Enviroment and Climate Regional Accession Network ECRAN

IED/Chemicals Working Group (Activity 2.8)

4th Interim Period
01 April 2015 – 30 September 2015

Coordinator ECRAN KE 2

Ike van der Putte

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IED/Chemicals Working Group Approach in the Work Plan development 2013 - 2016

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. The REACH and CLP regulations, interlinked amongst other with the Industrial Emissions Directive (IED), are covering major chapters of chemicals legislation and industrial pollution control.

Under the work plan, the following specific tasks will be implemented:
2.8.1 Organisation of the Annual meetings of the national coordinators of this WG
2.8.2 Capacity Building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED with:

- A Training Needs Analysis
- Organisation of regional training programmes (proposed number of four 3-day programmes)

Task 2.8.1: Organisation of annual Working Group meetings

In providing 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 (IED) as these are covering major chapters in chemicals legislation and industrial pollution control *(important for selection of WG members and training participants)*

No.	Date	Key outputs
1	30 January 2014- Skopje	Annual Meeting of NCs with work plan and presentations
2	10 February 2015- Vienna	Annual Meeting of NCs with annual report and presentations
3	4 February 2016	Annual Meeting of NCs TBC

Task 2.8.2 Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED

In REACH, various stakeholders will have their specific roles, responsibilities and competences (manufacturers/ importers, **national agencies/authorities**, downstream users).
The so called **"exposure scenarios"** in the REACH system are the Conditions of use for specific chemicals. REACH is complemented by the new Regulation for Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation, January 2009).

REACH and CLP are regulations and therefore directly applicable. As they enter into force, they will automatically form part of Member States' national laws.

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

Over five million classification and labelling notifications for more than 100 000 substances.
In Europe over 60 000 chemical substances on the market
(50% >1t per manufacturer/importer per year)

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The IED is the successor of the IPPC Directive and in essence, it is about minimising pollution from various industrial sources throughout the European Union.
Operators of industrial installations operating activities covered by Annex I of the IED are required to obtain an integrated permit from the authorities in the EU countries

About 50.000 installations were covered by the IPPC Directive and the IED will cover some new activities which could mean the number of installations rising slightly.

PROGAS, Montenegro

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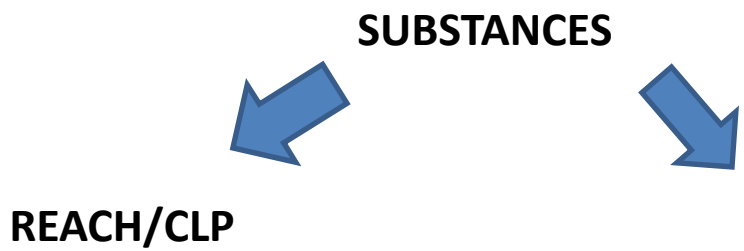

Attention needed for substances of very high concern **(SVHCs)** (draft IMPEL report REACH/IED)

An important synergy between REACH and the Industrial Emissions Directive is that information on the substance under the registration and authorisation procedures may be used to support the development of **BAT reference documents (Note permits!)**

The risk assessment of substances under REACH that are manufactured or placed on the market in quantities of 10 tonnes or more per year comprises the complete life-cycle of the substance and therefore includes the **use and manufacture** of these substances in industrial installations covered by this Directive and options to avoid and control emissions

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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	February 2014	Training Methodology, Training Programme and Training Materials
3	Training Workshop 13 -15 May, 2014	Training (1). General introduction chemicals and procedures REACH/CLP, IED (1), Montenegro with site visit (PROGAS). Training report and evaluation
4	Training Workshop 2-4 December, 2014	Training (2). Procedures REACH/CLP/IED. Albania with site visit at be Bankers Petroleum, a Canadian-based oil and gas exploration and production company. Training report and evaluation
5	Training Workshop 1-3 September 2015	Training(3). Technical aspects REACH /CLP, IED. Skopje FYR of Macedonia with site visit to MAKPETROL, biodiesel pilot factory. Training report and evaluation.
6	Training workshop 8-10 December 2015	Training (4). REACH/CLP downstream consequences, interlinkages with IED and other legislation; accession issues. To be organised in Istanbul, Turkey. Site visit to UNILEVER.

Activities	Achievements/challenges
Training workshops 1. General (Montenegro) 2. Procedures (Albania)	On schedule/ BiH did not participate in 1st training; Turkey did not participate in 2nd training. Diverging problems in countries in REACH/CLP implementation. Different levels of know-how. Clear need for transfer of know-how
3.Technical Aspects (FYR of Macedonia) 4. Down stream consequences and Accession issues (Turkey)	Scheduled for June 9-11, 2015 and implemented in 1- 3 September 2015 Scheduled in Istanbul 8 – 10 December, Turkey / participation of Croatia with their latest experience.

IMPACTS achieved through the outputs	
Outputs	Impacts
Regional Training workshops and site visits In cooperation with IMPEL and ECHA experts and experts from EU member states	- Harmonized approaches using ECHA and IMPEL tools/guides/analyses - Increased level of know how on REACH/CLP also including interlinks with IED in theory and practice (ref. site visits and exercises) and on the roles and responsibilities of authorities and other stakeholders - Exchange of experience between beneficiary countries and EU member states including the various approaches and preparatory actions for accession, (e.g. national chemicals inventory and cooperation between authorities). - Monitoring the state of play in the ECRAN countries (see reports) - Active input/participation of WG coordinators in e.g. organization of site visits and positive evaluations of the courses by participants (see reports)
Follow-up actions at a national scale	-Request and approval via ECRAN for TAIEX assistance on REACH/CLP issues (Albania)

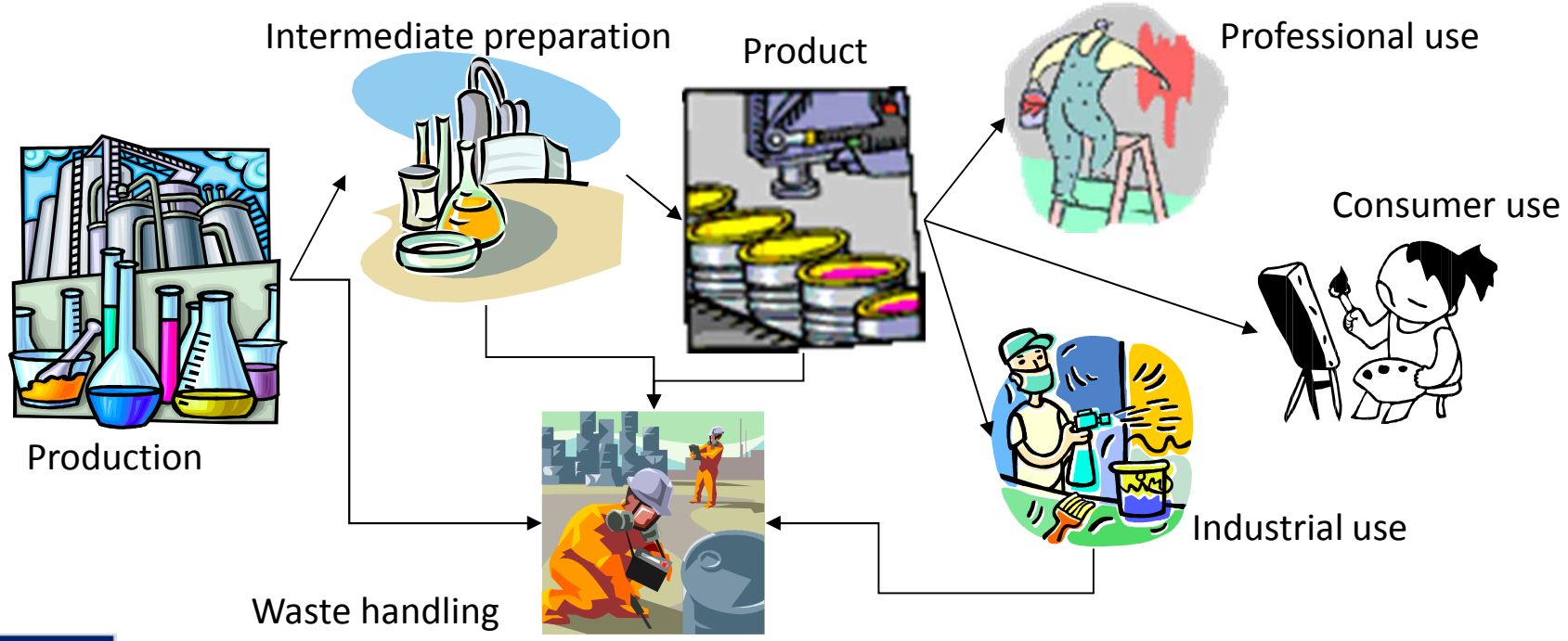
The TAIEX expert mission provided assistance to the Albanian Ministry of Environment on the compliance checking of the following draft legislation prepared:

a. Framework law on chemicals legislation
b. Classification, packaging and labelling of substances and chemical mixtures (CLP);
c. Import and export of hazardous substances;
d. Approval of substances and chemicals, manufacture, placing on the market and use of which is restricted or prohibited (Annex XVII of REACH);
e. List of hazardous substances which by their nature pose a serious risk to life, human health and the environment (Annex XIV of REACH).

The mission clarified what and how to transpose (i.e. only those obligations which are necessary before accession) and assisted in preparing four by laws on integrated chemicals management. Notification to the WTO was made and the law was sent to the parliament. Entry of the law is expected to take place in 3 years (for substances) and in 4 years for mixtures

A helpdesk will be established at the Ministry of Environment.

Thank you



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Introduction to REACH & CLP

Outline:

REACH & CLP in brief

Arnold van der Wielen

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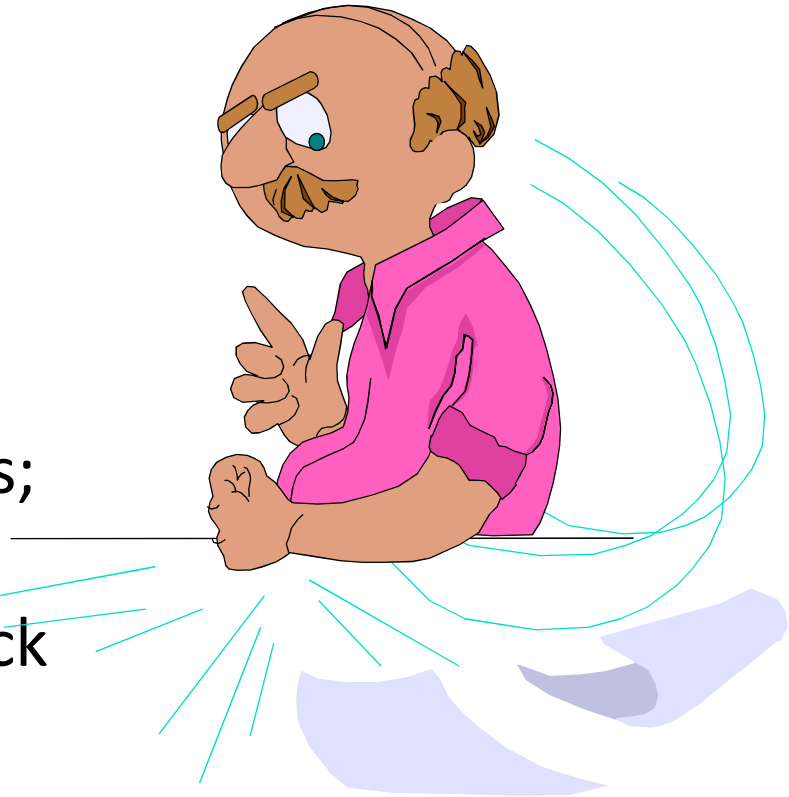
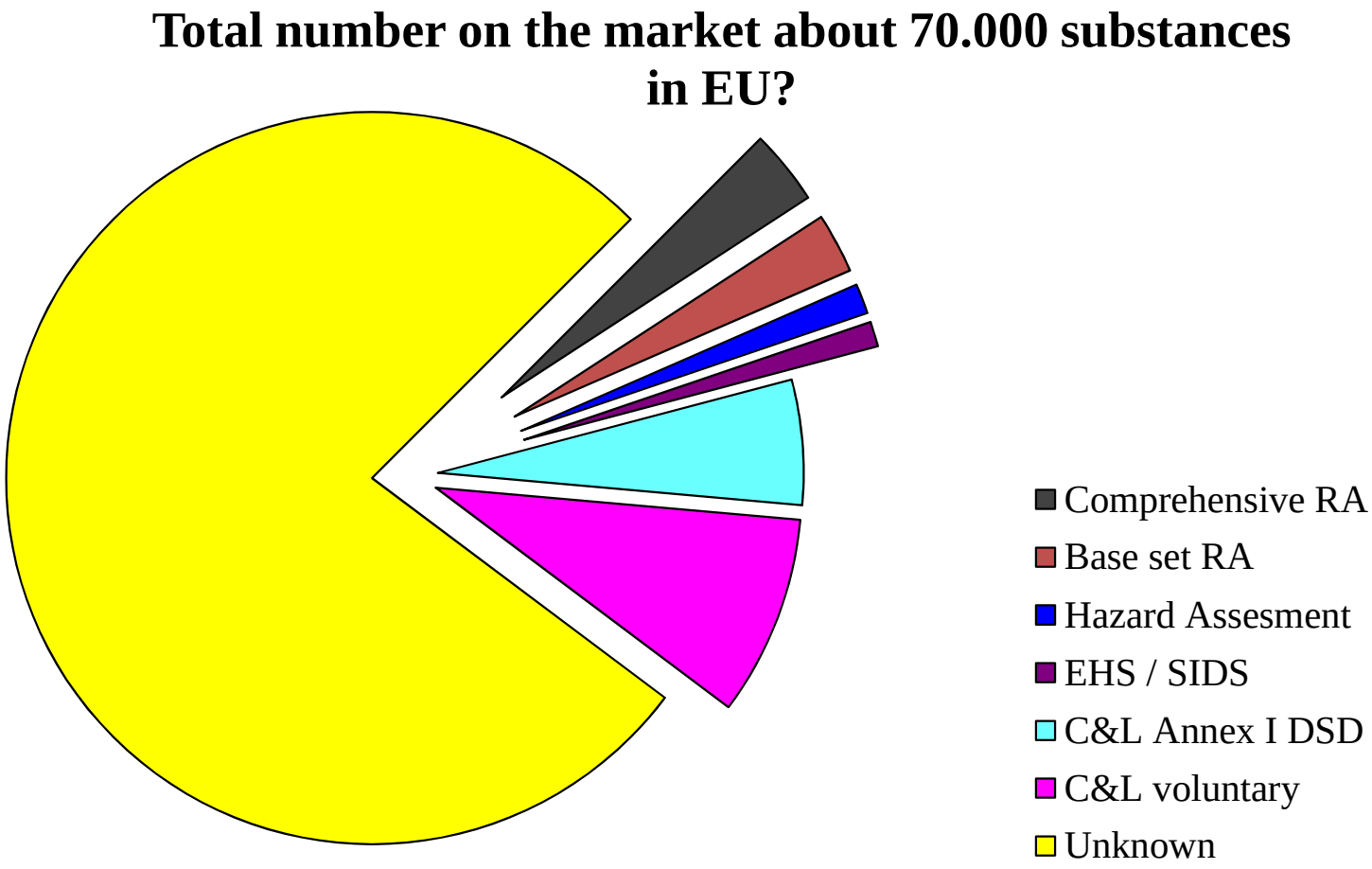
Why? The nature of the problem

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



Why? The size of the problem



Basic principles of REACH

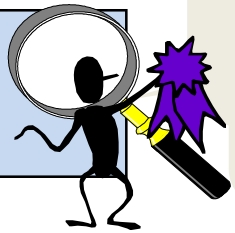
- **Sustainable development**
  - **Industry** is responsible for safe use of substances
  - **Authority** controls compliance of industry
  - **NGO's** must accept marketing of sustainable substances; no phasing-out across the board

- **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

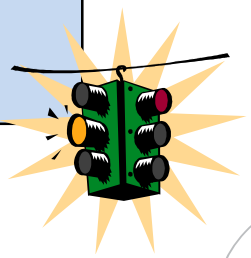
Evaluation by competent authorities



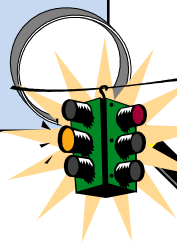
Scope:
- **evaluation required > 100 t/yr**
- **selective evaluation < 100 t/yr**
- **decisions for additional information**
- **proposal for authorisation**
- **Proposal for restriction measures**

