDS new style according to REACH Annex II (amended in Regulation 2010/453)
  - E-SDS (Extended SDS) with annex on exposure scenario(s)
- **Required, if substance/mixture is "classified", if identified as PBT/vPvB, if listed as candidate (SVHC)**
- **Shall be provided upon request for non-classified mixture containing**
  - **a classified (for human or environment) substance >1% (>0,2% for gases)**
  - **a substance of very high concern > 0,1%**

Safety Data Sheet – new style (e-SDS)

- **Should contain information in 16 prescribed sections compiled according to Annex II of REACH about**
  - Composition, components, hazards, C&L, use and storage, physical-chemical and (eco)toxicological properties, risk management measures, if applicable EU and/or national OEL, etc.
  - Information should be consistent with CSA
  - If registered substance, shall contain exposure scenario('s)
- **Provided information should comply with EU labour protection requirements (Chemical Agents Directive 98/24)**
- **To be drafted by competent person(s) in the official language(s) of the member state**
- **Shall be dated and clearly identified if revised**
- **Shall be distributed free of charge on paper or electronically to each client at first delivery and if revised.**

Structure of an e-SDS

0. (Status of SDS, trade name)
1. Identification of the substance/mixture
2. Hazards identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls / personal protection measures
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

Annex (Summary of a CSA in exposure scenarios)

Safety Data Sheet
according to Regulation (EC) No 1907/2006 (REACH)

Trade name:
Product. No: Version: 1.0 / EN Print date:
Specification No: Page 19 of 20 Revision date:

Annex to extended safety data sheet (eSDS)

Exposure scenario

	Exposure scenario identification	
1	Short title of the expsoure scenario	
2	Processes and activities covered by the exposure scenario	
3, 4.2, 4.3, 5	Operational conditions of use	
	Phase of production and application	
4.3, 6.1, 6.2 7	Risk management measures: Human (oral, dermal, inhalative, physical hazards) Environment (water, soil, air) Waste	Industrial, professional, consumer
	Phase of service life	
4.3, 6.1, 6.2 7	Risk management measures: Human (oral, dermal, inhalative, physical hazards) Environment (water, soil, air) Waste	Industrial, professional, consumer
	Information on estimated exposure and Downstream-user guidance	
8	Exposure estimation and reference to its source: Human Environment	Industrial, professional, consumer Water, soil, air Exposure assessment instrument/tool/method
(8)	Additional determinants of exposure	Substance characteristics: Molecular weight and -size Physico-chemical properties Biodegradation etc.
9	Evaluation guidance to (or upstream: from) downstream user	Adjustments of the exposition estimation Exposure scenario limitation: Necessary additional testing Uses advised against

Safety Data Sheet
according to Regulation (EC) No 1907/2006 (REACH)

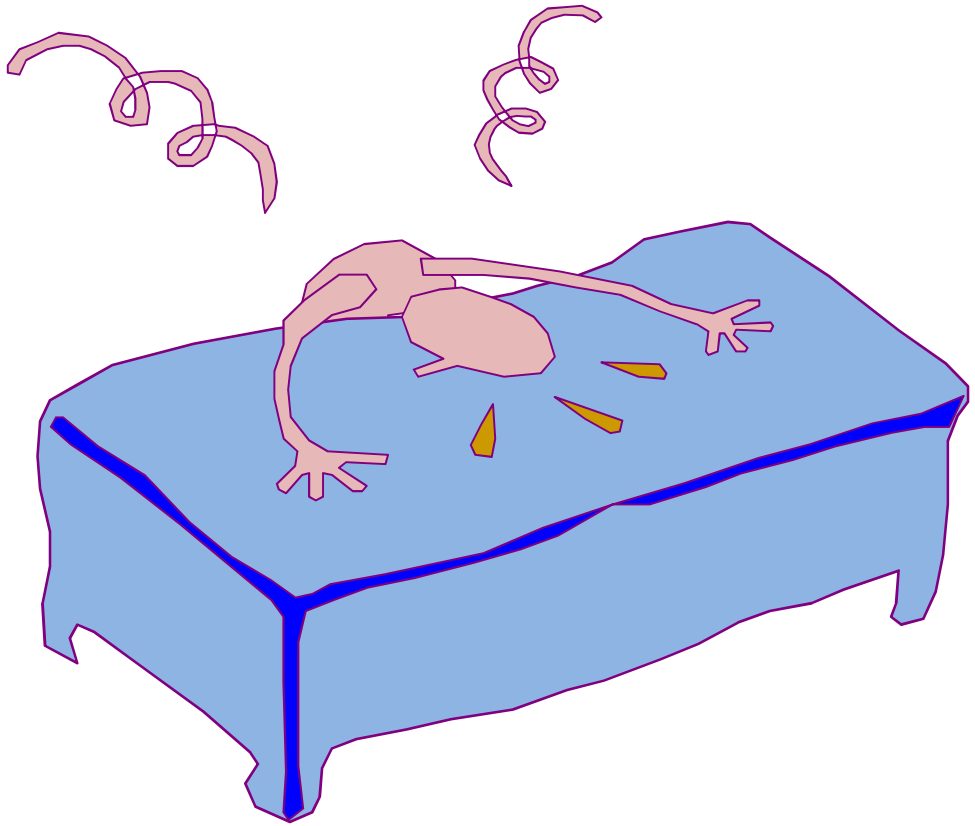
Trade name:
Product. No: Version: 1.0 / EN Print date:
Specification No: Page 20 of 20 Revision date:

1	Short title of the exposure scenario
2	Processes and activities covered by the exposure scenario
Operational Conditions of Use	
3.	Duration and frequency of use *Specify for workers, consumers, environment (where relevant)*
4.1	Physical form of substance or preparation; surface to volume ratio of articles *Gas, liquid, powder, granules, massive solids;* *Surface area per amount of article containing the substance (if applicable);*
4.2	Concentration of substance in preparation or article
4.3	Amount used per time or activity *Specify for workers, consumers, environment (where relevant)*
5	Other relevant operational conditions of use *For example* • *Temperature, pH, mechanical energy input;* • *capacity of receiving environment (e.g. water flow in sewage/river; room volume x ventilation rate)* • *wear and tear with regard to articles (if applicable); conditions related to service-life-time of articles (if applicable)*
Risk Management Measures	
6.1	Risk management measures related to human health (workers or consumers) *Type and effectiveness of single options or combination of options on exposure to be quantified [options to be phrased as instructive guidance]; specify for oral, inhalation and dermal route;*
6.2	Risk management measures related to the environment *type and effectiveness of single options or combination of options to be quantified [options to be phrased as instructive guidance]; specify for waste water, waste gas, protection of soil;*
7	Waste management measures at the different life cycle stages of the substances (including preparations or articles at the end of service life);
Information on estimated exposure and DU guidance	
8	Exposure estimation and reference to its source *Estimation of exposure resulting from the conditions described above (entries 3-7 and the substance properties; make reference to the exposure assessment tool applied; specify for routes of exposure; specify for workers, consumers; environment)*
9	Guidance to DU to evaluate whether he works inside the boundaries set by the ES *Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of variables (and a suitable algorithm) which together indicate control of risk, but which have some flexibility in the respective values for each variable. Note: This will mostly be specific conditions for a certain type of product; this section may also include a link to a suitable (e.g. easy-to-use) calculation tool.* *Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here as well.*

E-SDS and CSA

- **Information in SDS should be consistent with CSA:**
  - Physical chemical properties
  - (Eco)toxicological information
  - Risk characterisation / PBT/vPvB assessment
- **Conclusions and derived no-effect-levels should be consistent with CSA**
- **Recommended risk management measures should be implemented by downstream users, or adapted if motivated**

Questions ?



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Environment and Climate Regional Accession Network ECRAN

Enforcement of the REACH and CLP Regulations in EU Member States

Presented by: Ike van der Putte

Montenegro May 2014

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PART 1 Enforcement of REACH and CLP

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Enforcement of REACH/CLP

- **Contents**

✓ REACH/CLP requirements for enforcement

✓ The Forum

✓ Example: Enforcement in the Netherlands

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Enforcement of REACH/CLP

- **What is enforcement?**

- Enforcement of REACH and CLP means, generally, a range of actions that national authorities initiate to verify the compliance of the duty holders with REACH and CLP Regulations. For example, this includes checking whether the substance has been registered or pre-registered or verifying the presence and correctness of the Safety Data Sheets

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Enforcement of REACH/CLP

- **Who is responsible for enforcement?**

- Enforcement of REACH and CLP is a national responsibility, therefore each EU Member State, Norway, Iceland and Liechtenstein must ensure that there is an official system of controls

- ECHA has **no** enforcement responsibilities, since it is a Community-level institution. However, ECHA does host the Forum for Exchange for Information on Enforcement (Forum).

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Enforcement of REACH/CLP

- **Member states shall:**
  - maintain a system of official controls and inspections
  - set effective, proportionate and dissuasive penalties in national legislation
  - Inform the Commission about the provisions by 1 December 2008 (REACH)
  - Report enforcement activities to the Commission every five year including sanctions and measures
  - 1st report REACH 1 June 2010
  - 1st report CLP 20 January 2012

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Enforcement of REACH/CLP

- **The Forum**
  - Co-ordination across the European Union
  - Each Member State participates in the forum
  - Members are appointed for a 3-year term
  - Members are supported by technical advisors

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Enforcement of REACH/CLP

- **Tasks of the Forum:**
  - spreading good practice
  - highlighting implementation problems
  - agreeing on harmonised enforcement and inspection projects
  - identifying enforcement strategies
  - developing working methods and tools
  - coordinating exchange of inspectors

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Enforcement of REACH/CLP

- **Forum Documents (ECHA website)**

✓ Forum Work Programme 2011 - 2013
✓ Rules of procedure of the Forum (22/06/2011)
✓ REACH-EN-FORCE-1 project (August 2010)
✓ Agenda of the Forum's "Train the CLP Enforcement Trainers" Event (January 2011)
✓ Strategies for Enforcement of REACH and CLP (March 2011)
✓ Minimum Criteria for REACH and CLP Inspections (March 2011)
✓ Final report on PAHs in Tyres(2013) http://echa.europa.eu/documents/10162/13577/final_report_pah_en.pdf
✓ REACH-EN-FORCE-2 project (December2013) http://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

Strategies Enforcement REACH/CLP and minimum criteria inspections

"similar" approaches enforcement environmental legislation

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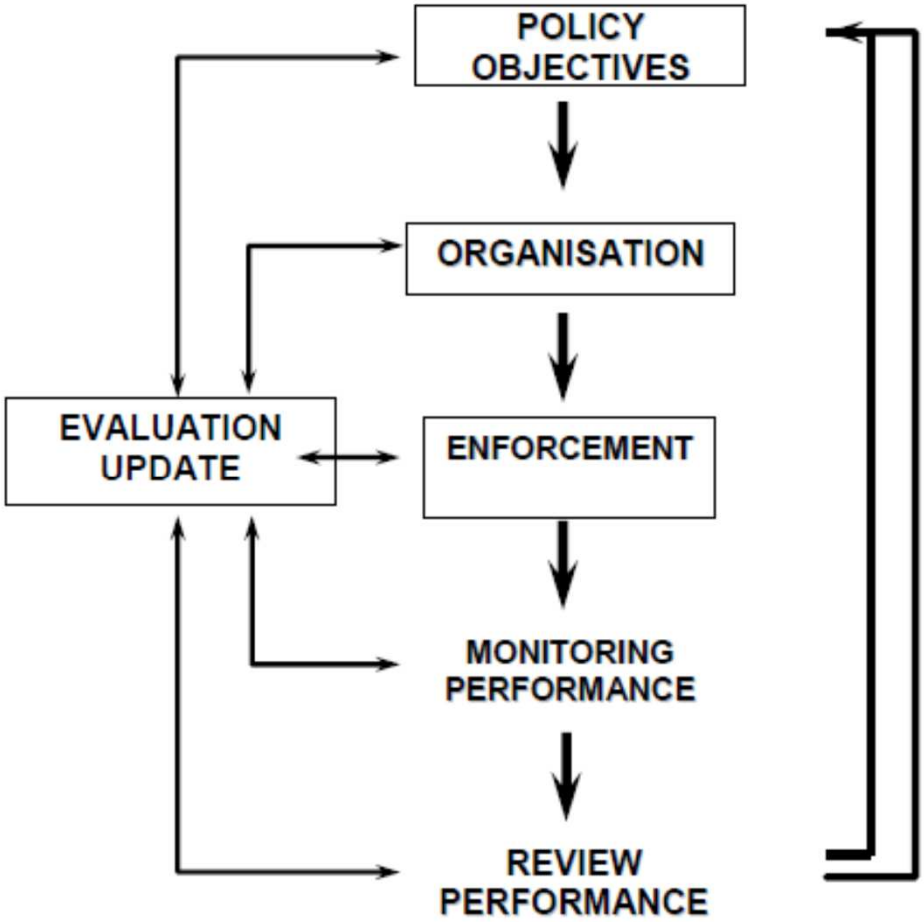
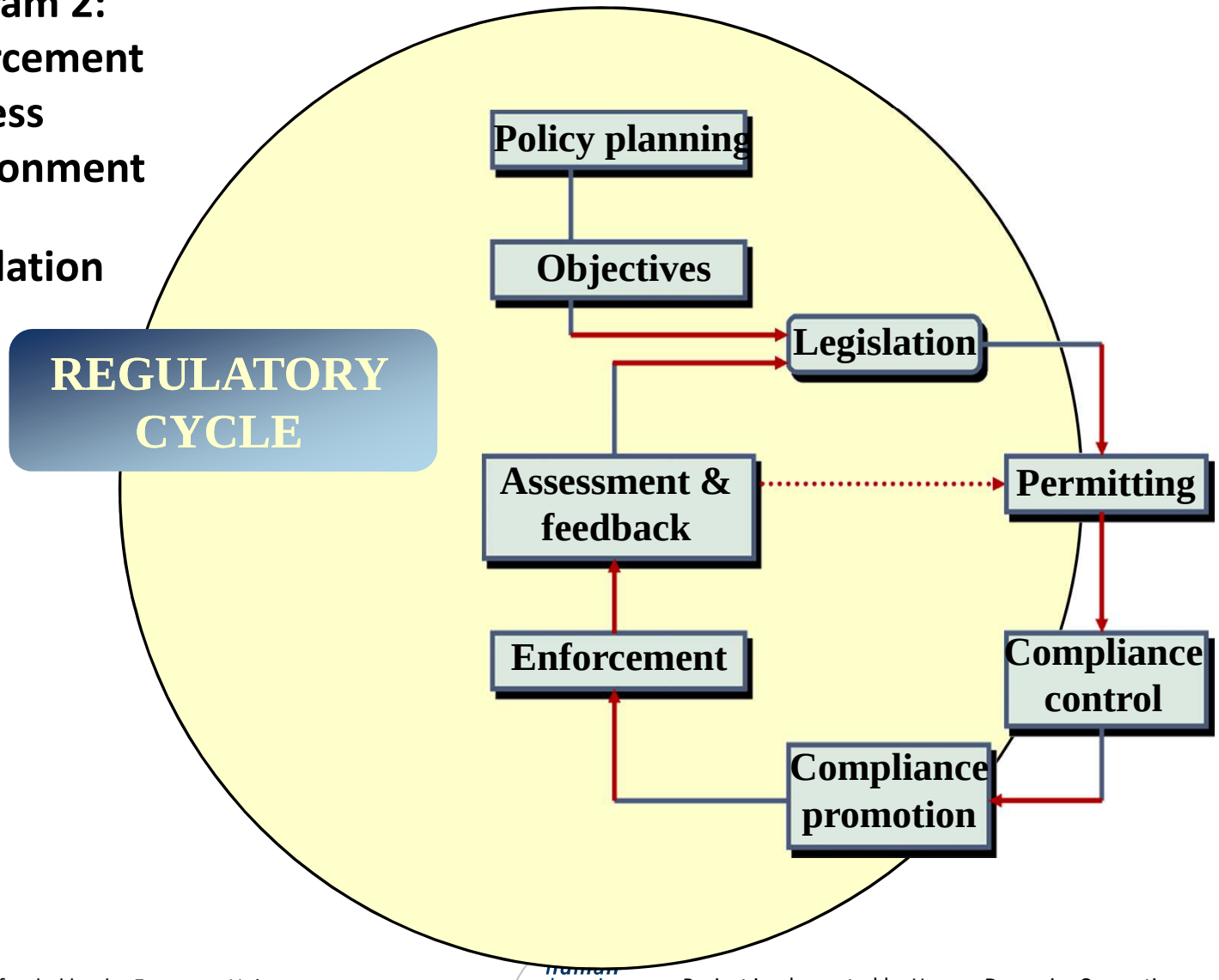


Diagram 1. Enforcement process for the REACH and CLP Regulation

- Diagram 2:
- Enforcement
- Process
- Environmental
- Legislation



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Minimum Criteria for REACH and CLP inspections - March 2011*

- **Contents**

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Minimum criteria for Environmental Inspections

- **Chapters**

✓ Organisation of inspections
✓ Inspection planning
✓ Site visits
✓ Reporting and follow-up
✓ Serious accidents, incidents, non-compliance
✓ General reporting
✓ Review

Recommendation of the European Parliament and of the Council of 4 April 2001 providing for minimum criteria for environmental inspections in the Member States (2001/331/EC)

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REACH Specifics 1

- Under REACH, each manufacturer or importer into the EU of chemicals in volumes of 1tonne or more per year – around 30,000 substances – will have to register them with the European Chemicals Agency (ECHA), submitting information on the properties, uses and safe ways of handling them.

- Duties are on 4 target groups:

✓ Manufacturers
✓ Importers
✓ Distributors
✓ Downstream users

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REACH Specifics 2

- For the purposes of enforcement, the requirements imposed by REACH can be divided up into three general areas, in terms of the nature of the duties that are placed on the target groups:

✓ **registration** related duties, imposed on manufacturers and importers;
✓ **supply chain** related duties, applicable to all target groups where appropriate; and
✓ **use** related duties, applicable to all target groups where appropriate

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CLP specifics 1

- CLP is different from REACH, it does not create a new approach to chemicals' control but replaces:

✓ Directive 67/548/EEC (Dangerous Substances Directive)
✓ Directive 1999/45 (Dangerous Preparations Directive)
✓ REACH, Title XI (Classification & Labelling)

- The objective of CLP should be to determine which properties of substances and mixtures should lead to a classification as hazardous in order for the hazards of substances and mixtures to be properly identified and communicated.

- The main responsibilities under CLP are that the manufacturers, importers and downstream users shall classify, label and package substances and mixtures before placing them on the market.