Scop
- **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

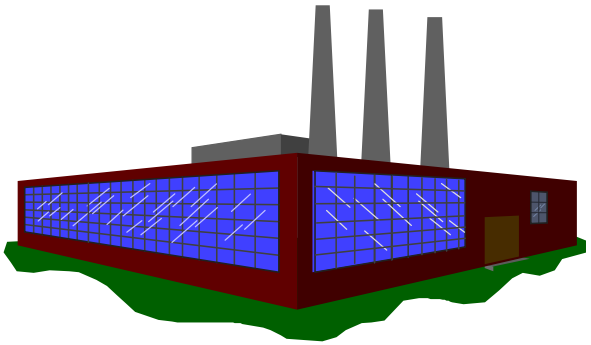
Evaluation of hazardous properties

Evaluation of exposure / emission

Risk assessment

Risk reduction measures

Belongs to responsibility of industry



Chemical industry

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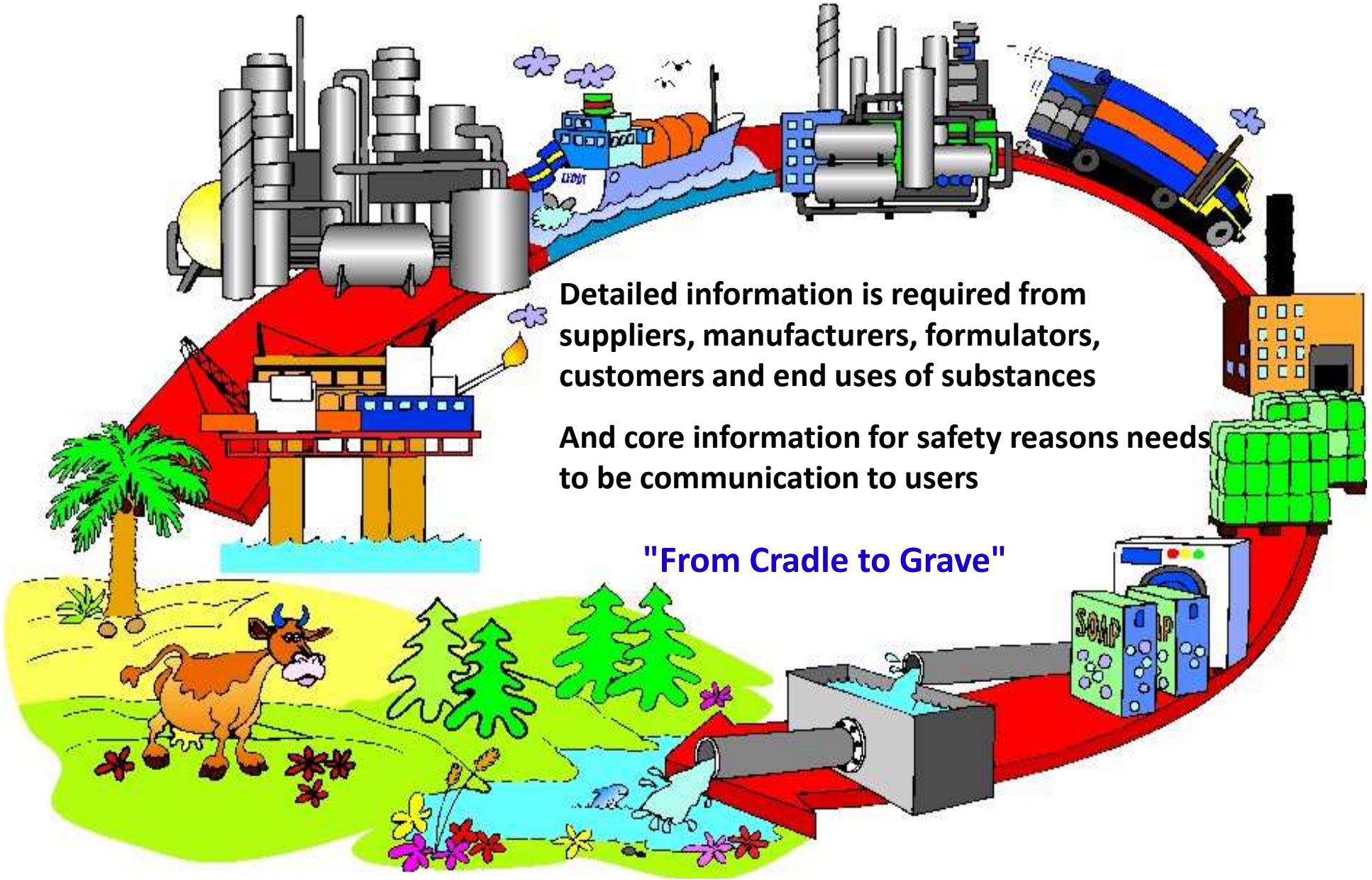
Communication up- and down supply chain



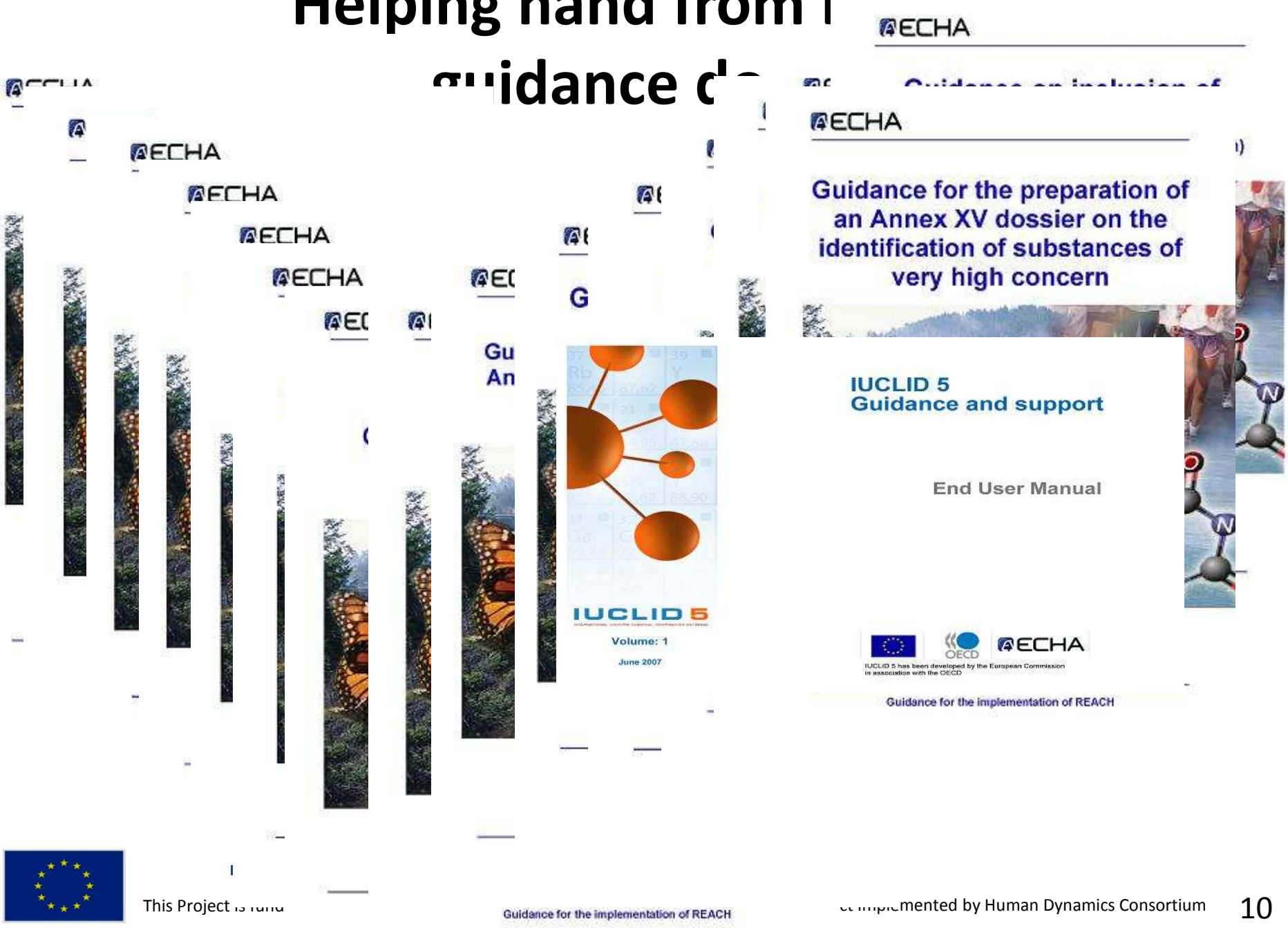
Legal structure of REACH

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

plus 17 annexes on technical details:

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

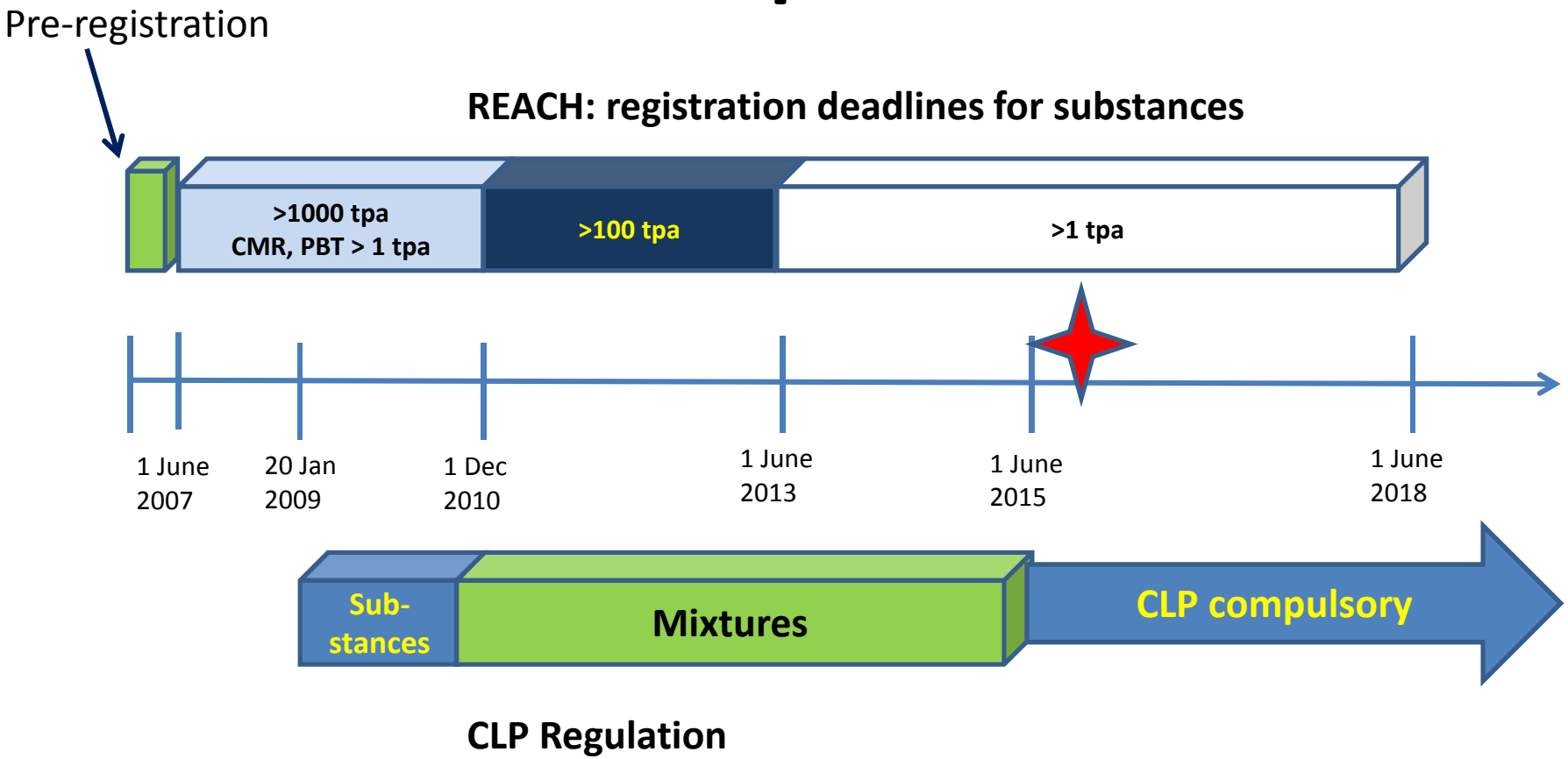
Helping hand from ECHA guidance d



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

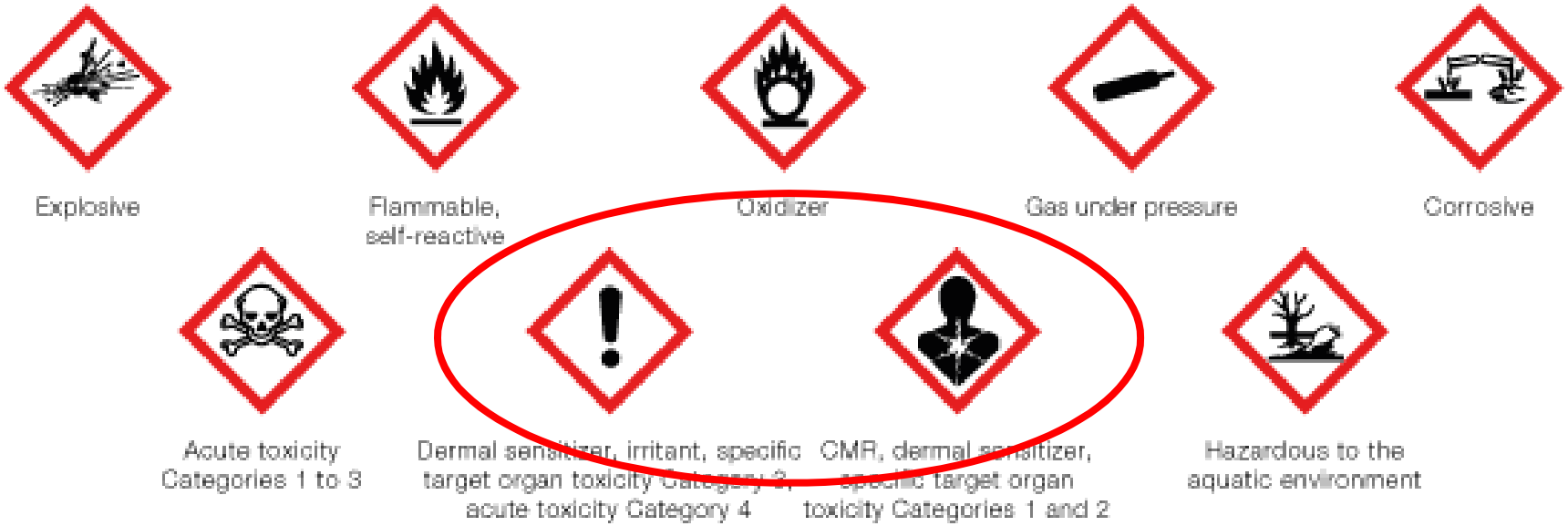
Critical CLP & REACH timelines within the European Union