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CLP Specifics 2

- One of the challenging issues with respect to enforcement is the transitional period 2010 – 2015 for CLP is that both classification systems can be used.
- The classification and labelling for any registered or hazardous substance placed on the market should be notified to ECHA to be included in a classification and labelling inventory.
- Any manufacturer or importer will have to submit information about the classification and labelling elements.
- In line with REACH, the system that CLP imposes is achieved by placing a wide range of duties on essentially four *target groups*: manufacturers; importers; distributors; and downstream users

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CLP Specifics 3

- For the purposes of enforcement, the requirements imposed by CLP can be divided up into two general areas, in terms of the nature of the duties that are placed on the target groups:

✓ **notification-**related duties, imposed on manufacturers and importers;

✓ **supply chain-**related duties, applicable **to all** target groups where appropriate; as classifying, labelling and package duties

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Enforcement of REACH/CLP in the Netherlands

- **Three inspections agency working together**
  - The Labour Inspection team (AI)
  - Food and Consumer Product Safety Authority (VWA)
  - Environmental Inspection (VI)

- **Together they have supervision of the compliance with REACH/CLP**
  - AI will supervise the professional users of substances, preparations and objects
  - VWA will supervise producers, importers and traders of substances, products and objects for consumers
  - VI will supervise producers, importers and traders of substances, products and objects for professional use.

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Enforcement of REACH/CLP-Strategy

- Enforcement in the beginning of the supply chain

  Main targets are importers and manufacturers

- Minimise the effects of the risks downstream

- Prioritizing of enforcement actions
  - *Risks for environment and human health*
  - *Compliance behaviour*
  - *Motives for compliance or non-compliance behaviour*

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Enforcement of REACH/CLP

- At first focus will be on increasing the knowledge of the target group
  - What are the risks of non-compliance
  - What are the REACH obligations

- Later on:
  - Registration of substances
  - Information exchange (Safety Data Sheets)
  - Authorisation and restrictions

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Enforcement of REACH/CLP-Instruments

- Enforcement is possible in two ways
  - Administrative sanctions
  - Criminal sanctions (Criminal penalties and enforcement)

- Administrative sanctions
  - Aim of avoiding a repeat of the infringement
  - Order for incremental penalty payments, enforcement of an administrative order, administrative fine

- Criminal sanctions
  - Penalise infringements which are regarded as an environmental offence

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Enforcement of REACH/CLP

- List of administrative and criminal sanctions
- Failure to comply with a duty under REACH/CLP is an environmental offence (with reference to Economic Offences Act)
- Penalties:
  - Fines (up to € 740.000 is possible)
  - Up to six years imprisonment for serious environmental offences
  - Other penalties e.g. temporary halting or suspension of all part of the enterprise, publication of the court judgement

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Dutch Example (1) - Quiz

Infringements and the related penalties in The Netherlands:

Art. 5: "No data no market"

HEAVY

Art. 7-2: Obligation to notify the Agency for the production or importing of articles.

LIGHT

Art. 22-1: Obligation to update the registration.

LIGHT

Art. 31-1: Obligation to provide Safety Data Sheet to the recipient of the substance or preparation.

HEAVY

Dutch Example (2) - Quiz

Infringements and related penalties in The Netherlands (2):

Art. 25-1 Unnecessary testing with vertebrate animals and duplication of animal testing.

LIGHT

Art. 37-5: Downstream User shall identify, apply and recommend appropriate measures to adequately control

HEAVY

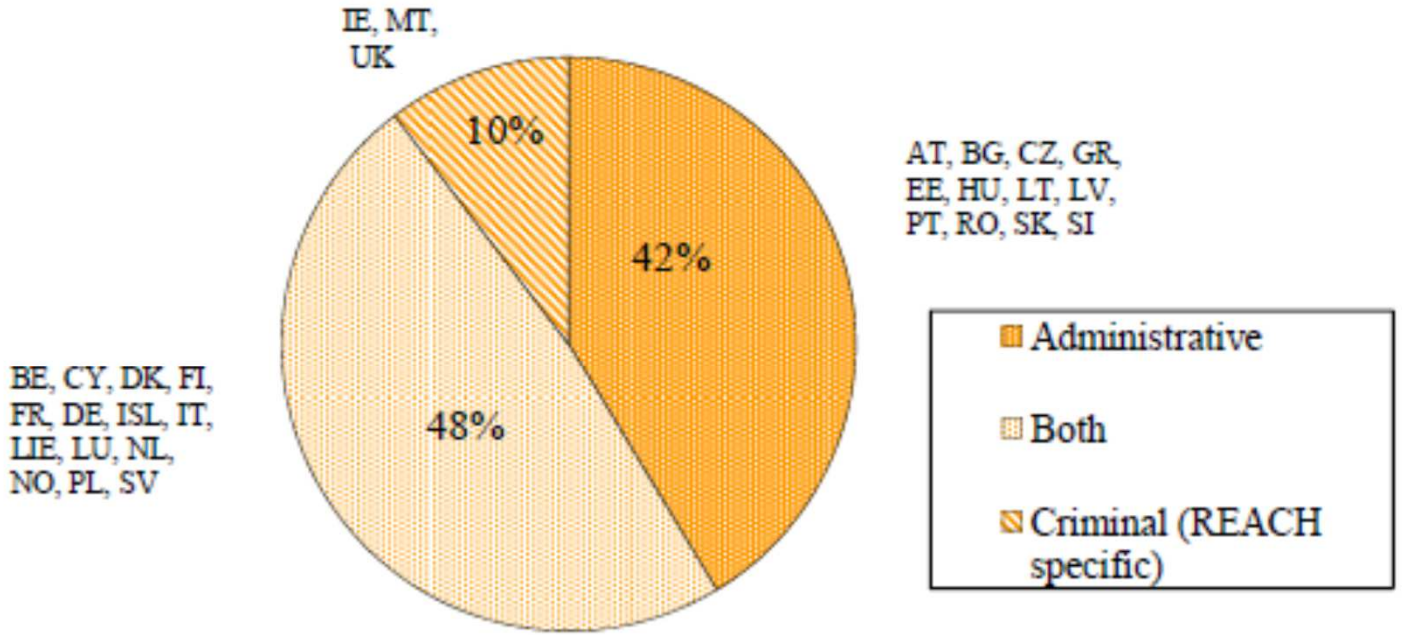
Art. 14-1:Obligation to perform a Chemical Safety Assessment and to complete a Chemical Safety Report (>10 t/y)

HEAVY

Art. 46-2: The registrant shall submit the information required to the Agency by the deadline set.

LIGHT

Enforcement regimes REACH*



*Source: Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States. Milieu March 2010.

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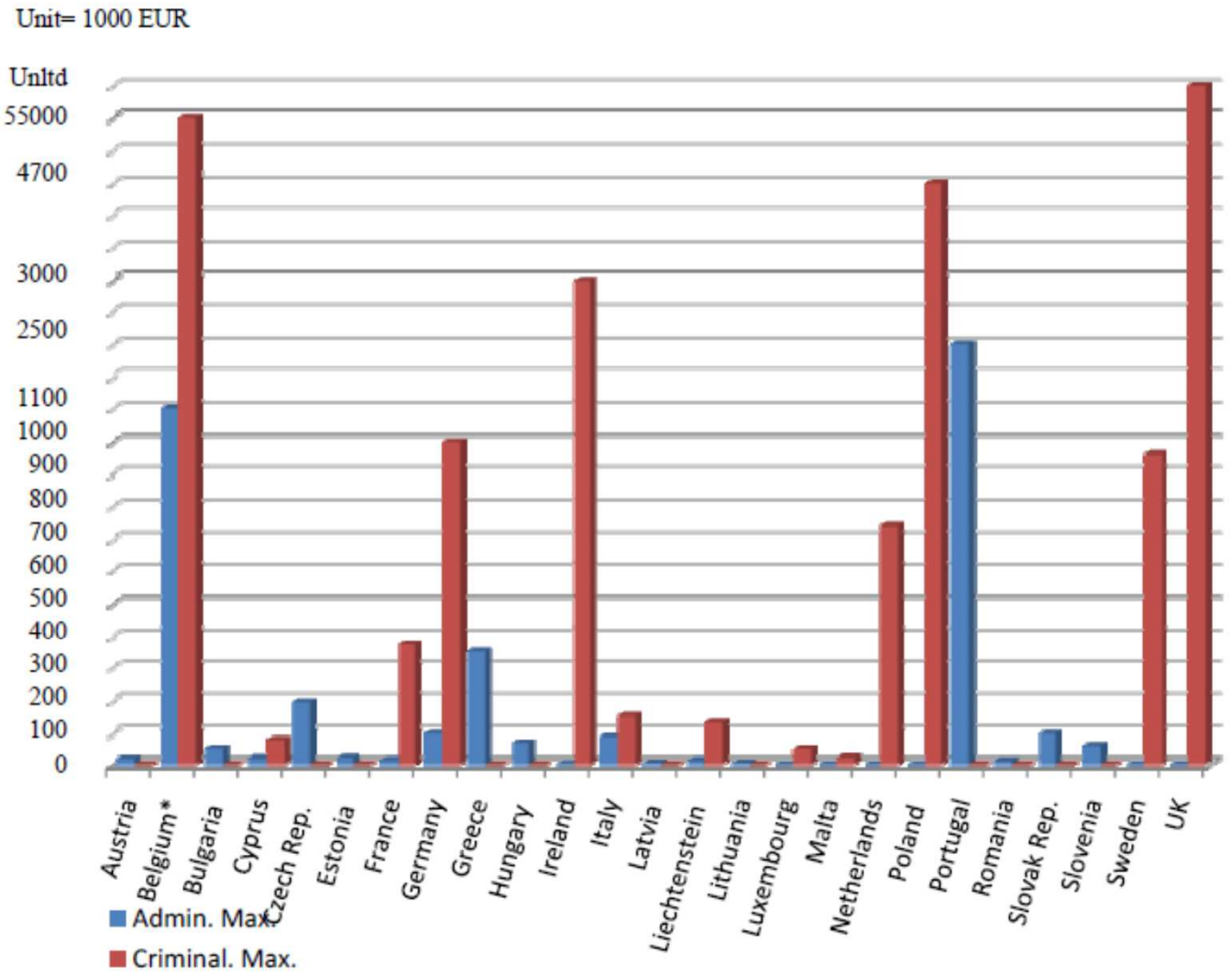
Chart 2 Level of administrative and criminal fines



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Substances in permitting and inspection of industrial installations

Gisela Holzgraefe

Podgorica, Montegro

13 – 15 May 2014

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Content of this presentation

- Background – general principles
- Substances in permitting and inspection
- The regulatory cycle of IED permitting and inspection
- Relevant procedures on substances in IED / REACH

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background

- Big variety of different industrial enterprises works with chemical substances.
- They belong to different industrial branches.
- They are of different size - micro, small, medium or non-SME.
- Enterprises may have various roles – many of them have more than one role (manufacturer, down stream user, distributer, importer)

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Duty holders under REACH / CLP

	Registration of substances	reg. of substances released of articles intentionally	Notification SVHC in articles	PPORD notifications	DU CSA	authorisations	restrictions	Info in the supply chain	Classification, labelling & pkg
Manufac-turer									
Importer									
DU									
Distributer									
OR									
Producer articles									

Duty holders under REACH/CLP and …

- Obligations are carried out in relation to different premises e.g sites under REACH, such as refineries, large chemical plants, installations for producing mixtures (paints, cleaning mixtures etc.) …
- The facilities are at the same time subject to other EU requirements relevant for controlling impacts of chemicals, e.g.
- health and safety of workers, e.g. Chemical Agents Directive (98/24/EC), Carcinogens and Mutagens Directive (2004/37/EC)
- environment e.g. Directive on Industrial Emissions (2010/75/EU) (IED), Priority Substances Directive (2008/105/EC),
- Product requirements, e.g. VOCs in Paints Directive

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Background – legal frame

- Requirements for permitting and inspection of industrial installations

  a) European level: Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) – ANNEX I Categories of activities requiring IED permitting and inspection

  b) Member States (MS) have implemented the provisions of IED into national laws, regulations and administrative provisions (deadline 7 January 2013)

  c) Member States have implemented legislation on national level for permitting and inspection of other activities and smaller installations

- Focus on a) and b)

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background – IED content

- rules on integrated prevention and control of pollution arising from industrial activities and
- rules designated to prevent or, where that is not practicable to reduce emissions into air, water and land and prevent the generation of waste
- aim: achieve a high level of protection of the environment taken as a whole
- approach: provisions for permitting and inspection of IED installations
- IED Directive - many references to hazardous substances and risks

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relation between IED and REACH

For IED purposes REACH information may be used:

- Article 12 par. 2 IED: where other information is supplied or produced in response to other legislation and it fulfils the requirements concerning the application documents, that information may be included in, or attached to the application.

- Example: chemical safety report - relevant parts may be
  - used by the operator for writing the application documents,
  - relevant for the permit writer for the assessment of the application,
  - relevant for the permit writer for writing the permit conditions.

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relation between IED and REACH

- Article 14 par 3 IED: BAT conclusions shall be the reference for writing the permit conditions. One criterion for the determination of the Best Available Technique is the use of less hazardous substances.

- Article 22 par. 2: Where an activity involves the use, production or release of relevant hazardous substances .... the operator shall submit to the competent authority a baseline report on soil and groundwater contamination before starting operation. For this purpose he can also use information that is supplied or produced in response to other legislation.

  In case of cessation of the activity the operator has to take measures to return the site to the state before starting it.

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relation between IED and REACH

- „baseline report“ = information on state of soil and groundwater contamination by relevant hazardous substances
- „Hazardous substances“ means substances or mixtures as defined in Article 3 of Regulation (EC) no. 1272/2008 of 16 December 2008 on classification, labelling and pacckaging of substances and mixtures.

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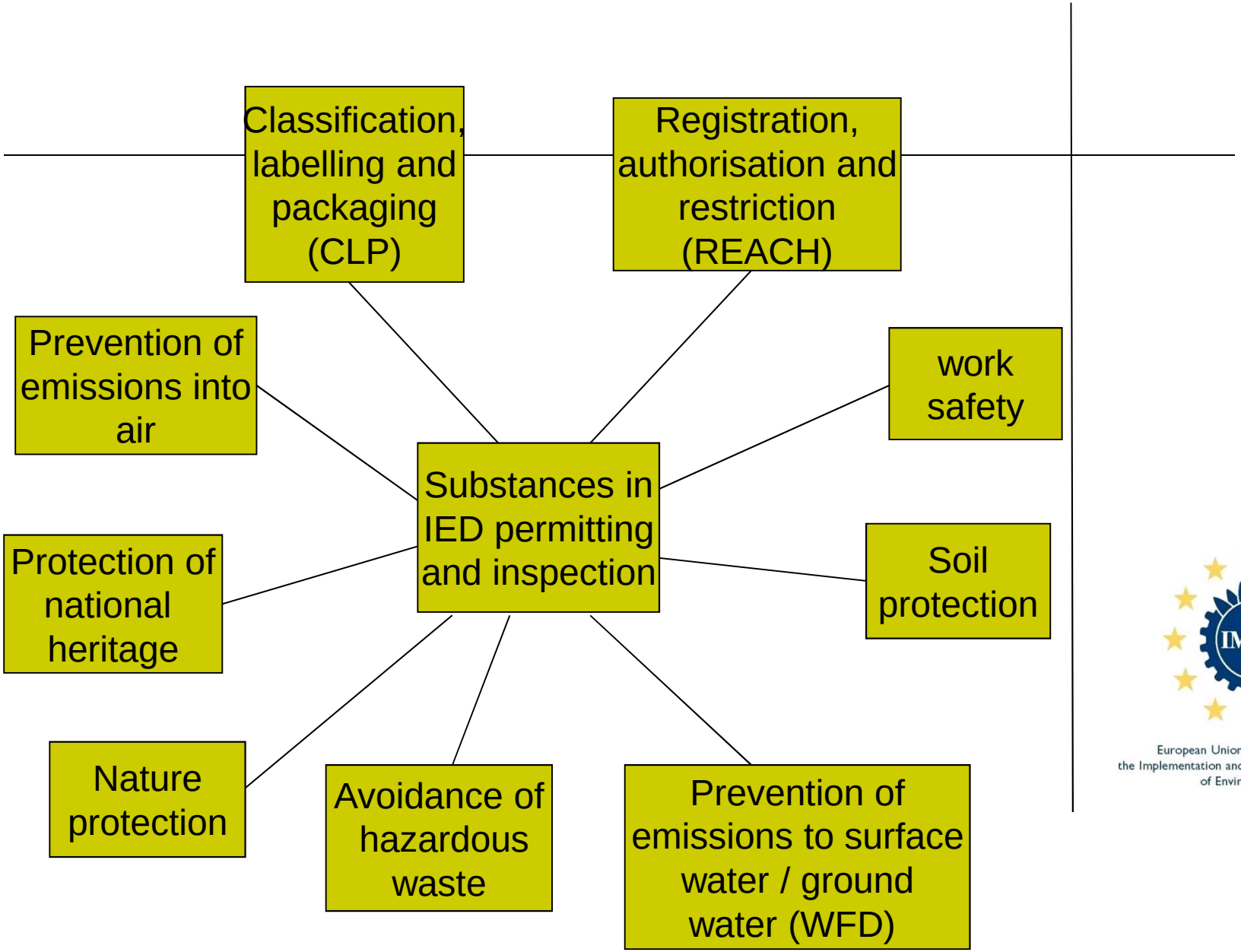

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Background – legal frame

- wide range of legal acts has to be taken into consideration during permitting and inspection
- If there are no requirements for a chemical substance in a media specific directive or the conclusions on the best available technique (BAT) → permit writers can subject them to emission limit values taking into account their nature and their potential to transfer pollutants from one media to another (Art. 14 par. 1 a) IED). For that purpose sources like REACH data can be used.