GHS/CLP pictograms

Old hazardous substance symbols valid until 2015

New hazardous substance symbols valid since 2010



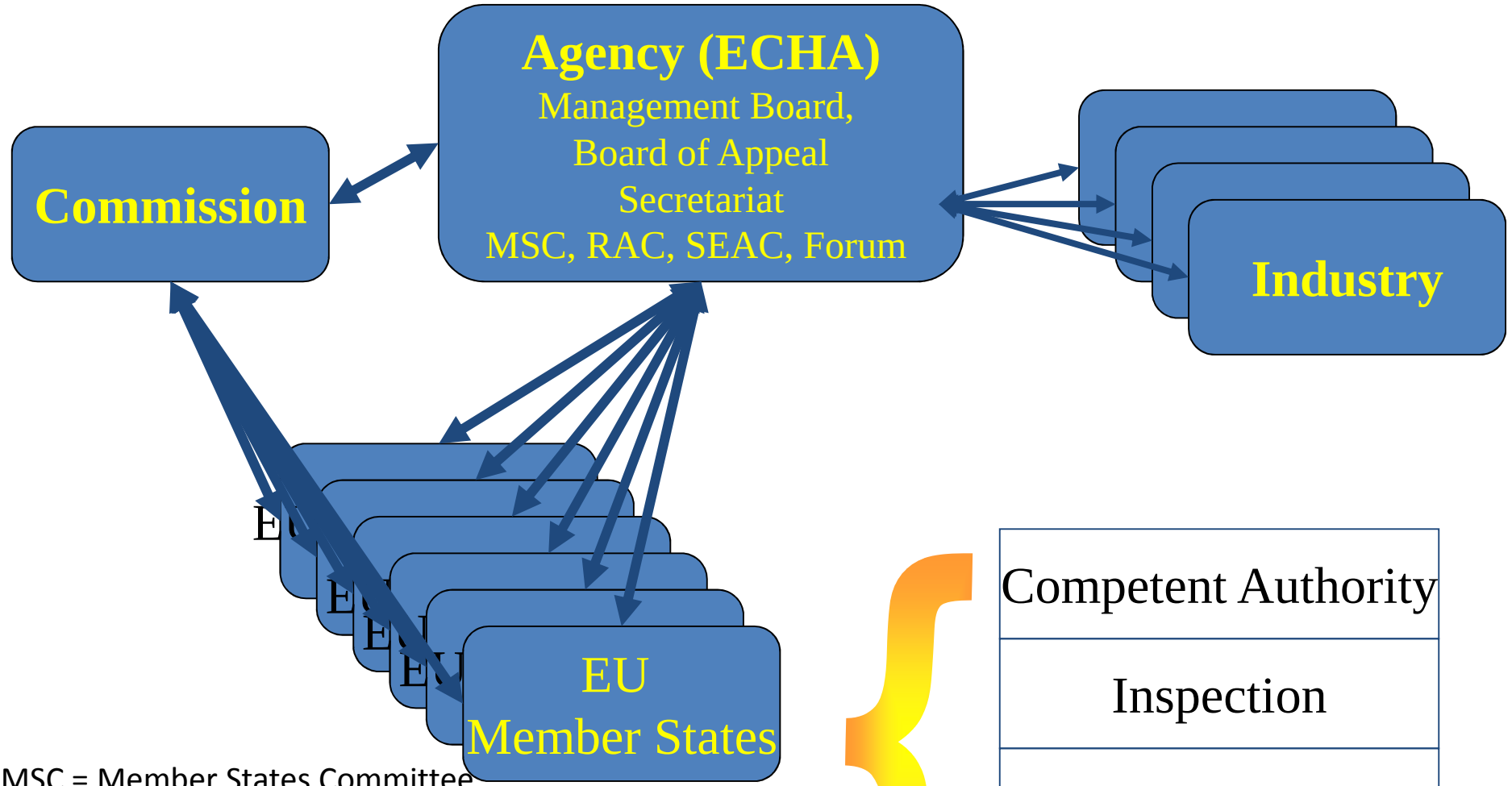
Legal structure of CLP

- **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

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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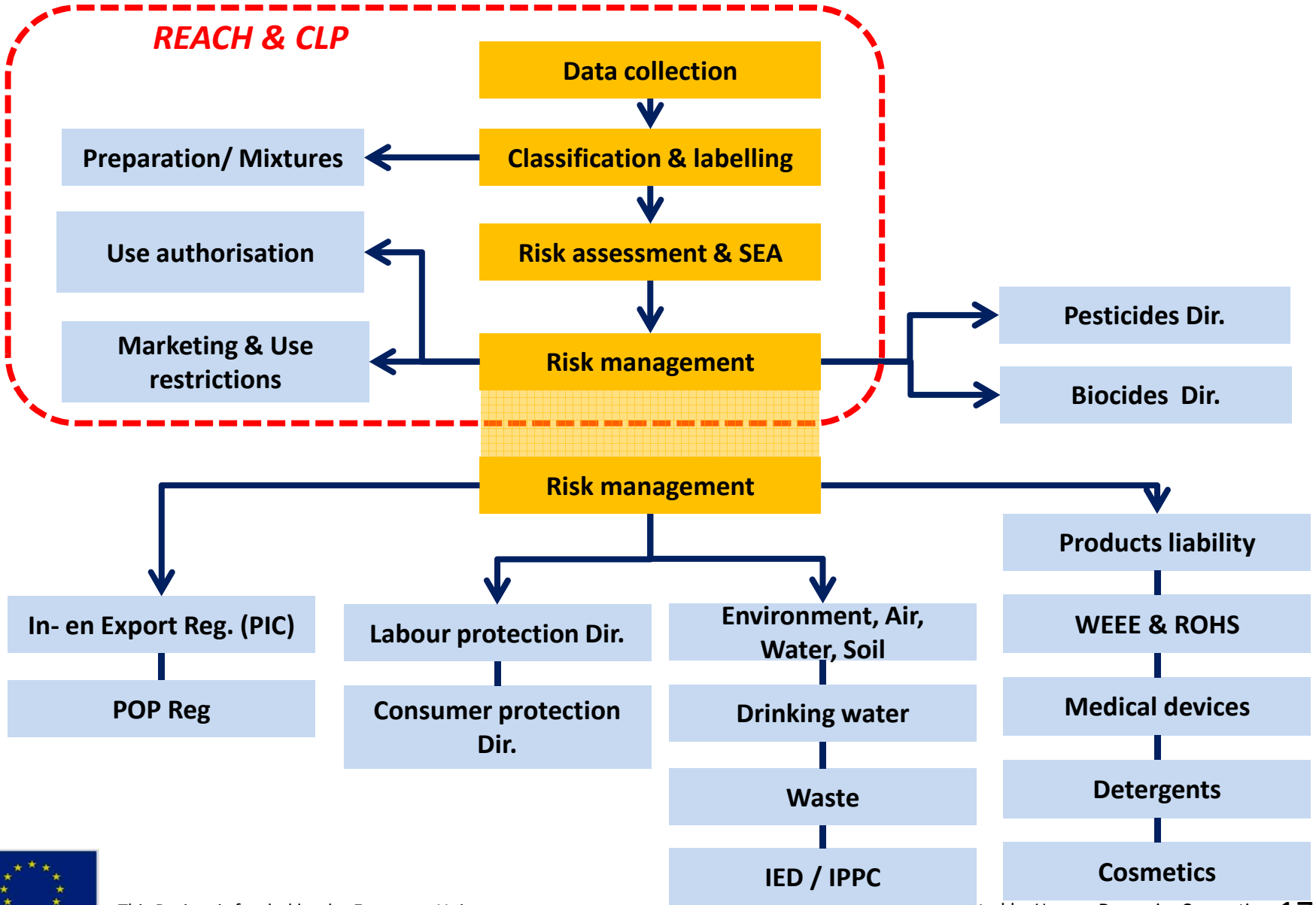
ECHA building, Helsinki

EU chemicals management with REACH/CLP



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Conclusion on Risk management system

- **Risk assessment = integrated tool**
  - Harmonised methodology
  - Resulting in risk characterisation
  - Allows justified risk control measures
- **Used by**
  - Industry: in Chemical Safety Assessment → **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

Dynamic to the future….

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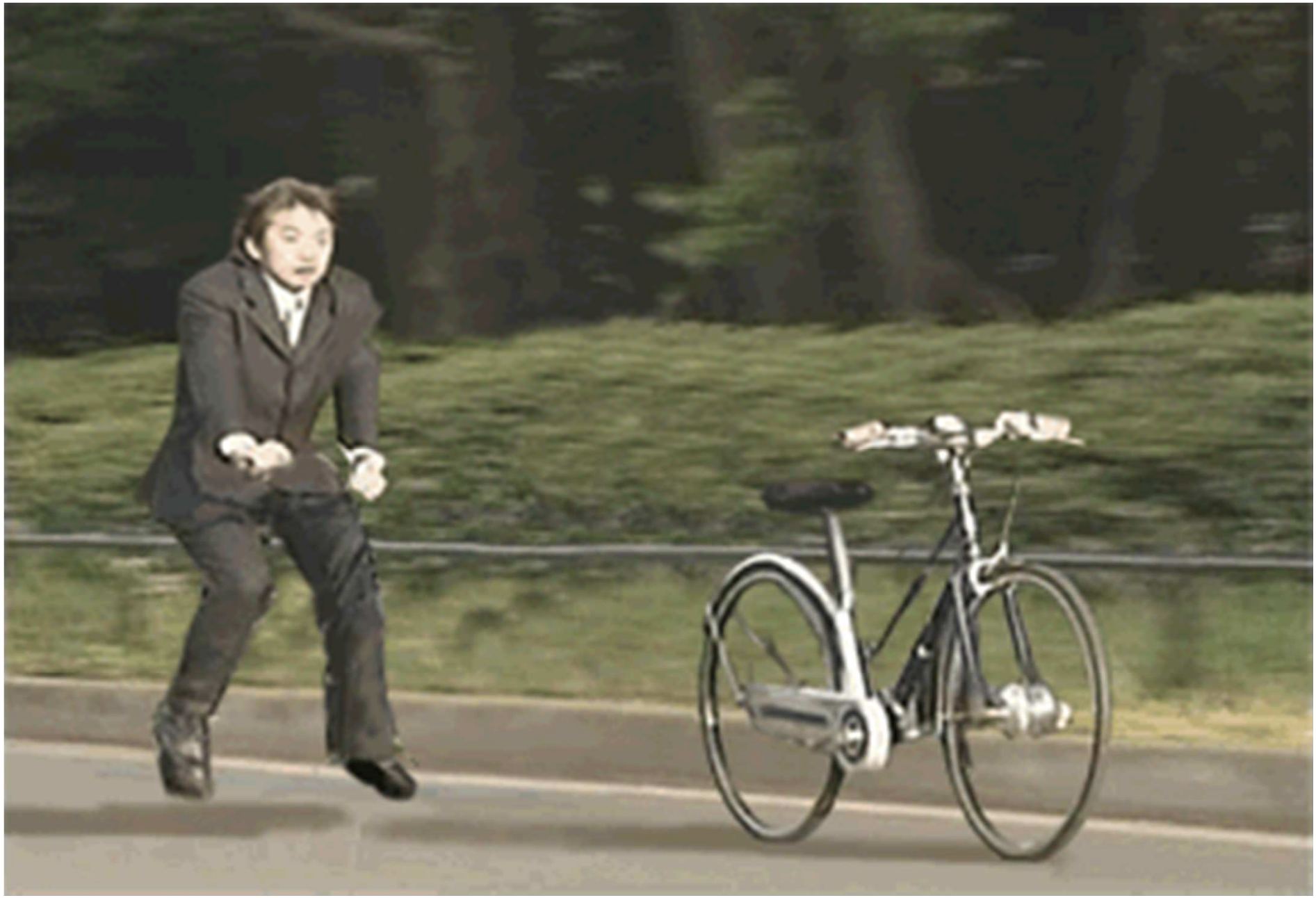

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REACH Specifics
Roles & Responsibility

Outline:

A: Short refreshment on REACH

B: Roles in REACH

C: Responsibility at each role

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Roles of a company

REACH requirements related to activity

- **Manufacturer** of a substance
- **Importer** of a substance on its own, as component in a preparation, or in an article
- **User (Downstream User e.g. Formulator)** of a substance or preparation (professional)
- **Distributor**, distributive trades
- **Producer** of an article

Attention: a company may perform several roles

Registration obligation in REACH

- **Distinction in phase-in and non phase-in substances**
  - Phase-in ≅ existing substances
  - Non phase-in ≅ new substances

  (Dependent on implementation strategy in Accession States)

- **All non phase-in substances to submit registration before manufacturing, importing or placing on the market**

- **For phase-in substances transitional arrangements depending on yearly quantity and hazardous properties**

Defined in more detail – 1/3?

- **Manufacturer:**
  - Legal entity established within the EU (EEA) producing or extracting substances in the natural state;

    Production = chemical reaction process Extraction = isolation
- **Importer:**
  - Legal entity established within the EU (EEA) importing a substance on its own or as component in a mixture (= physical introduction into the customs territory of the Community/your country);
- **Placing on the market:**
  - supplying or making available, whether in return for payment or free of charge, to a third party within the EU (EEA). Import is placing on the market

NOTE: Distinction between manufacturing as such and manufacturing plus placing on the market

Defined in more detail – 2/3?

- **Downstream User:**
  - Legal entity within the EU (EEA) using a substance, either on its own or in a mixture, in the course of his industrial or professional activities
  - use = any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation

- **Producer of an article:**
  - Legal entity within the EU (EEA) making or assembling an article
  - Article = object composed of one or more substances or mixtures given a specific shape, surface or design.

    (Recent Court decision: Complex article is composed of individual articles)

Defined in more detail – 3/3

- **Distributor:**
  - Legal entity within the EU (EEA), including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties

- **Only representative (OR):**
  - Legal entity within the EU (EEA) appointed by a manufacturer, formulator or producer of an article established outside the EEA to fulfil the obligations of importers within the EEA
  - An OR might be an importer within the EU (EEA) or an independent company with sufficient background in the practical handling of substances and the information related to them to be able to fulfil the obligations of importers

Importer according to EU-REACH

"Import" means from outside EU/EEA

Within EU/EEA is "internal market"

EEA (European Economical Area) =

EU member states plus Norway, Iceland, Liechtenstein (NOT Switserland)

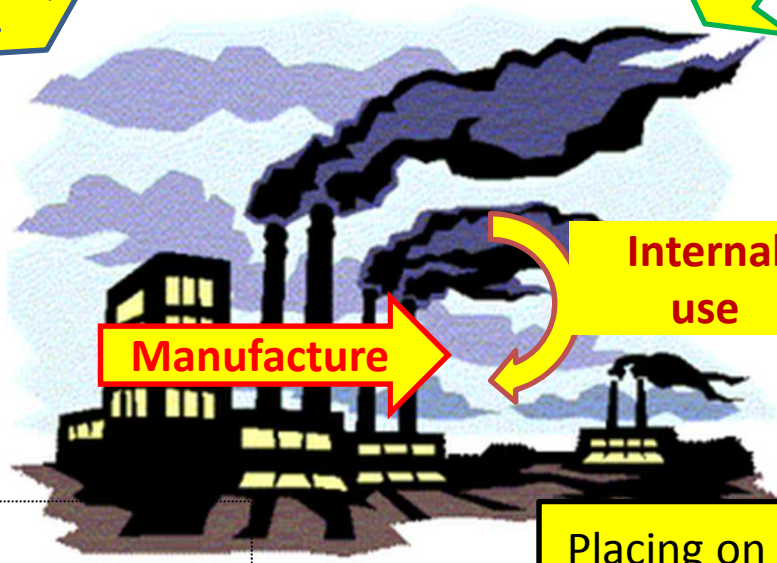
Reminder: Companies always have several roles

Non-EU market/
Non-national

Starting material
Maintenance material

Starting material
Maintenance material

EU/national market



Internal use

Manufacture

Placing on the market

EU/national market and/or export

Manufacture
Internal use (Intermediate)
Placing on the market
Importer
Downstream use (e.g. formulator)

Tasks in detail for M / I / OR (registrants)

Responsibility of a manufacturer / importer / only representative is to register a substance within the legal deadlines according to volume and hazardous properties

- Data required (dependent from quantity range)
  - physical-chemical data
  - (eco)toxicological data
  - emission / exposure data (also for use downstream)
- Chemical Safety Assessment
  - for use/production on site
  - for intended uses downstream

Chemical Safety Report

- Risk reduction measures on site being implemented
- Proposal for additional testing (if > trigger level)
- Proposal C&L

Classification & Labelling

- Safety Data Sheet (SDS)
  - Annexed for intended use(s) exposure scenario(s) and recommended risk reduction measures

Safety Data Sheet

- Communication with downstream users
  - Data on uses downstream from clients

Tasks in detail for DUs

Responsibility DUs (= downstream users)

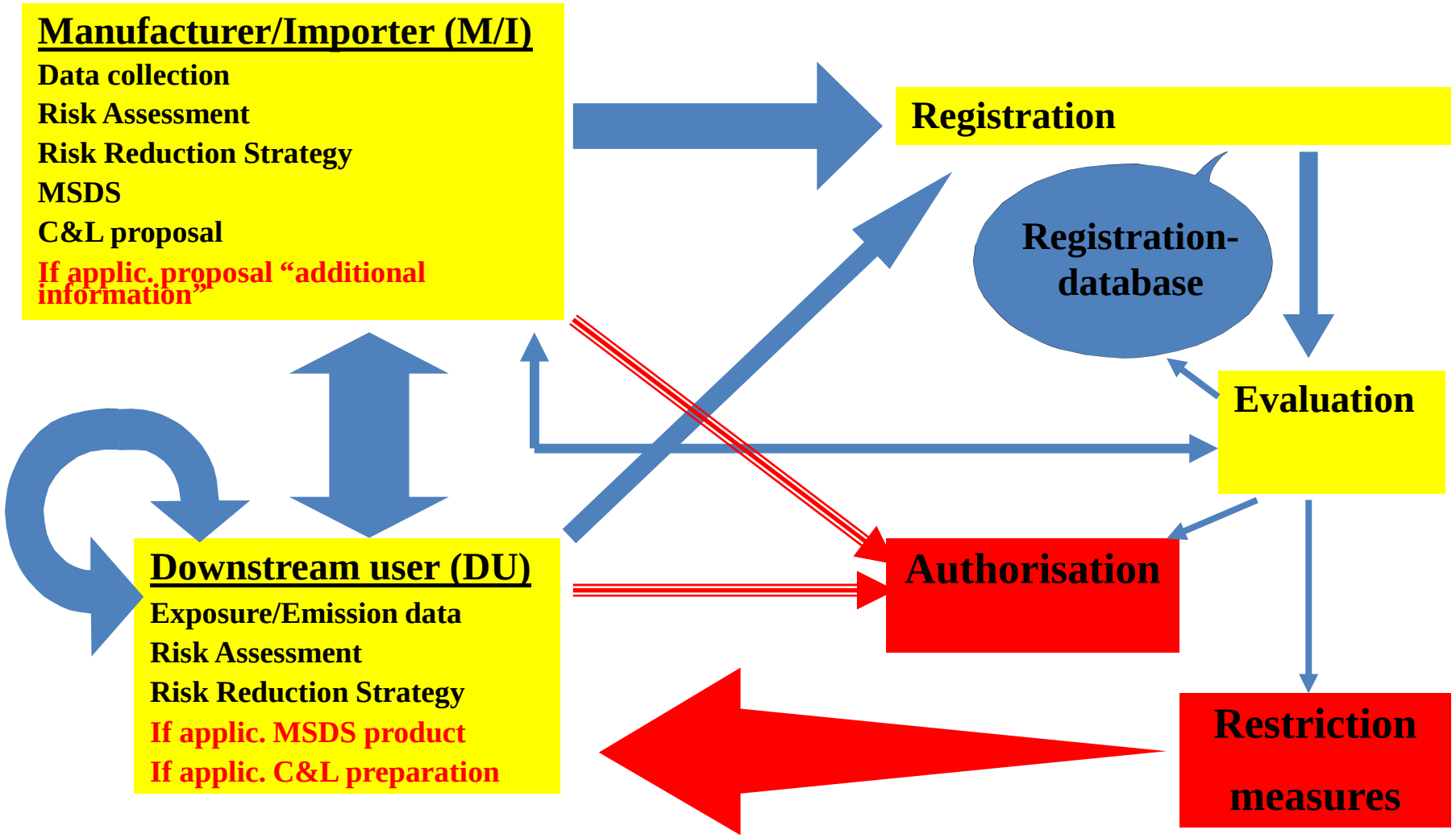
- **Chemical Safety Report needed ?**
  - Identified uses: actualising M/I CSA (exposure/emission)
  - Not-identified uses: completion of M/I CSA

Chemical Safety Report

- **Implementation Risk Reduction Measures on site based on recommended measures from supplier**
- **If applicable, C&L for preparation; SDS for preparation**
- **Communication with downstream users (SDS)**

Supplementary notification to the Agency in the case of non-identified use(s).

REACH system running in practise - simplified: responsibility to industry



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Manufacture

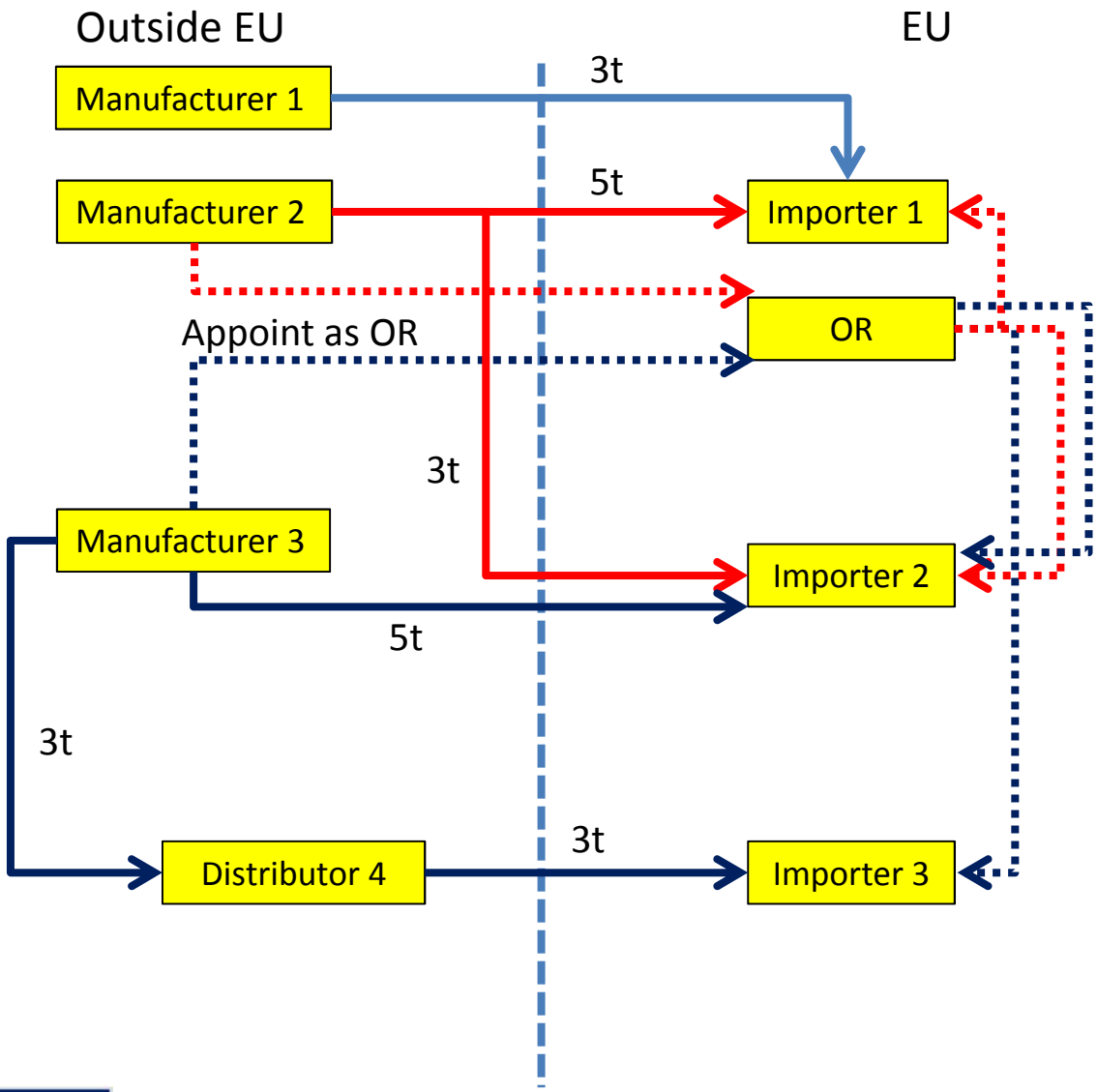
Manufacturing without placing on the market

- Manufacture for its own use:
  - Isolated intermediates in the case of batch-wise manufacturing with temporary storage between processes
- Manufacture for use by other “manufacturers”
  - Transported isolated intermediates

Requirements

- (Transported) isolated intermediates to be registered with limited set of data

Explaining roles



Roles and Registration obligations

M1, M2, M3 and D4 no REACH obligations

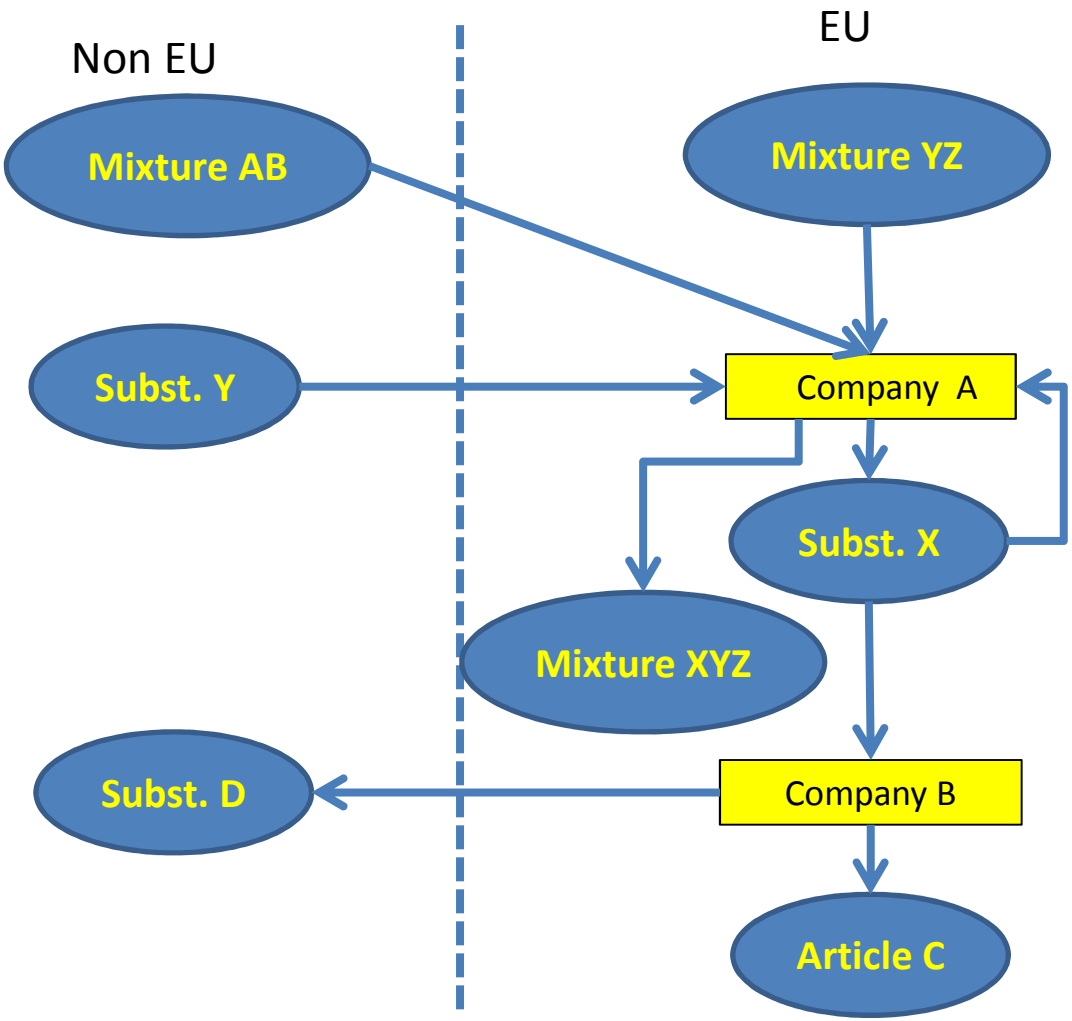
I1 registers 3t

OR for M2 /M3 registers 8t S1 and 8t S2

I2 no registration required = "DU"

I3 no registration required = "DU"

Company may have different roles



Roles

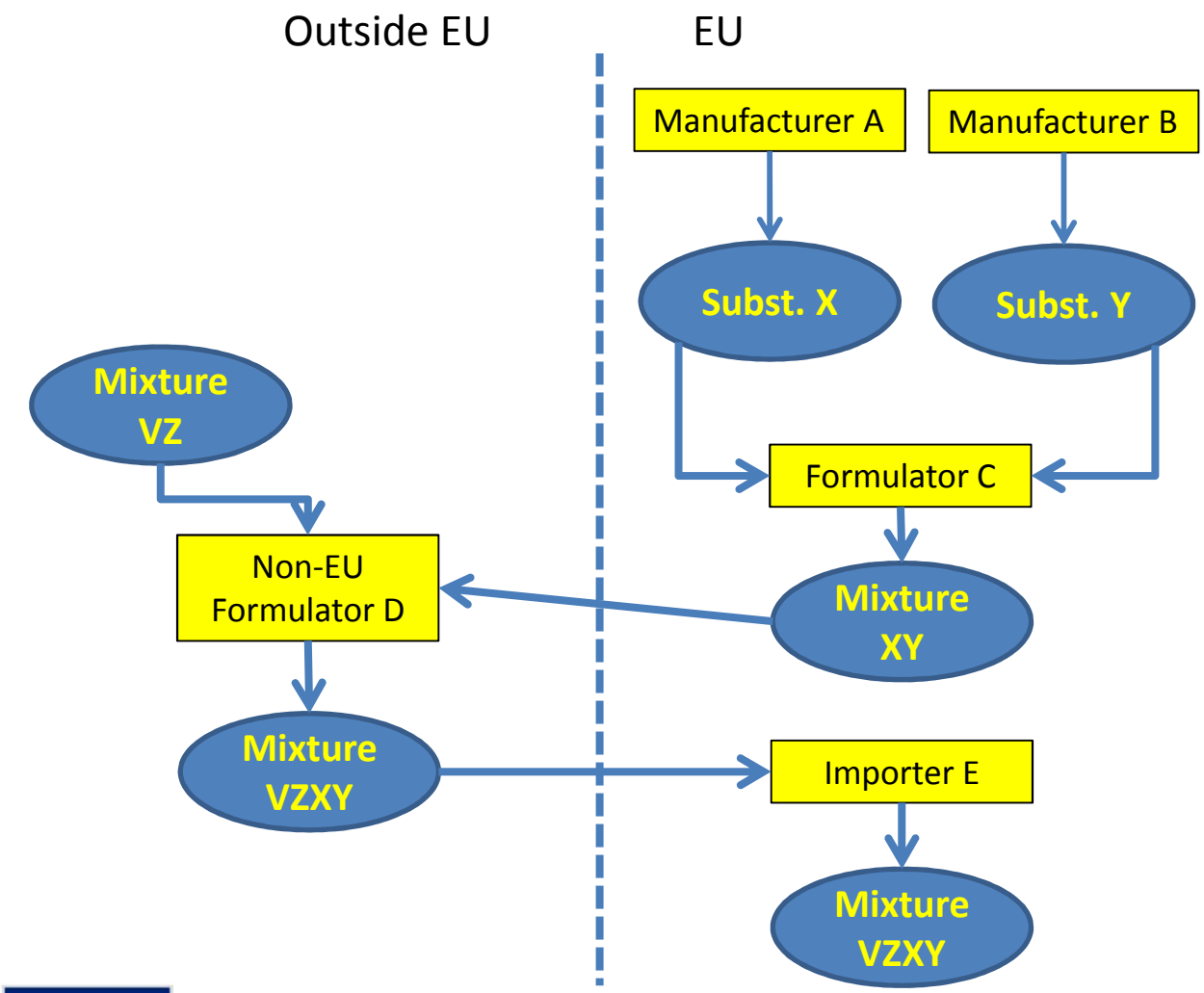
Company A:
+ Manufacturer of X partly isolated intermediate
+ Importer of A, B, and Y
+ DU (user) of mixture YZ
+ DU (formulator) of XYZ

Company B:
+ DU of X for further processing
+ Producer of article C
+ Manufacturer of D solely for export

Specific situation: re-import

- **Re-import of an exported substance**
  - Manufactured or imported substance, fully registered, exported as such or in a mixture and re-imported as component in another mixture within the same supply chain
  - does not need to be registered, if ….
    - registered before export
    - must be the same substance
    - must proceed from the same supply chain
    - re-importer must have the information from the exported substance

Example of re-import



Registration obligations

Manufacturer A register X
Manufacturer B register Y

X and Y are re-imported
Importer E registers only substances V and Z
Substances X and Y are within the same supply chain

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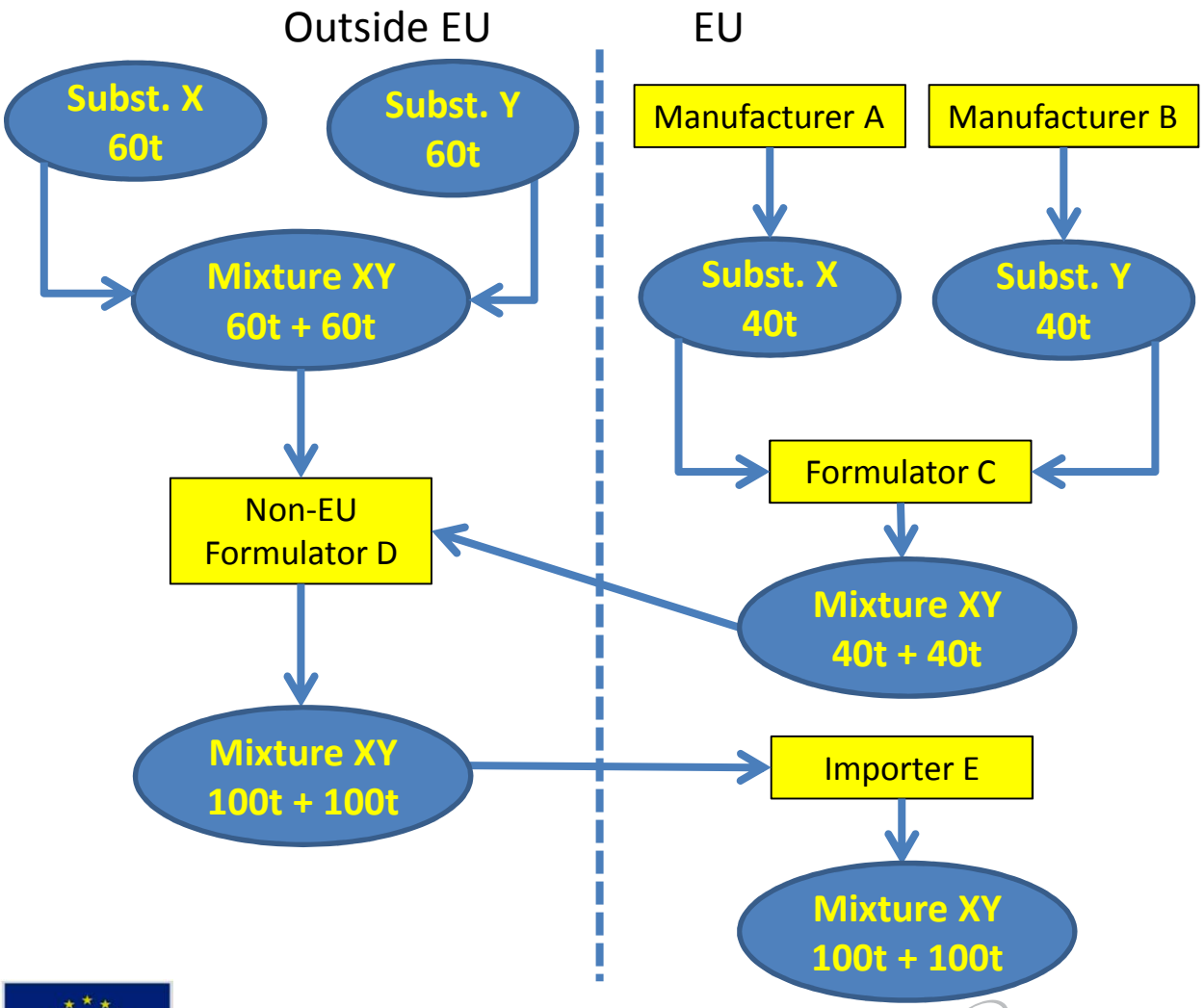
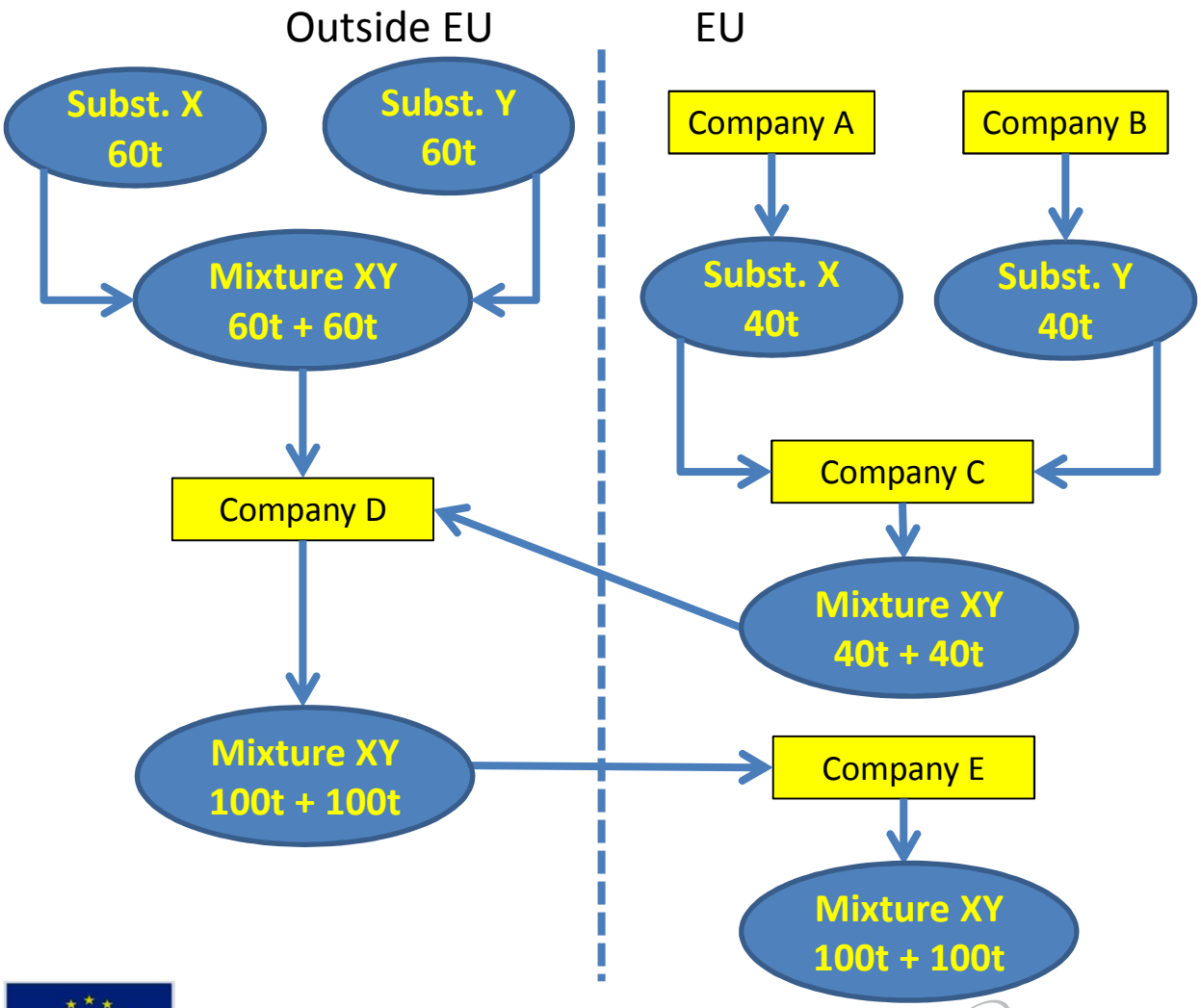
Exercise