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regulatory cycle of IED

Steps of the regulatory cycle of IED permitting and inspection:

1. Determination of the installation
2. Application
3. Assessment of application documents
4. Involvement of the public
5. Permit decision
6. Monitoring and reporting
7. Inspection
8. Review of the permit

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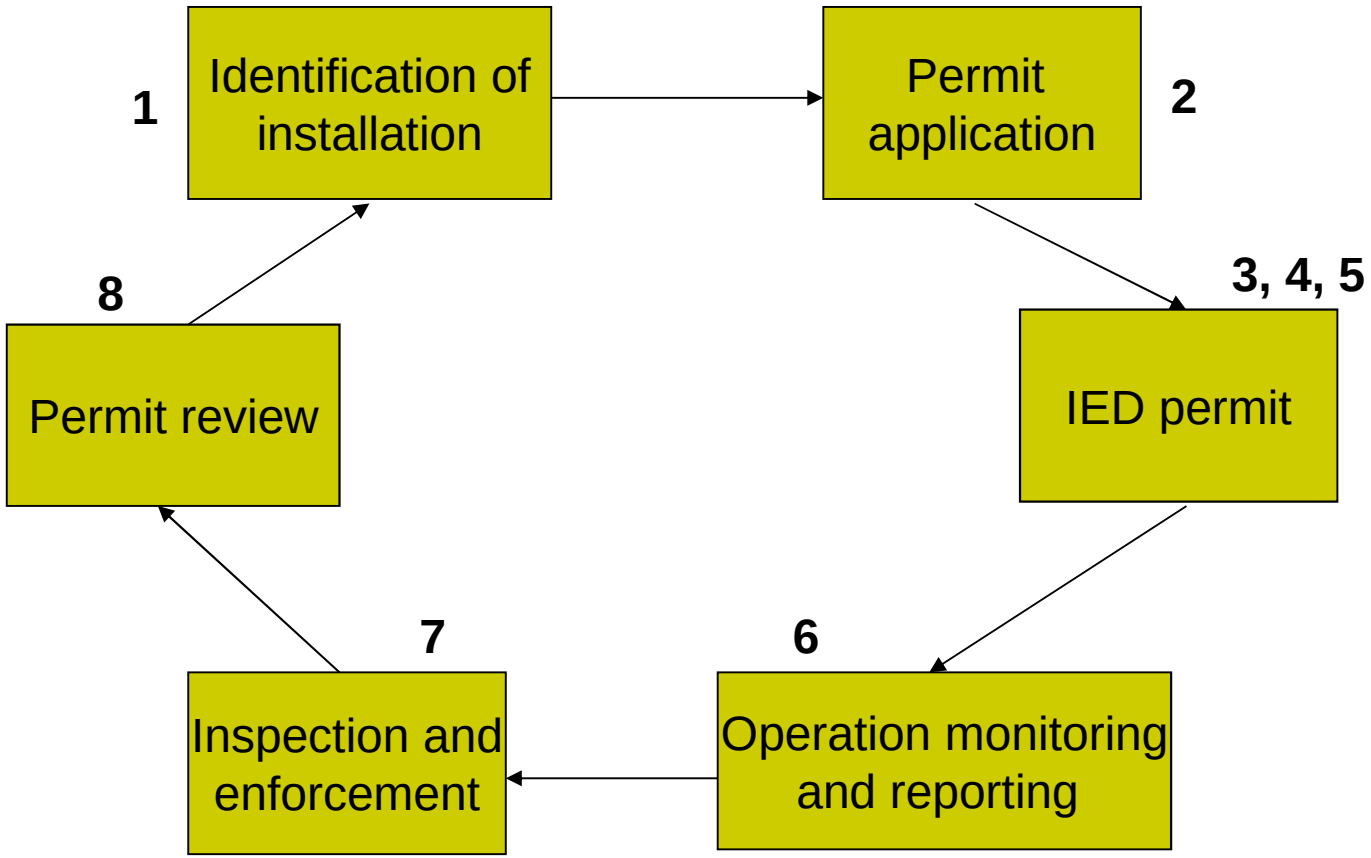
regulatory cycle of IED



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regulatory cycle of IED:

1	physical scope of the site	**+**	scope of activities	**+**	direchtly associated activities
2	BREFs, BAT conclusions	**+**	national legis-lation and BAT guidance	**+**	guidance for applicants
3, 4, 5	environmental quality standards	**+**	permit conditions: ELV‘s, management, monitoring, reporting, work safety measures		

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regulatory cycle of IED:

6 monitoring and reporting – task of operator acc. to permit conditions

7 Results of monitoring **+** inspection **+** sanctions

8 new BREF, new BAT conclusions **+** changes to installation **+** new env. objectives / limit values

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chemical substances in permitting and inspection

- IMPEL (European Network on Implementation and Enforcement of Environmental Law) carried out a project on chemical substances in permitting and inspection and the link between IED and REACH in 2013. Some findings:
- authorities provide guidance to the applicants including documents and data that have to be submitted concerning substances
- authorities provide templates or electronic tools for applicants to get the relevant data including REACH information and duties under REACH
- authorities have checklists or flowsheets in place for systematic evaluarion of safety data sheets (SDS) or systematic assessment of substances

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Template for application - example

Information about substances including waste water and waste material and their flows (Template 3.5 Schleswig-Holstein and several other Länder)

Name of chemical substance / mixture / article	**total amount (t)**	**Composition, content (weight %)**			
		Name of component	CAS-no	content (weight %)	
				Min.	Max.
1	2	3	4	5	6

calorific value (MJ/kg)	**EWC code**	**input material reactant raw material**	**inter-mediate**	**pro-duct / article**	**bypro-duct**	**waste**	**waste water**
7	8	9	10	11	12	13	14

template for substances in permit applications – example (3.5)

Relevant concerning emissions to air	Regulated under Seveso	Hazardous substance	REACH relevant	Submission of SDS
15	16	17	18	

climate impact / ozone layer depleting	hazardous to water	ordinance on industrial safety and health	comment
19	20	21	22

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template for application – example REACH duties (16.1)

SU No.	Name of chemical substance / mixture / article	Role under REACH	Total annual amount (t/y)	component					
				name of compo-nent	number			Subst. with registration	
					CAS	EG	In-dex	Yes ?	Reg-no
1	2	3	4	5	6	7	8	9	10

SU = subunit of installation on site

template for application – example REACH duties (16.1)

composition							
Substance regulated?			content (weight %)		nano-scaled	Identified use acc. to SDS / registration	comment
under annex		Candidate list	Mmn.	max			
XIV	XVII						
11	12	13	14	15	16	17	18
▯	▯	▯			▯	▯	

Ozone layer depleting substances / substances with climate impact

SU	kind of instal-lation	name of filling substance / refrigerant	amount of refrigerant / filling substance per unit?	number of instal-lations	leakage detection system in place?	interval of leak tests
1	2	3	4	5	6	7

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Procedures on substances in IED

- aim IED: achieve a high level of protection of the environment taken as a whole
- Procedures:

– Permitting of industrial activities with determination of defined emission limit values for pollutants according to BAT and obligation to use less hazardous substances

– In case of substantial changes the permit has to be updated or a new permit is neccessary

– Monitoring and reporting obligations are permit conditions

–

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Procedures on substances in IED

- Inspection: according to IED MS have to establish a system for routine and non-routine inspections,
- For determination of period between two inspections a risk based approach is used (chemical substances processed or produced play an important role), period lies between 1 year and 3 years
- Sanctions: MS have defined sanctions with regard to the nature of infringement

→ substances play an important role!

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Procedures on substances in REACH

- aim REACH: ensuring a high level of protection of human health and the environment from the risks that can be posed by chemicals
- Procedures:

– REACH registration of substances by companies that manufacture or import them at or above 1 tonne per year.

– For that purpose companies have to assess hazards and potential risks, communicate and implement RMM

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Procedures on substances in REACH

- Aim of REACH authorisation of substances of very high concern (SVHC) is to ensure that risks are properly controlled and that SVHC are progressively replaced by less dangerous substances or technologies
- Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals → limitation or ban of manufacture, placing on the market or use of.
- Inspections: compliance with a number of obligations has to be checked on site
  e.g. substance manufactured or used on site has been registered, identity of substance = comparison of name and other identifiers, taking samples, classification and labelling correct ….

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Processes under IED and REACH

IED	REACH
Achieve a high level of protection of the environment as a whole	Ensure a high level of protection of human health and the environment
Permitting	Registration, Authorisation and Restrictions
Monitoring and reporting	Updating
Inspections	Inspections
Sanctions	Sanctions

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Recommendations

.

- Permit procedures: requirements concerning REACH obligations should be part of check lists, templates and electronic tools that authorities provide for the applicants of IED permits
- good cooperation between authorities dealing with enforcement of REACH / CLP, work safety and IED permitting is highly recommended
- training of permit writers and inspectors in workshops

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Thank you for your attention !

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des Landes Schleswig-Holstein

Relevance of interaction between IED and REACH

Interlink analysis REACH / IED

Substances in IED-inspection tasks

Date: 06.05.2014

Dr. Gisela Holzgraefe

Ministry for Energy, Agriculture, the Environmant and Rural Areas

of Land Schleswig-Holstein (Germany)

Content

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- Relevance of interactions between IED and REACH / CLP
- Interlink analysis REACH / IED
- Substances in IED-inspection tasks

interactions REACH / CLP and IED

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- Link between IED and REACH = substances and their properties / characteristics
- three examples for explanation of relevance of interactions between REACH / CLP and IED
- Example 1: baseline report and waste
- Example 2: baseline report and not classified substances or mixtures
- Example 3. new classification of formaldehyde an consequences

Examples 1 and 2 baseline report

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- The baseline report on soil and groundwater contamination is a new instrument - there is a need for guidance on its content and for criteria concerning “the relevant hazardous substances” and “the relevant amounts”. Adoption of guidance is announced by COM for first half 2014.

- Example 1: Baseline report - IED only refers to relevant hazardous substances or mixtures as defined in Article 3 of CLP Regulation → hazardous waste is not covered. Hazardous waste can contaminate soil and groundwater in the same way. Here seems to be a gap. (Better solution was found in Sevewso Directive?)