What are the roles of companies (M/I/OR/DU)
A
B
C
D
E

What are the registration obligations of the companies incl. volumes
A
B
C
D
E

Exercise explained



Roles and registration obligations

A, B are manufacturers
C is formulator (DU)
D is non-EU formulator
E is importer

Manufacturer A registers 40t X
Manufacturer B registers 40t

Importer E imports 100t substance X and 100t substance Y, but registers only 60t X and 60t Y.
40t X and 40t Y are within the same supply chain

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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 Industrial Emission Directive – Technical aspects, downstream consequences and accession issues

ECRAN

Risk assessment

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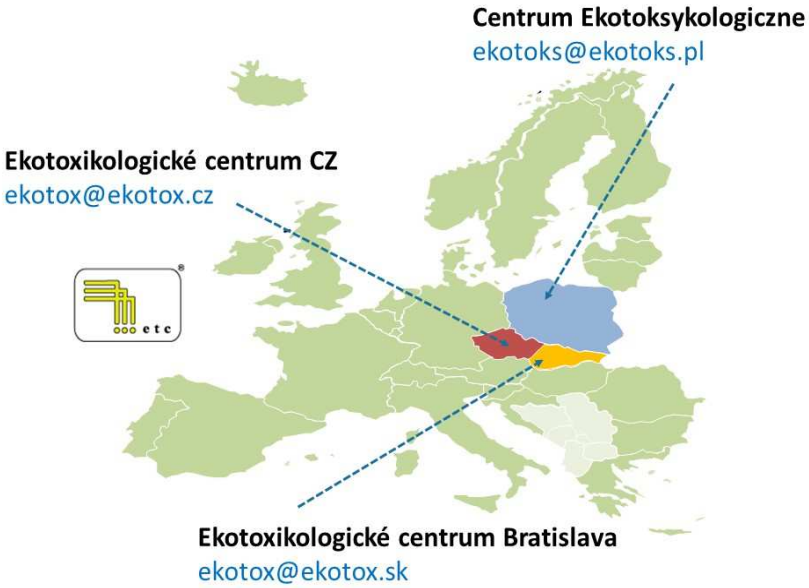

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RISK ASSESSMENT in legislation

- **Legislative background**
  - **Industrial Chemicals**
  - Pesticides
  - Biocides
  - Pharmaceuticals
  - Medicinal products
  - …contaminated areas (“specific risk assessment”)

- **Assessment of a Priority Chemicals – SVHC**
- **Hazard vs Risk**
- **RISK ASSESSMENT – RISK MANAGEMENT**

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Environmental Risk Assessment (ERA) of Genetically Engineered Plants

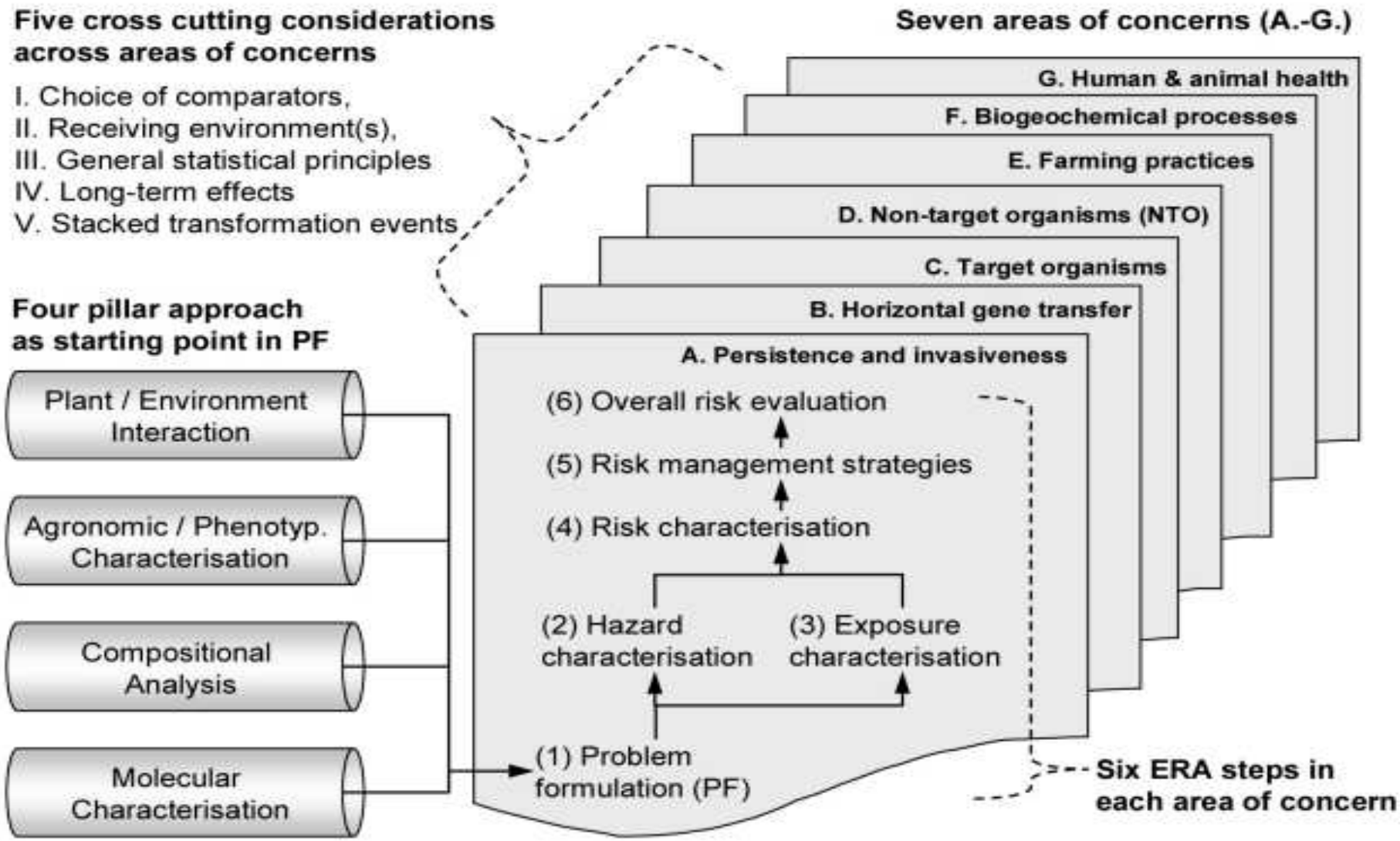

Figure: The structure of the EFSA GMO Panel guidance document for the ERA of GM plants.

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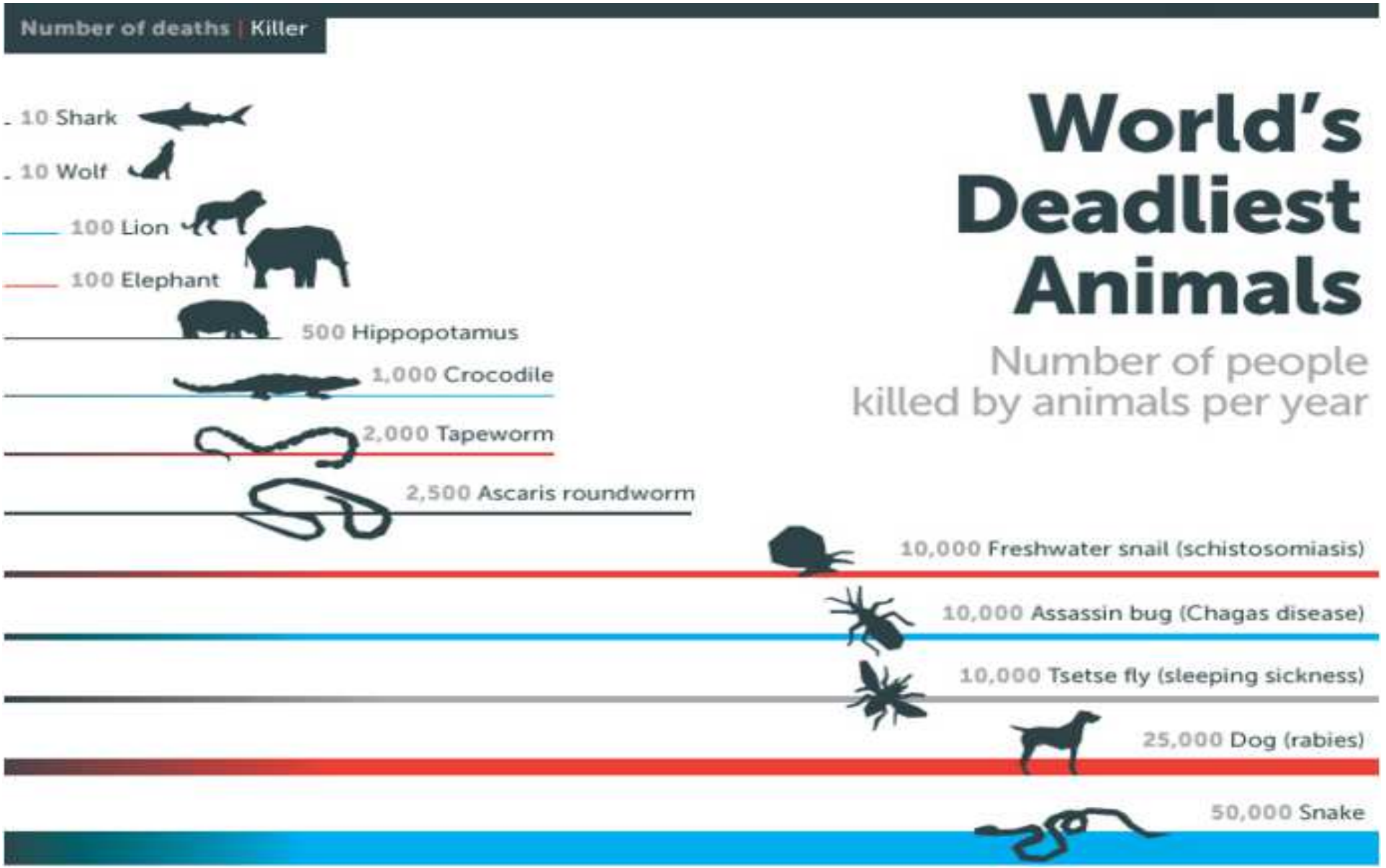

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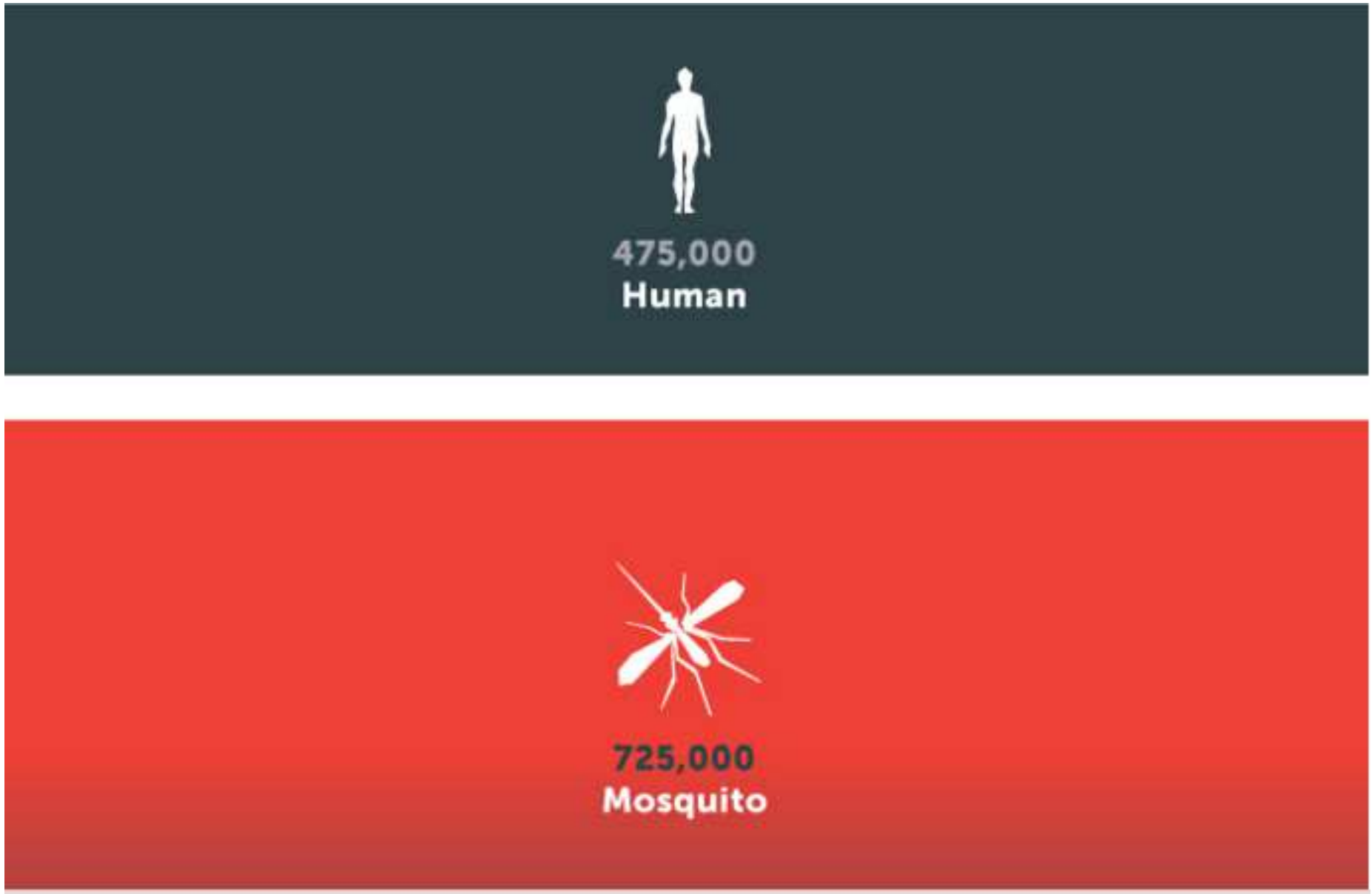

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US National Health Service (NHS) 2014

the numerous manufacturing industries provide jobs that expose workers to chemical carcinogens; some examples are:

- rubber manufacturers, furniture making industries, PVC manufacturers,
- metal industries that make use of cutting oils,
- manufacturers of chemically based as well as chemically treated products,
- and the list could go on if all industry sectors (not just that of manufacturing) are to be examined, like drug laboratories, mining, farming, fishing, building and all other industries that make use of chemical substances as they are all capable of creating a hazardous work environment.

Some of the most recently included are the micro-electronic industries and their wide use of solvents, acids, plasmas, gases and toxic metals.
They all require more than a hundred different types of chemicals that include the commonly known chemical carcinogens. Micro-electronic industries mostly employ women to process silicon chips in the industry's semi-conductor section. These are used in the production of advanced technological devices for home entertainment, office equipment and mostly communications, which include cell phones as well as computers.

Summary Table of Available Tools for Risk Assessment

Categories		Links to Available Materials	Explanation
Hazard Assessment	**Gathering existing information**	OECD Existing Chemicals database	OECD-wide agreed hazard assessments elaborated in the OECD Co-operative Chemicals Assessment Programme
		eChemPortal	Global Portal to Information on Chemical Substances
		Manual for the Assessment of Chemicals (Chapter 2)	A set of guidance documents for (initial) risk assessment developed for the OECD Co-operative Chemicals Assessment Programme. See chapter 2 for gathering data
	Evaluating existing information	Manual for the Assessment of Chemicals (Chapter 3)	See chapter 3.1 for determining the quality of existing data
	Generating new data	Test guidelines	Test methods for assessing (hazard) properties of chemicals
		The OECD (Q)SAR Project	Guidance and tools for filling data gaps by non-testing methods.
	Assessing the hazards	Manual for the Assessment of Chemicals (Chapter4) & (Chapter 5)	Chapter 4 provides guidance assessing the hazards of chemical substances to man and the environment Chapter 5 provides guidance on elaborating a hazard assessment report.
		Series on Testing and Assessment	Guidance documents and reports related to assessment of several inherent effects

This Project

What is risk assessment?

EPA uses risk assessment to characterize the nature and magnitude of health risks to humans (e.g., residents, workers, recreational visitors) and ecological receptors (e.g., birds, fish, wildlife) from chemical contaminants and other stressors, that may be present in the environment. Risk managers use this information to help them decide how to protect humans and the environment from stressors or contaminants. Note that "risk managers" can be:

- federal or state officials whose job it is to protect the environment,
- business leaders who work at companies that can impact the environment, or
- private citizens who are making decisions regarding risk.

At EPA, environmental risk assessments typically fall into one of two areas:

- Human Health
- Ecological

Risk assessment is, to the highest extent possible, a scientific process. In general terms, risk depends on the following factors:

- How much of a chemical is present in an environmental medium (e.g., soil, water, air),
- How much contact (exposure) a person or ecological receptor has with the contaminated environmental medium, and
- The inherent toxicity of the chemical.

Risk Assessment

European Union

GENERIC RISK ASSESSMENT

- **Human Health RA**
  - scenarios for workers and consumers
- **Environmental RA**
  - exposure through environ. compartments
  - ecosystems & human beings

USA

SITE SPECIFIC RISK ASSESS.

- **Human Health RA**
  - all exposure routes incl. environ. compartments
- **Ecological RA**
  - ecosystems, endangered species
  - all stressors

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Risk Assessment

- **Effect Assessment**

Data: toxicological and ecotoxicological data incl. environmental fate
ADI/TDI (UN); RfD (US EPA); DNEL (EU) / PNEC

- **Exposure Assessment**

Data: measured concentrations, monitoring, models

Exposure levels / PEC

- **Risk Characterisation**

Data: toxicity / ecotoxicity, emissions into environment and exposure based on standardised conditions

GOAL: control and management of chemicals

Generic Risk Assessment

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EU legislation - Risk Assessment

- **Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commision Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances**

European Commision, CR-48-96-001-EN-C

REACH Regulation – Guidance documents

http://echa.europa.eu/guidance-documents/guidance-on-reach

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* RA for Human Health
* Use of (Q)SARs / models
* RA Report Format
* Environmental Risk Assessment
* Use Categories
* Emmision Scenario Documents

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Guidance on
information requirements and
chemical safety assessment

Chapter R.10: Characterisation of dose [concentration]-response for environment

ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on information requirements and chemical safety assessment

Part E: Risk Characterisation

ECHA
http://echa.europa.eu

Guidance on
information requirements and
chemical safety assessment

Chapter R.16: Environmental Exposure Estimation

Guidance on
information requirements and
chemical safety assessment

Part B: Hazard assessment

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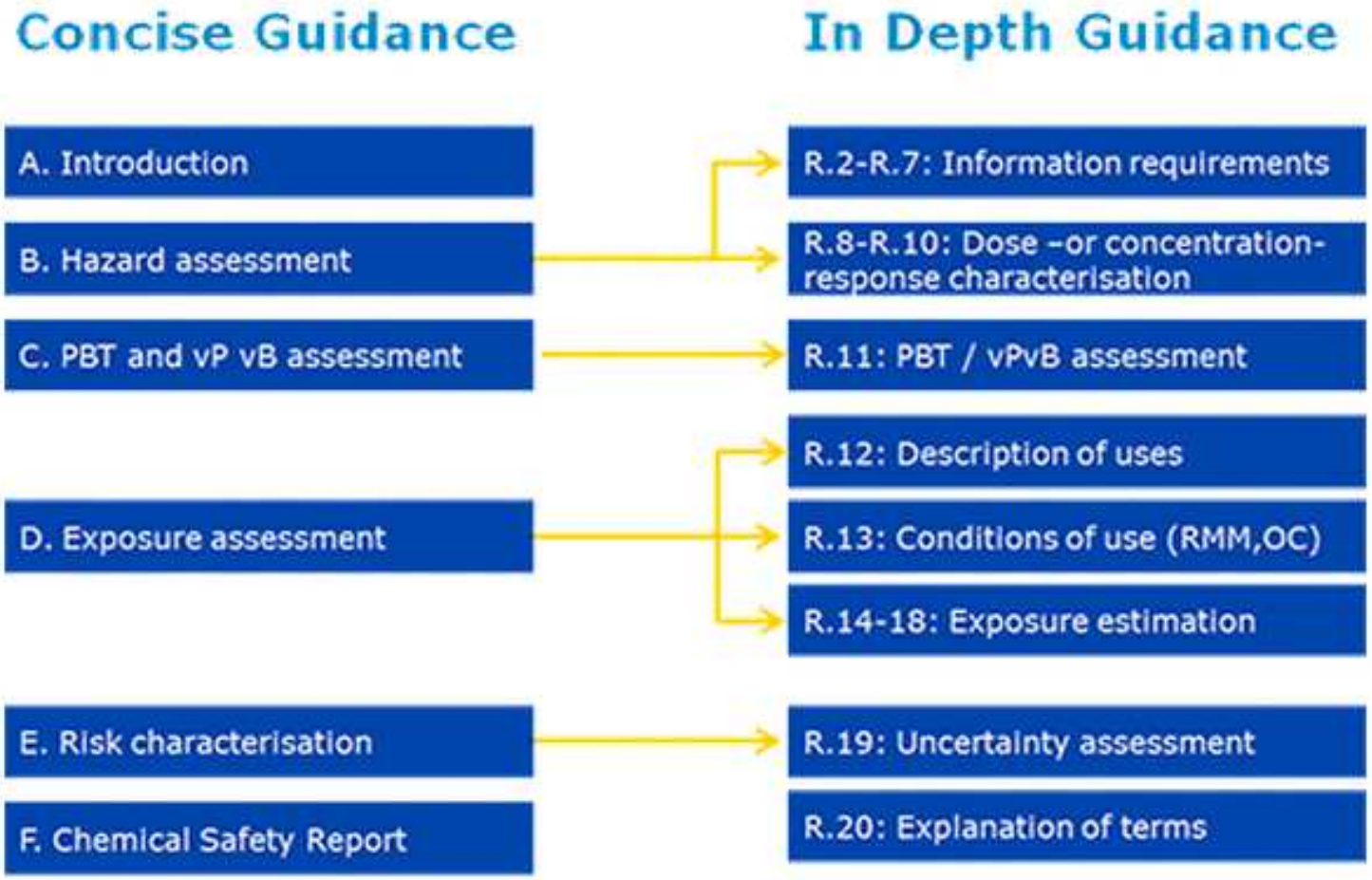
EU Risk Assessment Guidance



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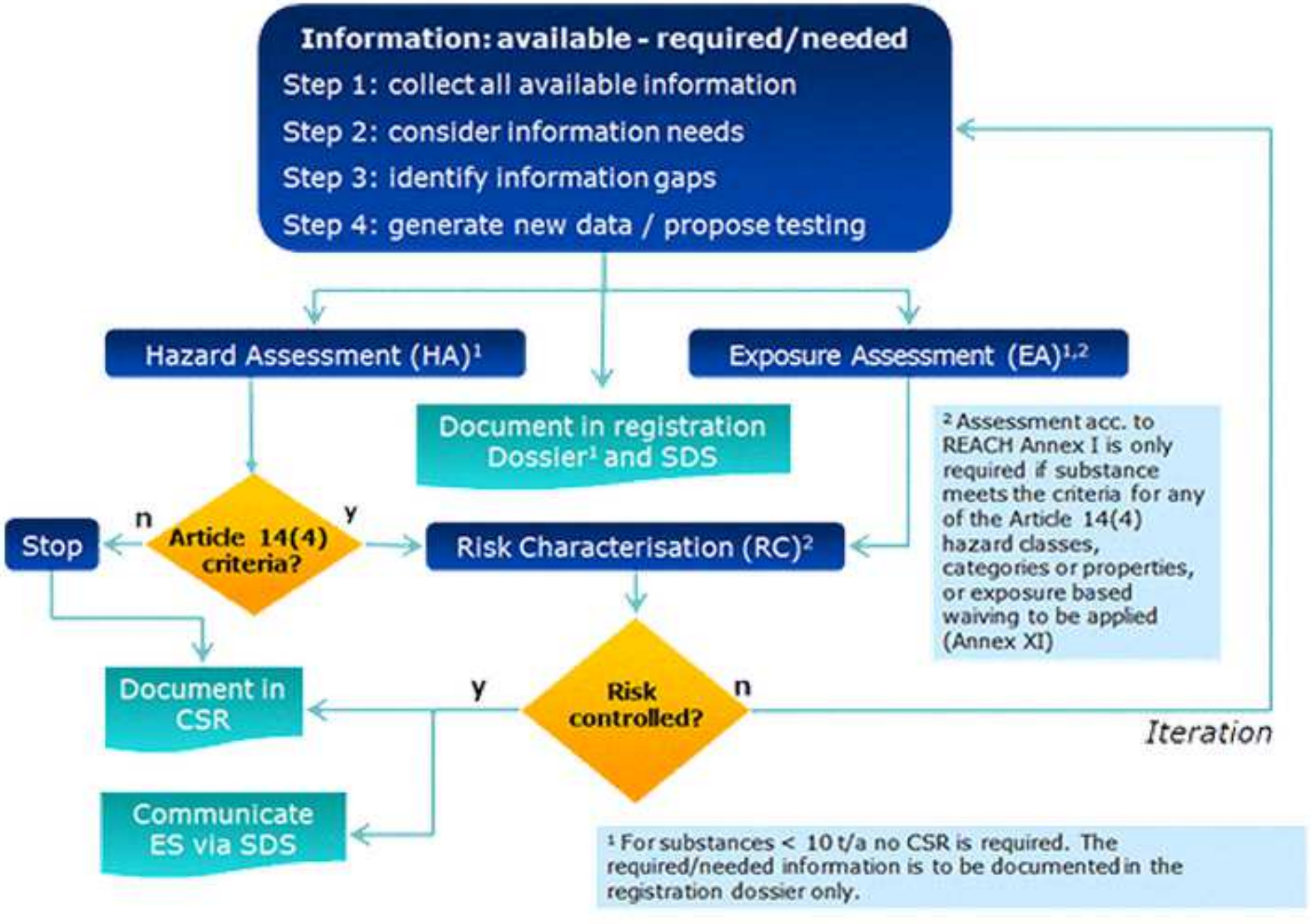
Information: available - required/needed
Step 1: collect all available information
Step 2: consider information needs
Step 3: identify information gaps
Step 4: generate new data / propose testing
Hazard Assessment (HA)1
Exposure Assessment (EA)1,2
Document in registration Dossier1 and SDS
2 Assessment acc. to REACH Annex I is only required if substance meets the criteria for any of the Article 14(4) hazard classes, categories or properties, or exposure based waiving to be applied (Annex XI)
n
Article 14(4) criteria?
y
Stop
Risk Characterisation (RC)2
Document in CSR
y
Risk controlled?
n
Iteration
Communicate ES via SDS
1 For substances < 10 t/a no CSR is required. The required/needed information is to be documented in the registration dossier only.

EU Chemical Safety Assessment under REACH

4 HOW TO PREPARE THE CHEMICAL SAFETY ASSESSMENT

The Chemical Safety Assessment (CSA) is meant to deliver the following outputs:

- **Assessment** of any hazards the substance may present.
- **Identification** of the conditions under which the risks arising from the manufacture and uses of the substance can be considered under control, i.e. exposure scenarios.
- **Documentation** of the relevant data, justifications and conclusions in a Chemical Safety Report (CSR).
- **Implementation** of the conditions of manufacture and use controlling risks at the registrants' premises.
- **Communication** to the customers further down the supply chain of the conditions of use ensuring control of risks.

Hazard Assessment

4.1 Hazard assessment

The CSA starts with the hazard assessment. The assessment normally comprises the following steps:

1. Information gathering and evaluation
2. Hazard identification
3. Classification and labelling
4. Derivation of threshold levels
5. PBT and vPvB assessment

PNEC

Predicted No Effect Concentration (PNEC)

The **Predicted No Effect Concentration or PNEC** is the concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short term exposure. The PNEC needs to be determined for each environmental sphere (aquatic, terrestrial, atmospheric, sewage treatment, food chain).

The PNEC for each environment is estimated by dividing the dose descriptor by the relevant **assessment factor**. Since dose descriptors are obtained from laboratory tests involving a limited number of species, the assessment factor is required to account for the uncertainties involved in the extrapolation to the real ecosystems. Where several dose descriptors are available for an environment, all the possible PNECs will be derived.

The lowest PNEC for each environmental sphere is reported in the CSR and in the safety data sheet, where required. The PNECs will later be used for risk characterisation in the CSA.

Effects Assessment

- **Hazard Identification**
  - **classification / other hazard**
- **Dose (concentration) - response (effect) assessment**
  - **Predicted No-Effect Concentration (PNEC)**
    - **ecosystem sensitivity depends on the most sensitive species**
    - **protecting ecosystem structure protects community function**

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Table R.10-1 Overview of toxicity test endpoints and guidance on derivation of L(E)C50 and NOEC values

Short-term studies:

If a test report does not indicate the L(E)C50 values but the raw data are presented, the L(E)C50 should be calculated, for example by regression analysis. If only one toxicity value lies between the L(E)C0 and the L(E)C100, the L(E)C50 cannot be calculated e.g. by Probit analysis. Instead, the L(E)C50 may be estimated by, e.g., linear regression.

If results are presented as >L(E)C10 and <L(E)C50, they can be rated as L(E)C50 while results clearly above a L(E)C50 can only be used as an indication of the short-term toxicity of the chemical considered.

Table R.10-1 Overview of toxicity test endpoints and guidance on derivation of L(E)C50 and NOEC values

Long-term studies:

An EC10 for a long-term test which is obtained using an appropriate statistical method (usually regression analysis) will be used preferentially. The **NOEC** (no observed effect concentration) is defined as "the highest concentration tested at which the substance is observed to have no statistically significant effect ($p<0.05$) when compared with the control, within a stated exposure period" (OECD 211, 1998b) or the test concentration immediately below the LOEC, which then compared with the control has no statistically significant effect ($p<0.05$) within a stated period (OECD 211, 1998b). There has to be a concentration-effect relationship.

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Assessment Factors to derive a PNEC (simplified training set)

Data availability	Assessment factor
At least one short-term L(E)C_{50} from each of three trophic levels of the base-set (fish, Daphnia and	1000
One long-term NOEC (either fish or Daphnia)	100
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10
Field data or model ecosystems	Reviewed on a case by case basis

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Table R.10-2. Relationship between different targets of the risk characterisation for different inland compartments

Target	Medium of exposure (PEClocal / PECregional)	Section	PNEC	Section
Aquatic organisms	Surface water	R.16.5.6.2. R.16.5.6.8	$PNEC_{water}$	R.10.3
Benthic organisms	Sediment	R.16.5.6.3 R.16.5.6.8	$PNEC_{sed}$	R.10.5
Terrestrial Organisms	Agricultural soil	R.16.5.6.6 R.16.5.6.8	$PNEC_{soil}$	R.10.6
Fish-eating Predators	Fish	R.16.5.7	PNECoral from $NOAEL_{avian/mammalian}$	R.10.8
Worm-eating Predators	Earthworms	R.16.5.7	PNECoral from $NOAEL_{avian/mammalian}$	R.10.8
Microorganisms	STP aeration tank	R.16.5.5	$PNEC_{microorganisms}$	R.10.4

Table R.10-3. Relationship between different targets of the risk characterisation for different marine compartments

Target	Medium of exposure (PEClocal / PECregional)	Section	PNEC	Section
Aquatic organisms	Seawater	R.16.5.6.4	$PNEC_{water}$	R.10.3.2.3
Benthic organisms	Marine sediment	R.16.5.6.5	$PNEC_{marine\ sed}$	R.10.5.3
Fish-eating predators	Fish	R.16.5.7	$PNECoral_{predators}$	R.10.8
Top predators	Fish-eaters	R.16.5.7	PNECoral, top predators	R.10.8

Hazard Assessment Starting-point:

A. physico-chemical inherent properties of a compound

- molecular weight
- distribution coefficient octanol / water (Kow)
- water solubility
- vapor presure
- boiling point

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Acute Toxicity

- **Acute toxicity:** It involves lethal concentrations and short-term exposures
- Acute effects of a toxin appear immediately after exposure.
- The end point is usually death (lethal), hence it is used to derive $LD_{50,}$ LC_{50}
- An LD_{50} / LC_{50} is a dose / concentration of a toxic chemical that kills half of the population.
- LD_{50} is obtained by plotting, for a given dose the proportion of the population that responded to that dose and all lower doses
- Other end-points:

  EC = effective concentration IC = inhibitory concentration

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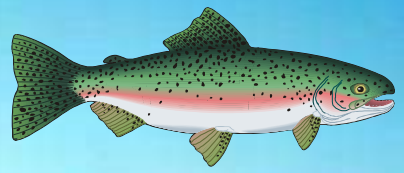
BASE SET REQUIREMENT