- Example 2: there are some uncertainties concerning certain mixtures, e.g. manure from intensive rearing of pigs and poultry. Discussions on national and European level have not yet produced a result. Example is in F&Q catalogue concerning IED.

interactions REACH / CLP and IED

- Example 3: proposal for new classification of **formaldehyde**,
  EC number: 200-001-8, CAS number: 50-00-0

Sept. 2011	proposal submitted by France to ECHA,
Nov. 2012	Committee fo Risk Assessment (RAC) adopted opinion on the proposal for harmonised classification and labelling of formaldehyde (mutagenicity and carcinogenicity)
2014	adoption by COM, then proposal for Adaptation to Tech. Progress (18 month?)

	CLP	DSD
Current entry in Annex VI to Regulation (EC) No 1272/2008	**Carc. 2 – H351**	**Carc. Cat. 3; R40**
Proposal by submitter consideration by RAC	**Muta. 2 – H341** **Carc. 1A – H350**	**Muta. Cat. 3; R68** **Carc. Cat. 1; R45**
Opinion of the RAC	**Carc. 1B – H350** **Muta. 2 – H341**	**Carc. Cat. 2; R45** **Muta. Cat. 3; R68**

interactions REACH / CLP and IED

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- **Example formaldehyde,** consequences from classification in category 1B, “presumed to have carcinogenic potential for humans, classification is largely based on animal evidence”
  (instead of suspected human carcinogen):

1. **emission limit values for a number of industrial activities have to be adjusted, e.g.:**
   - organic fine chemicals industry
   - pulp and paper industry
   - ceramic manufacturing industry
   - food, drink and milk industries (e.g. coffee roasting: main contaminants in exhaust air: CO_2, dust and formaldehyde)
   - textile industry

- **European level: review of BREF documents and conlusions necessary**

interactions REACH / CLP and IED

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- **Example formaldehyde**
- **national level,** e.g. consequences in **Germany** for industrial installations:
- approach of TA Luft:
  - ❖ now general emission limit value (ELV) for organic substances in exhaust air: 20 mg/m³ or 0,1 kg/h plus specific ELVs for different types of installations
  - ❖ then: change to carceogenic substance class III → general ELV 1 mg/m³ or 2,5 g/h
- expert discussions show that it is difficult to find technologies that will comply with that → big efforts are necessary

2. work safety requirements have to be adjusted

- Discussion about the measures started in Germany last week
  → occupational exposure limit value (OEL), identification of alternatives

Interactions of REACH / CLP and IED …

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- **IED and REACH - relation between them? = substances**
- **Aim of REACH:** to ensure a high level of protection of human health and the environment as a whole from the risks that can be posed by chemicals.
- **aim of IED:** to prevent pollution and where that is not practicable to reduce emissions from industrial activities into air water and land in order to achieve a high level of protection of the environment as a whole**.**

→ **IED covers a subgroup of chemicals under REACH**

- **IMPEL project** on the item assessed relevant REACH processes and their relevance for the interactions between IED and REACH
  - Project report provides an overview of the information generated in the REACH processes and the availability to different parties
  - Best practice examples show how REACH information is used for IED tasks

interactions REACH / CLP and IED …

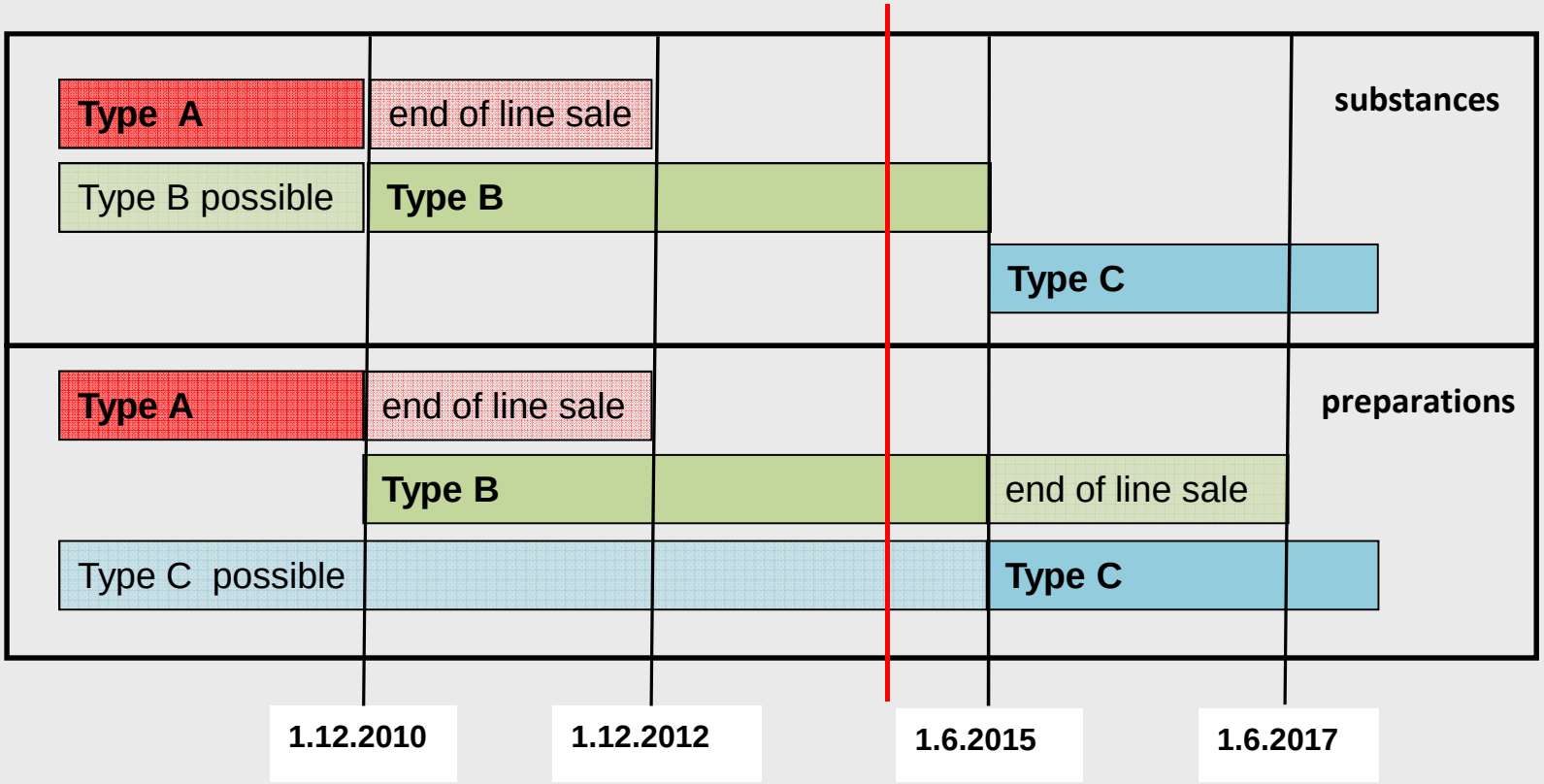
- The REACH text (rec. 14) promotes the use of information in Community legislation
- ECHA strategic objective 1: Maximise the availability of high quality data to enable the safe manufacture and use of chemicals
- Part of the ECHA actions address understanding and processing of information at the end-users' level
- ECHA has identified further need to promote efficient use of information in a multi/cross legislative context
- Information flow between REACH and activities under IED, WFD, CAD, CMD is beneficial and to be supported
- Target group: operators of industrial installations and industrial activities taking place within the installations
- ECHA carries out an interlink analysis (ready ?)

Information sources from REACH

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- SDS known document for a long time, problem was / is quality
- REACH brought some format changes and more content/quality
- Contains a lot of information, potential for a more intensive use of data

Formats Safety Data Sheets



TYPE A: Annex II to first version of REACH Regulation
TAPE B: Annex I to Regulation 453/2010, amending Annex II to REACH Reg., date: 01.12.2010
TYPE C: Annex II to Regulation 453/2010, amending again Annex II to REACH Reg., date 01.06.2015

Safety Data Sheets for Preparations

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

section	REACH Annx. II (A)	453/2010, Annex. 1 (B)	453/2010, Annex. 2 (C)
1.2	use	relevant identifiied uses or uses adviced against	see B
2	Classification acc. to Dangerous Preparations Directive 1999/45/EC	Clssification and labelling acc. to Dangerous Preparations Directive 1999/45/EC	Clssification and labelling acc. to CLP
3	Composition of preparation Classification of substances acc. to Dangerous Substances Directive	Composition of preparation Classification of substances acc. to Dangerous Substances Directive and CLP	Composition of preparation Classification of Substances acc. to CLP
15	Regulatory information labelling	Regulatory information	Regulatory information

Information sources from REACH

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- **Extended SDS as source of information:** a chemical safety report (CSR) has to be completed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant.
- If the registrant concludes that the substance meets the criteria for classification as dangerous or is assessed to be a PBT or vPvB exposure scenarios (ES) for all identified uses are necessary.
- Exposure scenarios have to be provided as annexes to SDS
- Exposure scenarios may be important sources of information for permitting and inspection activities.

Information sources from REACH

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- **Exposure Scenario**
- **New communication tool** in the supply chain
- Set of **conditions**, including operational conditions and risk management measures, that describe **how** the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users **to control exposure of humans and the environment**.