AQUATIC

ACUTE TOXICITY LC50

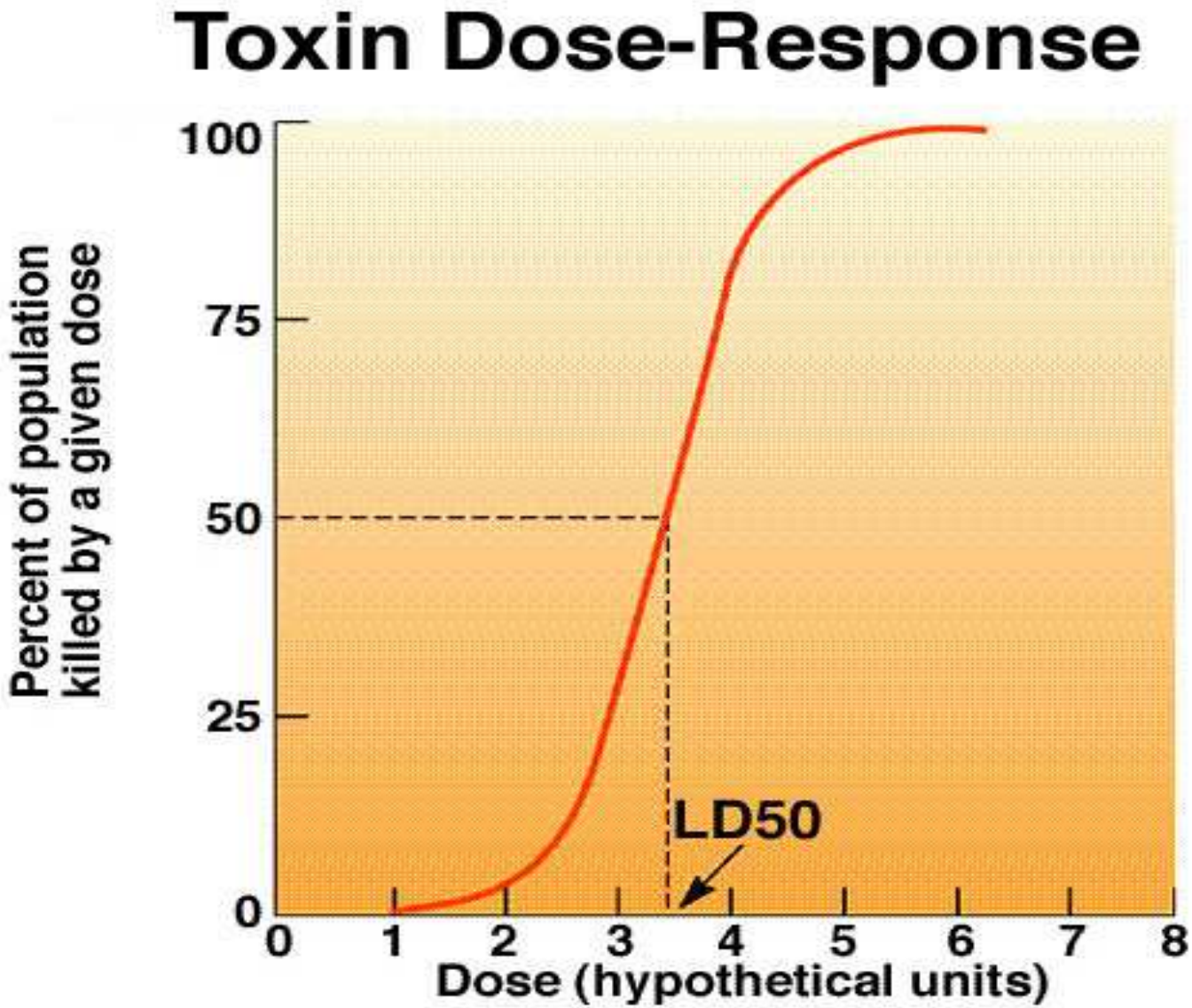


Fish

Algae

Daphnia:

CHEMICALS: Major Types of Toxicity



Dose-Response Curves

- Dose-response
- Nonthreshold
- Threshold

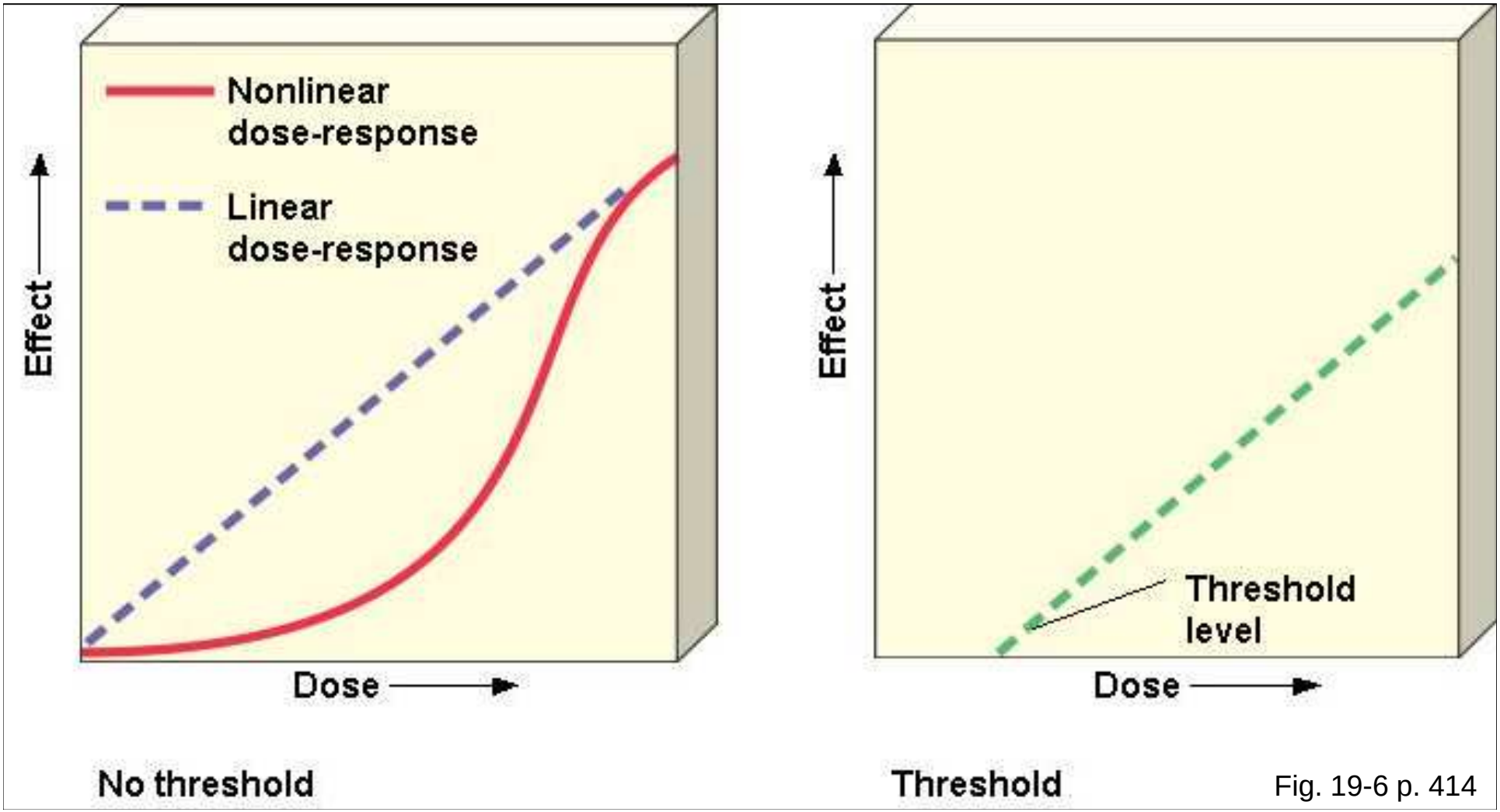
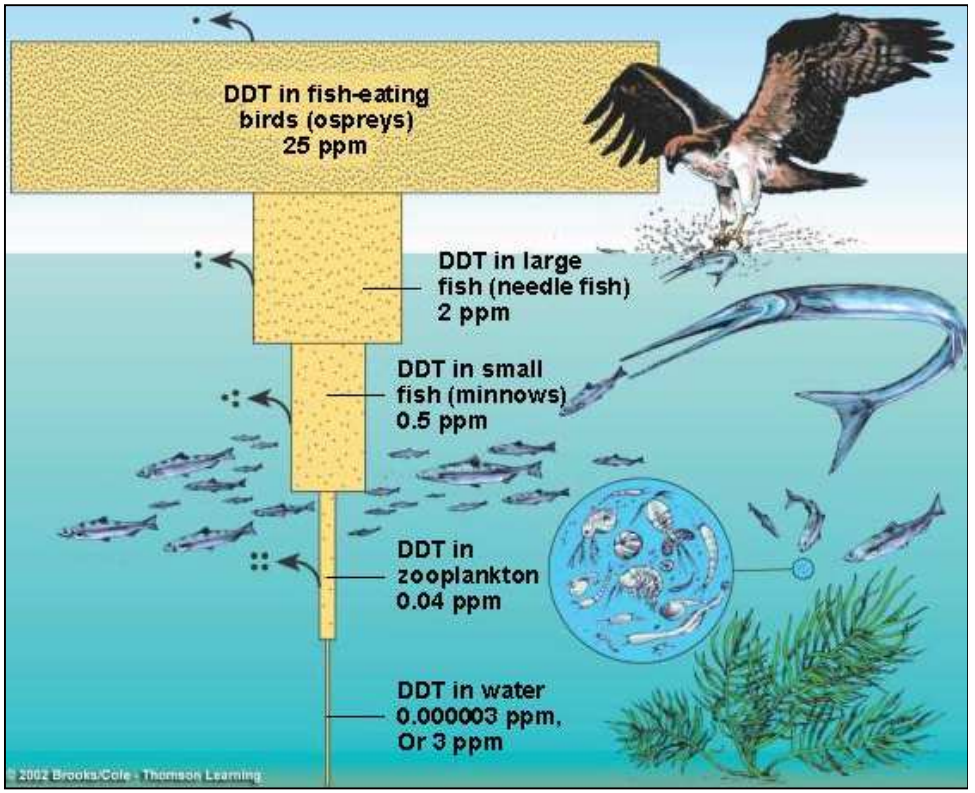


Fig. 19-6 p. 414

Factors Affecting Harm Caused By A Substance

1) Solubility (water soluble move through environment easily)
2) Fat Soluble (can accumulate in body tissue and cells)
3) Persistence (how long before it breaks down)

- Bioaccumulation
- Biomagnifications



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human dynamics public sector consulting

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C.1. ACUTE TOXICITY FOR FISH

1. METHOD

1.1. INTRODUCTION

The purpose of this test is to determine the acute lethal toxicity of a substance to fish in fresh water. It is desirable to have, as far as possible, information on the water solubility , vapour pressure, chemical stability, dissociation constants and biodegradability of the substance to help in the selection of the most appropriate test method (static, semi-static or flow-through) for ensuring satisfactorily constant concentrations of the test substance over the period of the test.

Additional information (for instance structural formula, degree of purity, nature and percentage of significant impurities, presence and amounts of additives, and n-octanol/water partition coefficient) should be taken into consideration in both the planning of the test and interpretation of the results.

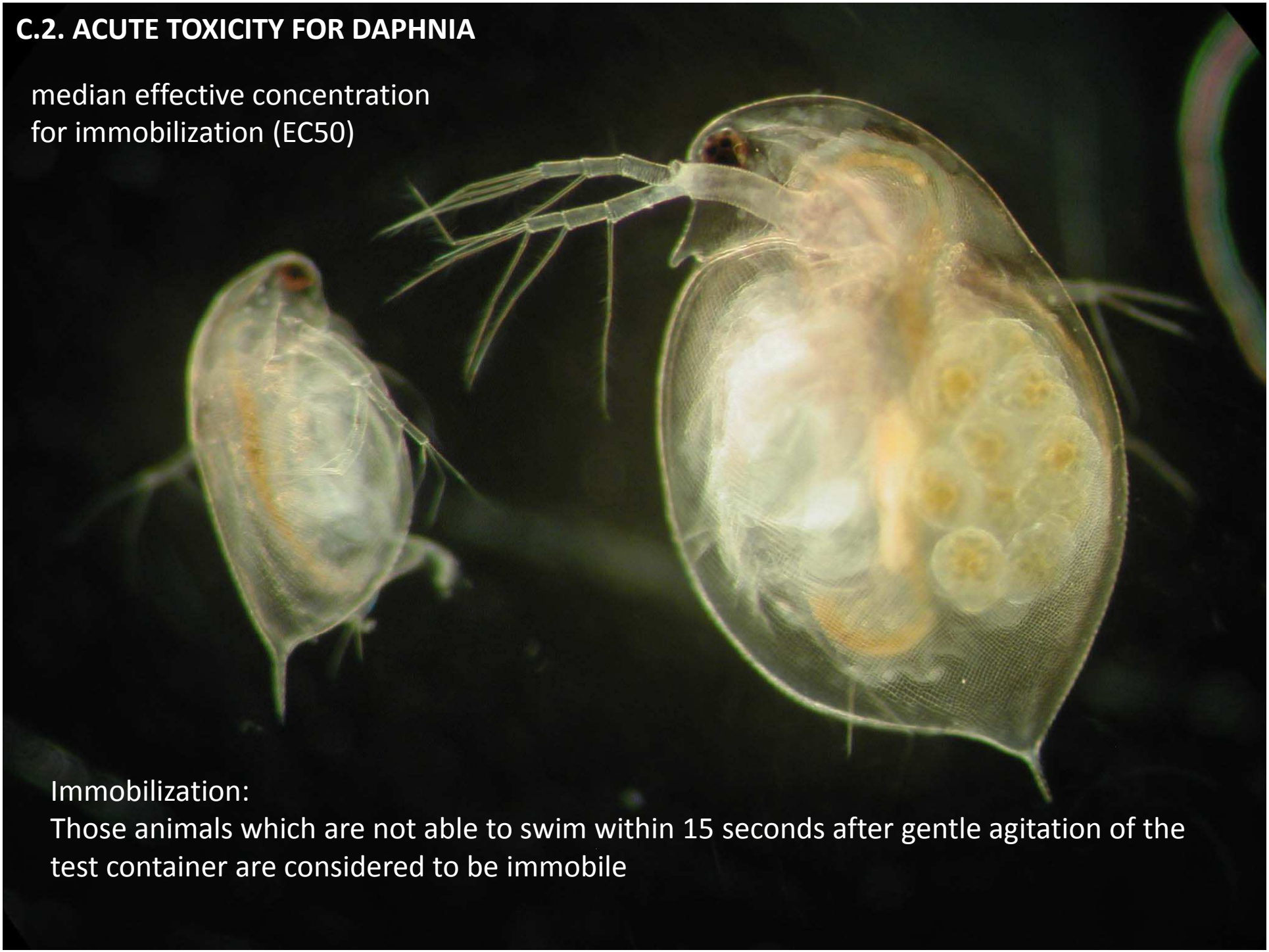
1.2. DEFINITIONS AND UNITS

Acute toxicity is the discernible adverse effect induced in an organism within a short time (days) of exposure to a substance. In the present test, acute toxicity is expressed as the median lethal concentration (LC_{50}), that is the concentration in water which kills 50% of a test batch of fish within a continuous period of exposure which must be stated.

All concentrations of the test substance are given in weight by volume (milligrams per litre). They may also be expressed as weight by weight ($mg.kg^{-1}$).

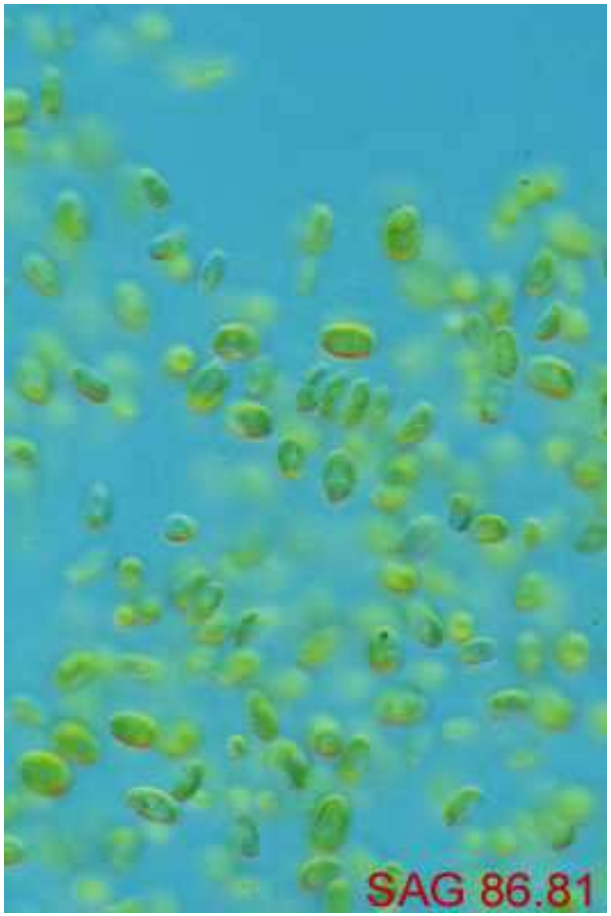
C.2. ACUTE TOXICITY FOR DAPHNIA

median effective concentration
for immobilization (EC50)



Immobilization:
Those animals which are not able to swim within 15 seconds after gentle agitation of the test container are considered to be immobile

C.3. Algal Inhibition Test



- End-point – inhibition of growth
- effects of a substance on the growth of a unicellular green algal species.

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C.4. DETERMINATION OF 'READY' BIODEGRADABILITY

Test	Analytical Method	Suitability for substances which are:		
		poorly soluble	volatile	adsorbing
DOC Die-Away	Dissolved organic carbon	—	—	+ / –
Mod. OECD Die-Away	Dissolved organic carbon	—	—	+ / –
CO_2 Evolution	Respirometry: CO_2 evolution	+	—	+
Manometric Respirometry	Manometric respirometry: oxygen consumption	+	+ / –	+
Closed Bottle	Respirometry: dissolved oxygen	+ / –	+	+
MITI	Respirometry: oxygen consumption	+	+ / –	+

Test	DOC Die-Away	CO_2 Evolution	Manometric Respirometry	Modified OECD Screeing	Closed Bottle	MITI (I)
Concentration of Test Substance as mg/l mg DOC/l mg ThOD/l	10-40	10-20	100 50-100	10-40	2-10 5-10	100
Concentration of Inoculum (in cells/l, approximatively)	≤ 30 mg/l SS or ≤ 100 ml effluent/l ($10^7 - 10^8$)			0,5 ml secondary effluent/l (10^5)	≤ 5 ml of effluent/l ($10^4 - 10^6$)	30 mg/l SS ($10^7 - 10^8$)
Concentration of elements in mineral medium (in mg/l) P N Na K Mg Ca Fe	116 1,3 86 122 2,2 9,9 0,05-0,1				11,6 0,13 8,6 12,2 2,2 9,9 0,05-0,1	29 1,3 17,2 36,5 6,6 29,7 0,15
pH	7,4 ± 0,2					preferably 7,0
Temperature	22 ± 2 °C					25 ± 1 °C

DOC = Dissolved organic Carbon

ThOD = Theoretical Oxygen Demand

SS = Suspended Solids

C.4 Ready biodegradability

- Normally, the test lasts for **28 days**. Tests however may be ended before 28 days, i.e. as soon as the biodegradation curve has reached a plateau for at least 3 determinations. Tests may also be prolonged beyond 28 days when the curve shows that biodegradation has started but that the plateau has not been reached day 28.
- Inocula may be pre-conditioned to the experimental conditions, but not pre-adapted to the test chemical. Pre-conditioning consists of aerating activated sludge in mineral medium or secondary effluent for 5-7 days at the test temperature. Pre-conditioning sometimes improves the precision of the test methods by reducing blank values. It is considered unnecessary to pre-condition MITI inoculum.