Should contain

- Title section
- Conditions of use affecting exposure
- Exposure assessment
- Additional advice

Information sources from REACH

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

Authorisation

candidate List - Authorisation List as well as the authorisation decisions = relevant elements concerning interactions between REACH and IED.
Why? They give clear signals and regulate which substances are to be substituted as soon as technically and economically feasible alternatives are available or require an authorisation. This information can be used for IED purposes (e.g. BAT). Additionally the process generates information about possible alternatives that can also be interesting for IED purposes (permitting and inspection).

Restrictions

The registry of intentions provides early information of substances which may be subject to restriction. Once the substance restriction has been adopted by the European Commission, industry (manufacturers, importers, distributors, downstream users and retailers) must comply. Restriction List regulates which substances or uses are not allowed or allowed under specific conditions and this information can be used for IED purposes (e.g. BAT).

Substances in IED inspection tasks

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- Art. 23 IED MS shall set up a system of environmental inspections of installations (routine and non-routine inspections)
- MS shall ensure that all installations are covered by an inspection plan
- Inspection plan is regularly reviewed and updated
- Based on the inspection plan competent authorities have to draw up programmes for routine environmental inspections including the frequency of site visits (period between two visits 1 year up to 3 years)
- Determination of frequence by using a risk based approach
- Appraisal of the risk shall be based at least on:
  - potential and actual impacts of the installation on human health and the environment taking into account the type of emissions, the sensitivity of the local environment and the risks of accidents
  - the record of compliance with permit conditions
  - the participation in the EU eco-management and audit scheme

  MS have developed electronic tools for the risk assessment

Substances in IED inspection tasks

- **IMPEL** (European Network on Implementation and Enforcement of Environmental Law) has developed
  - Integrated Risk Assessment Method (**IRAM**)
  - electronic tool for determination of frequency
  - tool for drawing up an IED-IRAM Inspection Programme
  - documents and reports see www.IMPEL.eu
  - free access to the system

- IRAM criteria are based on European legislation
- it is a scoring system (scores from 0 to 5, operator performance -1, 0, 1)
- the highest number produces the highest frequency
- operator performance less relevant, important is the impact of the activity on the environment

Substances in IED inspection tasks

Ministerium für Energiewende,
Landwirtschaft, Umwelt
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des Landes Schleswig-Holstein

no	criterion	description
1	Type and kind of installation	IPPC/IED-Installation, Seveso
2	Impacts on human health or the environment	No of complaints and incidents / accidents in the last 5 resp. 2 years
3	Releases to air	Activity in Annex I EPRTR / releases of Annex 2 substances to air with thresholds
4	Releases to water	See above
5	Releases to land	See above
6	Off-site-transfer of waste	Non-hazardous or hazardous and amounts
7	Input of waste	See above and transfrontier shipment of hazardous waste with thresholds
8	Quality of local environment	Contribution by the installation to the env. quality (no up to contributionto violation of quality standard > 3 %)
9	Sensitivity of local environment	Distance from installation to sensitive area
10	Risk of accidents	Based on Seveso Directive

Substances in IED inspection tasks

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

no	criterion	description
11	noise	No emissions, below limit value and limit value exceeded plus thresholds
12	Compliance	No relevant non-compliance, one and more than one
13	Attitude of the operator	Immediate reaction in case of non-compliance, after a warning letter, only after warning letter or administrative decree
14	Environmental management system	Registered under EMAS, not registered under EMAS but other accepted system, Not under EMAS and no other system

- IRAM: 8 out of 14 criteria refer to the substances or to waste material
- other scoring systems are in place, they use similar criteria

Substances in IED inspection tasks

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- criteria for risk appraisal are based to a good deal on the hazardous substances on site and the nature of the emissions (emissions of substances to air, soil and water, hazardous waste as well as noise and vibrations etc.)
- Steps: preparation of the inspection – site visit – report and follow-up – make the report available for public access
- inspectors have developed check lists for their inspection work taking into account the individual type of installation

Substances in IED inspection tasks

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- chemical substances used, produced or stored on site in significant amounts have direct impact on potential risks and emissions → the check of the inventory of chemical substances should always be one item of environmental inspections.
- for new substances on site their properties and classification have to be checked and the authority has to determine whether a review of the permit is necessary.
- Other hazardous substances on site: Baseline report on soil and groundwater contamination necessary? Art. 22 IED requires the submission of the baseline report before starting operation of an installation or before a permit for an installation is updated.
- substances newly identified as SVHC → assessment of consequences. Update of permit necessary? Subsequent order?

Substances in IED inspection tasks

Ministerium für Energiewende,
Landwirtschaft, Umwelt
und ländliche Räume
des Landes Schleswig-Holstein

- IED inspectors can refer to the safety data sheets for the check of the inventory of chemical substances and the assessment of the risk management measures on site,
- Inspectors generally use additional literature and other expertise to prepare inspections and do the follow-up work. It is not the task of IED inspectors to check the quality of the SDS systematically.
- If they find inconsistencies they should inform the competent REACH authority about their findings.
- Challenge of high numbers of different substances on site: Cases with more than 250 are known.
- Close cooperation of competent REACH and IED authorities would be valuable and should be established.


Thank you for your attention?
Any questions?

Environmental Classification & Hazard Assessment

CASE STUDY

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Environmental Hazard / Risk Assessment – Case Study

Goal of the Case Study is brief practical introduction into a proces of **„Generic Risk Assessment“**.

Tasks:

1. Classify chemical substances (caprolactame, diphenylamine, dioctylphthalate) for environmental hazard
2. Define endangered environmental compartments based on P-CH properties
3. Perform effects assessment – calculate Predicted No Effect Concentration (**PNEC**)
4. Calculate Predicted Environmental Concentration (**PEC**)
5. Explain (calculate) **Risk Quotients**
6. Make proposals for future factory production / limitations - RMMs

Environmental Hazard / Risk Assessment – Case Study

Results

Existing production

Caprolactame		
Classification	GHS Pictogram	
	Signal Word	
	Hazard Statement	
Effects assessment		
	PNEC	
Exposure assessment	Endangered env. ompartments	
	PEC – aquatic environment	
Risk Quotients	$RQ_{surface\ water}$	
Proposals / comments:		

Diphenylamine		
Classification	GHS Pictogram	
	Signal Word	
	Hazard Statement	
Effects assessment		
	PNEC	
Exposure assessment	Endangered env. ompartments	
	PEC – aquatic environment	
Risk Quotients	$RQ_{surface\ water}$	
Proposals / comments:		

New production

Dioctylphthalate		
Classification	GHS Pictogram	
	Signal Word	
	Hazard Statement	
Effects assessment		
	PNEC	
Exposure assessment	Endangered env. ompartments	
	PEC – aquatic environment	
Risk Quotients	$RQ_{surface\ water}$	
Proposals / comments:		

P-CH Tables

Estimates for the emission factors (fractions released)

Conditions		Emmision factors to:		
Solubility (mg/l)	**Vap. (Pa)**	**Air**	**Waste water**	**Soil**
<100	< 100	0.65	0.25	0.0005
	100 – 1 000	0.8	0.1	0.0025
	≥ 1 000	0.95	0.05	0.001
100 – 1000	< 100	0.4	0.5	0.005
	100 – 1 000	0.55	0.35	0.002
	≥ 1 000	0.65	0.25	0.001
1 000 - 10 000	< 100	0.25	0.65	0.005
	100 – 1 000	0.35	0.55	0.002
	≥ 1 000	0.5	0.4	0.001
≥ 10 000	< 100	0.05	0.85	0.005
	100 – 1 000	0.1	0.8	0.002
	≥ 1 000	0.25	0.65	0.001

Overall emmisions concerning production volume:
< 1000 per annum – 0,02
> 1000 per annum – 0,002 – 0,0005

Classes of affinity of chemicals for the different environmental compartments in relation to the phzsico-chemical characteristics of the molecules

Affinity	**WATER**	**AIR**	**SOIL**	**ANIMAL BIOTA**	**PLANT BIOTA**
	S v mg/l	H v Pa m^3/mol	log Koc	log Kow	log Koa
high	> 10 000	> 10	> 5	> 5	> 8
medium high	10 000 – 100	10 – 10^{-1}	5 – 4	5 – 3.5	8 – 7
medium	100 – 10	10^{-1} – 10^{-2}	4 – 2	3.5 – 3	7 – 5
medium low	10 – 0,1	10^{-2} – 10^{-4}	2 – 1	3 – 1	> 4
low	< 0,1	< 10^{-4}	< 1	< 1	< 4

S = water solubility
H = Henry law constant
Koc = Soil Adsorptive Coefficient
Kow = octanol/water distribution coefficient
Koa = oktanol/air distribution coefficient

Units recalculation

1 atm = 1013 mbar = 1013 hPa = 101300 Pa = 760 mmHg
1 mmHg = 133,3 Pa

Formalised criteria (simplified scheme) for classification of chemical substances

Valid only for the aquatic environment

Acute toxicity: min. F, D, A: L(E)C_{50} (mg/l)	**No readily biodegradable**	**Potential for bioaccumulation: Log P_{ow}>3 or BCF > 100**	**Classification: Hazard symbol R-phrases**
< 1	**-**	**-**	 N **R50 (very toxic...)**
< 1	**+ and / or**	**+**	 N **R50/53 (very toxic... and may cause long-term adverse effects in the aquatic environment)**
1-10 and	**+ and / or**	**+**	 N **R51/53 (toxic... and may cause long-term adverse effects in the aquatic environment)**
10-100 and	**+ and**	**+/ -**	**R52/53* (Harmful... and may cause long-term adverse effects in the aquatic environment)**
-, but S_w< 1	**+ and**	**+**	**R53* (May cause long-term adverse effects in the aquatic environment)**

F, D, A: Fish, Daphnia, Algae = fish, Daphnia, algae; S_w = water solubility.
* without classification in case when substance has documented abilitt for ready degradability in the water environment, or NOEC (long-term) for fish or Daphnia ≥ 1 mg/l (R52) or higher then Sw (R53).

Classification categories for hazardous to the aquatic environment

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008

Acute (short-term) aquatic hazard

Acute Category 1 (Note 1)

96 hr LC50 (for fish) ≤ 1 mg/l and/or

48 hr EC50 (for crustacea) ≤ 1 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) ≤ 1 mg/l. (Note 2)

Chronic (long-term) aquatic hazard

Chronic Category 1 (Note 1)

96 hr LC50 (for fish) ≤ 1 mg/l and/or

48 hr EC50 (for crustacea) ≤ 1 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) ≤ 1 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4).

Chronic Category 2

96 hr LC50 (for fish) > 1 to ≤ 10 mg/l and/or

48 hr EC50 (for crustacea) > 1 to ≤ 10 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) > 1 to ≤ 10 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4), unless the chronic toxicity NOECs are > 1 mg/l.

Chronic Category 3

96 hr LC50 (for fish) > 10 to ≤ 100 mg/l and/or

48 hr EC50 (for crustacea) > 10 to ≤ 100 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) > 10 to ≤ 100 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4) unless the chronic toxicity NOECs are > 1 mg/l.

Safety net' classification

Chronic Category 4

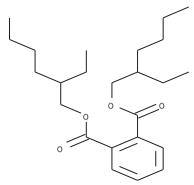
Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility (note 3), and which are not rapidly degradable and have an experimentally determined BCF ≥ 500 (or, if absent, a log Kow ≥ 4), indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or evidence of rapid degradation in the environment.

Note 1
When classifying substances as Acute Category 1 and/or Chronic Category 1 it is necessary at the same time to indicate an appropriate M-factor (see table 4.1.3).

Note 2
Classification shall be based on the ErC_{50} [= EC_{50} (growth rate)]. In circumstances where the basis of the EC_{50} is not specified or no ErC_{50} is recorded, classification shall be based on the lowest EC_{50} available.

Note 3
'No acute toxicity' is taken to mean that the $L(E)C_{50}$(s) is/are above the water solubility. Also for poorly soluble substances, (water solubility < 1 mg/l), where there is evidence that the acute test does not provide a true measure of the intrinsic toxicity.

DIOCTYLPHTHALATE



CAS No.:	**117-81-7**
EINECS/ELINCS No.:	**204-211-0**
Formula:	**C24-H38-O4**
Molecular weight:	**390,54 g/mol**
Form:	light colored liquid; colorless oily liquid; sl

Melting point:	-50°C	**Boiling point:**	230 °C pri 5mm Hg
Flash point:	215 °C (open cup)		[R 13]
Autoignition temperature:	390 °C		[R 13]
Vapor pressure:	1,32 mm Hg pri 200 °C; 9,75x10^{-6} mm Hg pri 25 °C		[HSDB]
Henry constant:	1,1x10^{-5} atm x m^3 /mol; log H (Pa.m^3.mol^{-3}) = -2,8		
Density:	0,9861 at 20 °C		[HSDB]
Water solubility:	less then 0,01% at 25 °C		[HSDB]
	0,340 mg/l at 25 °C		[HSDB]
Solubility in org. solvents:	miscible with mineral oil and hexane		
Log Kow:	7,60 [EPIWinv.2,0]	**BCF:**	640 [IUCL104]
Ready biodegradability:	No		
Inherent biodegradability:	Yes		
Soil Adsorptive Coefficient	Koc = 165400; logKoc = 5,219 [EPIWin v.2.0]		
Half-life of deg.	7 days (model. river), 60 days (model. lake)		
Photolysis			
Hydrolysis	half-live: at pH 8 = 195 days; at pH 7 = 5 years		

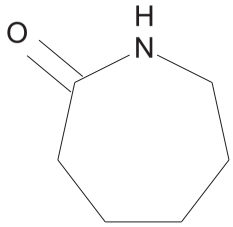
5. Ecotoxicology 5.1 Microorganisms

Taxonomic group	Sp.	Effect	Parameter	Effective conc.	Units	Test duration	Lit.
Bacteria	*Pseudomonas putida*		EC10	>1400	mg/l	6 h	[IUC141]
	Fauschlamm		EC0	100	mg/l	30 d	[IUC142]

5.2 Water organisms 5.2.1 Short-term studies

Taxon. group	Sp.	Effect	Parameter	Effective conc.	Units	Test duration	Lit.
Fish	*Gasterosteus aculeatus*	NOEC LC0 LC50 EC50	> = 0,3 > = 0,3 > 0,3 > 0,3	mg/l mg/l mg/l mg/l		96 h 96 h 96 h 96 h	[IUC126]
	Jordanella floridae	NOEC LC50	> = 0,32 > 0,32	mg/l mg/l		96 h 96 h	[IUC126]
	Leuciscus idus	LC0 LC50	22 61	mg/l mg/l		48 h 48 h	[IUC124]
	Leuciscus idus	LC0 LC50	11 533	mg/l mg/l		48 h 48 h	[IUC124]
Crustations	*Daphnia magna*	LC50	> 0,32	mg/l		48 h	[IUC86]
	Daphnia magna	LC50 LC50	11 > 64	mg/l mg/l		48 h 24 h	[IUC128]
	Daphnia magna	LC50	9,4	mg/l		48 h	[IUC129]
	Daphniapulex	LC50	> 0,4	mg/l		96 h	[IUC131]
Algae	*Selenastrum capric.*	EC50	> 0,1	mg/l		96 h	[IUC132]
	Gymnodinium breve	LC50	100	g/l		96 h	[IUC139]
	Gymnodinium breve	EC50 LC50	31 100	g/l g/l		96 h 96 h	[IUC139]

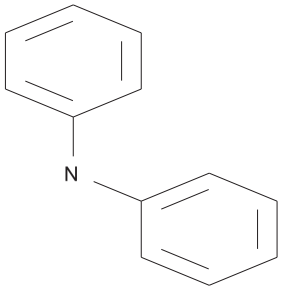
Ecotoxicological properties
Caprolactame



2H-Azepin-2-one, hexahydro-

Substance	caprolactame
CAS No.	105-60-2
EC No.	203-313-2
Formula	$C_6H_{11}ON$
Molecular weight [g/mol]	113.16
Relative density [g/cm^2]	1.014
Melting point [°C]	69 –71
Boiling point [°C]	270
Water solubility [mg/l]	820000 2000
Vapore pressure [mm Hg]	0.001
Henryho constant [atm×m3/mol]	evaporation not significant
log K_{ow}	- 0.19
Hydrolysis, $t_{1/2}$ [days]	n.a.
Photolysis, $t_{1/2}$ [days]	n.a.
Ready biodegradability [%]	82 (MITI I test) 95 – 100 (14 days)
Bioaccumulation, BCF	< 1
Toxicity, microorganisms [mg/l]	EC10 = 1740 *(Pseudomonas)* EC50 = 4200 *(Pseudomonas)*
Toxicity, algae [mg/l]	EC50 = 130 *(Scenedesmus subspicatus)*
Toxicity, crustations [mg/l]	EC50 > 500 *(Daphnia magna)*
Toxicity, fish [mg/l]	LC50 = 930 *(Lepomis macrochirus)* Toxicity = 5000 – 10000 NOEC = 1000
Soil Adsorptive Coefficient	Koc = 57,35; logKoc = 1,759

Ecotoxicological properties
Diphenylamine



Benzenamine, N-phenyl-

Substance		Diphenylamine
CAS No.		122-39-4
EC No.		204-539-4
Formula		$C_{12}H_{11}N$
Molecular weight	[g/mol]	169.22
Relative density	[g/cm^2]	
Melting point	[°C]	53 –54
Boiling point	[°C]	302
Water solubility	[mg/l]	200 - 300 40
Vapore pressure	[mm Hg]	1.61×10^{-4} (20°C) 0.11
Henryho constant	[atm×m3/mol]	0.90×10^{-6}
log K_{ow}		3.5 3.62
Hydrolysis, $t_{1/2}$	[days]	
Photolysis, $t_{1/2}$ [days]		0.08 – 1.4 (reaction product: karbazol)
Ready biodegradability	[%]	0 (MITI I)
Bioaccumulation, BCF		51 – 253 *(Cyprinus carpio)* 30 *(Pimephales promelas)* 70
Toxicity, microorganisms	[mg/l]	Inhibition > 10 (saprophytic microflora) NOEC = 100 *(Nitrosomonas sp.)* NOEC = 1000 *(Pseudomonas fluorescens)*
Toxicity, algae	[mg/l]	EC50 = 0.048 *(Scenedesmus)*
Toxicity, crustations	[mg/l]	EC50 = 2.3 *(Daphnia magna)* EC0(21 days) = 0.16 *(Daphnia magna)* EC70(21 days) = 0.5 *(Daphnia magna)*
Toxicity, fish	[mg/l]	LC50 = 1 – 100 LC50(48 h) = 5.1 *(Oryzias lapites)*
Toxicity, earthworms	[mg/kg]	LC50(14 days) = 269 NOEC(14 days) = 178
Soil Adsorptive Coefficient		Koc = 1887; logKoc = 3,276