C.4. Test validity

- A test is considered valid if the difference of extremes of replicate values of the removal of test chemical at the plateau, at the end of the test or at the end of the 10 -day window, as appropriate, is less than 20% and if the percentage degradation of the reference substance has reached the level for ready biodegradability by 14 days.

  <u>If either of these conditions is not met, the test should be repeated.</u>
- Because of the stringency of the methods, low values do not necessarily mean that the test substance is not biodegradable under environmental conditions, but indicates that more work will be necessary to establish biodegradability. If in a toxicity test, containing both the test substance and a reference chemical, less than 35% degradation (based on DOC) or less than 25 % (based on ThOD or ThCO2) occurred in 14 days, the test chemicals can be assumed to be inhibitory (see also Annex IV). The test series should be repeated, if possible using a lower concentration of test chemical and/or a higher concentration of inoculum, but not greater than 30 mg solids/litre.

C. 9. BIODEGRADATION ZAHN -WELLENS TEST

- The purpose of the method is the evaluation of the potential ultimate biodegradability of water-soluble, non-volatile organic substances when exposed to relatively high concentrations of micro-organisms in a static test.
- The substances to be studied are used in concentrations corresponding to DOC-values in the range of **50 to 400 mg/litre** or COD-values in the range of 100 to 1000 mg/litre (DOC = dissolved organic carbon; COD = chemical oxygen demand). These relatively high concentrations have the advantage of analytical reliability. Compounds with toxic properties may delay or inhibit the degradation process.
- In this method, the measure of the concentration of dissolved organic carbon or the chemical oxygen demand is used to assess the ultimate biodegradability of the test substance.
- Activated sludge in an amount corresponding to 0,2 to 1,0 g/litre dry matter in the final mixture.

Effects Assessment - steps

- **Hazard identification**: The aim of the hazard identification is to identify the effects of concern. The aim is also to review the classification of the;
- **Dose (concentration) - response (effect) assessment:** At this step the predicted no effect concentration (PNEC), shall, where possible, be determined.

No GLP Studies?

NO GLP data may be used for the risk assessment, if valid conclusions can be drawn from them.

This means that the data, and the test methods used to generate them, must be evaluated in order to determine whether they are of sufficient quality for use in risk assessment. Such an evaluation will require the use of expert judgement, but the determination of data as being valid or not valid must be both justified and transparent.

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Chemicals bevaviour

Environment and Climate Regional Access to Network ECRAN

- Physico-chemical parameters that determine which compartment a chemical will go:

- Aboitic compartment
  - **Air: - Henry constant (H), The pressure of a gas above a solution is proportional to the concentration of the gas in the solution**
  - **water: - water solubility (S)**
  - **Soil/sediment:- soil sorption coefficient (Koc)**

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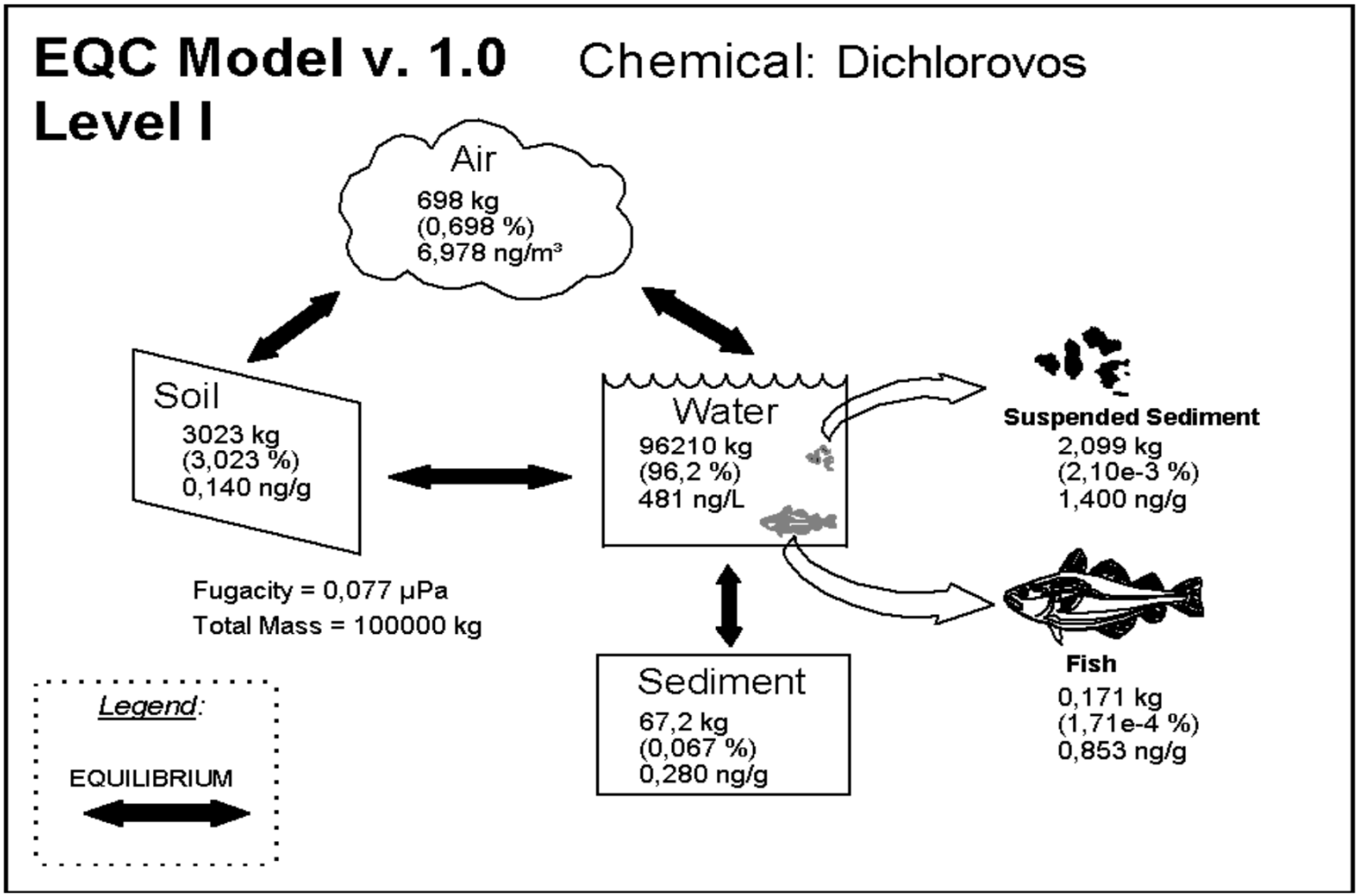
Fate in the environmental compartments - models

- Donald Mackay



This Project

Calculation of PNEC

- **assumptions are made concerning the aquatic environment which allow, however uncertain, an extrapolation to be made from single-species short-term toxicity data to ecosystem effects.**

It is assumed that:

- **ecosystem sensitivity depends on the most sensitive species, and;**
- **protecting ecosystem structure protects community function.**

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Uncertainties & Extrapolation

- **intra- and inter-laboratory variation of toxicity data;**
- **intra- and inter-species variations (biological variance);**
- **short-term to long-term toxicity extrapolation;**
- **laboratory data to field impact extrapolation (additive, synergistic and antagonistic effects from the presence of other substances may also play a role here).**

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Table 16 Assessment factors to derive a $PNEC_{aquatic}$

Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels of the base-set (fish, Daphnia and algae)	1000 [a]
One long-term NOEC (either fish or Daphnia)	100 [b]
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 [c]
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 [d]
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) [e]
Field data or model ecosystems	Reviewed on a case by case basis [f]

Effects Assessment for Microorganisms

Table 17 Test systems for derivation of $PNEC_{microorganisms}$

Test	Available value	Assessment factor
Respiration inhibition tests	NOEC or EC10	10
EU Annex V C.11; OECD 209 (1984f) ISO 8192 (1986)	EC50	100
Inhibition control in standardised biodegradation tests - Ready biodegradability tests EU Annex V C.4 A-F; OECD 301A-F (1992f) 92/69/EEC C4 (1992) ISO-7827 (1994), -9439 (1999), -10707 (1994), -9408 (1999) - Inherent biodegradability tests EU Annex V C.9; OECD 302 B-C (1981d-1992g) 88/302/EEC (1988) ISO-9888 (1999)	The tested concentration at which toxicity to the inoculum can be ruled out with sufficient reliability (cf. corresponding text section above) could be considered as a NOEC for the toxicity to microorganisms of a STP	10
Inhibition of nitrification	NOEC or EC10	1
ISO-9509 (1989)	EC50	10
Ciliate growth inhibition tests	NOEC or EC10	1
(preferably with *Tetrahymena*, cf. OECD, 1998a) [1)]	EC50	10
Activated sludge growth inhibition tests	NOEC or EC10	10
ISO-15522	EC50	100

Effects Assessment for Microorganisms in Sewage Treatment Plants (STP) 1

Pilot scale activated sludge simulation tests OECD 303A (2001b) ISO-11733	Based on case-by-case expert judgement, the tested concentration not impairing proper functioning of the CAS [2] unit could be considered as NOEC for microorganisms in STPs	Case-by-case down to 1
Growth inhibition test with *Pseudomonas putida* NF EN ISO 10712 (1995)	NOEC or EC10	1
	EC50	10
(Bringmann and Kühn, 1980)	to be used if no other tests are available	
Pseudomonas fluorescens (Bringmann and Kühn, 1960)	Not usable as it uses glucose as substrate	
Escherichia coli (Bringmann and Kühn, 1960)	Not usable as it uses glucose as substrate	
Vibrio fischeri (MICROTOX) NF EN ISO 11348-1, -2, -3 (1999)	Not relevant for STP as the bacterium is a saltwater species	

Notes to Table 17:

1) Ciliate testing would be required as the guideline becomes available
2) CAS: Continuous Activated Sludge

Secondary poisoning

- **Standard assays of ecotoxicological effects usually provide information about the direct toxic effects of a substance. Chemicals showing bioaccumulation and biomagnification may pose an additional threat due to exposure of organisms higher in the food chain, e.g. top predators.**
- **If this is the case, the oral intake of a chemical via fish or worms (PECoralfish and PECoralworm) is compared to a PNEC for fish- or worm-eating mammals or birds.**

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Environmental Risk Characterisation

PEC / PNEC

Predicted Environmental Concentration / Predicted No Effect Concentration

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What are consequences in „real“ case?

Example Sources	Example Pathways	Example Receptors
• Contaminated soils • Contaminated water • Leaking drums • Industrial process releases	• Air • Water • Soil • Food chain	• People • Domestic and commercial property • Infrastructure • Ecosystems • Animals • Plants • Controlled waters

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Acetone

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Ecotoxicological Information.001

Hazard for aquatic organisms | Hazard for terrestrial org

Hazard for aquatic organisms

Freshwater

Hazard assessment conclusion	PNEC aqua (freshwater)
	10.6 mg/L
Assessment factor	50
Extrapolation method	assessment factor

Ecotoxicological Information.001

Hazard for aquatic organisms | Hazard for terrestri

Assessment factor	100
Extrapolation method	assessment factor

STP

Hazard assessment conclusion	PNEC STP
	100 mg/L
Assessment factor	10
Extrapolation method	assessment factor

Formaldehyde

Ecotoxicological Information.001

Hazard for aquatic organisms | Hazard for terrestrial

Hazard for aquatic organisms

Freshwater

Hazard assessment conclusion	PNEC aqua (freshwater)
	0.47 mg/L
Assessment factor	10
Extrapolation method	statistical extrapolation

Ecotoxicological Information.001

Hazard for aquatic organisms | Hazard for terrestrial org

Extrapolation method	assessment factor

STP

Hazard assessment conclusion	PNEC STP
	0.19 mg/L
Assessment factor	100
Extrapolation method	assessment factor

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Naphthalene

Environment and Climate Regional Accession Network ECRAN

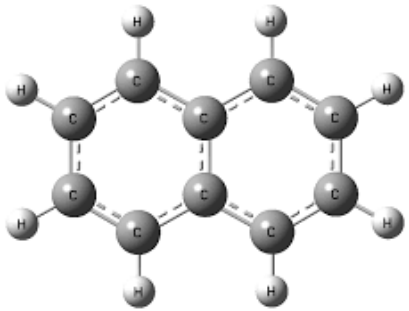
Ecotoxicological Information.001

Hazard for aquatic organisms | Hazard for terrestri

Hazard for aquatic organisms

Freshwater

Hazard assessment conclusion	PNEC aqua (freshwater
	2.4 µg/L
Assessment factor	50
Extrapolation method	assessment factor



Ecotoxicological Information.001

Hazard for aquatic organisms | Hazard for terrestr

Assessment factor	50
Extrapolation method	assessment factor

STP

Hazard assessment conclusion	PNEC STP
	2.9 mg/L
Assessment factor	10
Extrapolation method	assessment factor

This list of aquatic toxicants was developed using following sources:

List	Source	Date of publication
Water Directive	Water Frame Directive	October 2005
Water Directive Amendment	Decision No 2455/2001/EC	September 2007
Water Directive Amendment	Directive 2008/32/EC	January 2009
UBA's dangerous for water substances	German Environmental Ministry	October 2005

list of substances (water frame directive)

list of substances (german water pollutants)

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Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to Industrial Emission Directive – Technical aspects, downstream consequences and accession issues

ECRAN

PBT & vPvB Assessment

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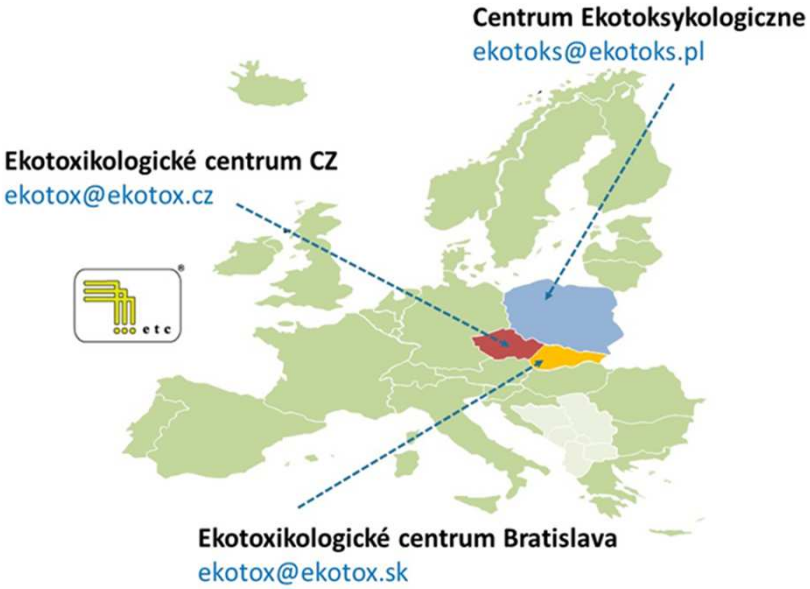

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Guidance on Information Requirements and Chemical Safety Assessment

Part C: PBT/vPvB assessment

Version 2.0

November 2014

This Project is funded by the European Union

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PBT/vPvB Assessment under REACH

1. The registrants of substances, manufacturing or importing in quantities equal to or more than 10 tonnes per year, conduct a PBT/vPvB assessment in accordance with Section 4 of Annex I and Annex XIII of the REACH Regulation. ECHA guidance provides support on how to carry out this assessment. If the registrants conclude that their substance fulfils the PBT or vPvB criteria, they are obliged to identify risk management measures and operational conditions (i.e. exposure scenarios) that minimise the releases and exposures in the whole life-cycle of the substance. The registrants have to implement such measures on their site(s) and communicate the relevant measures to their downstream users. The downstream users have an obligation to implement the measures on their site(s) and pass on the necessary information further in the supply chain.

2. Through dossier evaluation, ECHA can make sure that the registrants' PBT/vPvB assessments comply with the legal and scientific standards required by the REACH Regulation.

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Why PBTs and vPvBs ?

- Specific concerns occur specifically for substances that are highly accumulative and persistent
- Very high uncertainty in predicting PEC and/or PNEC
- A "safe" concentration cannot be established
- Traditional risk assessment may not address the risks adequately
- Draw parallel with known dangerous substances
- Early identification and fast implementation of risk reduction measures necessary to prevent future generations from long-term exposure

Why PBTs and vPvBs ?

- Persistent chemicals can reach remote regions
- Bioaccumulative substances can contaminate animals at the top of food chains – long-term effects are difficult to predict
- Exposure is difficult to stop due to long half-life

➢ Current risk assessment methods considered inadequate

PBT Assessment (TGD, 2003)

Part of the marine risk assessment

Protection targets:

- Aquatic ecosystem (incl. Sediment)
- Top predators (e.g. whales, marine birds)

Additional concerns:

- Accumulation
  - **a) effects unpredictable in the long-term**
  - **b) difficult to reverse**
- Remote areas should remain untouched

Testing Strategies for PBTs (TGD, 2003)

P: Use of standard biodegradation testing methods and (Q)SARs

B: Use of log Kow and QSARs for BCF

T: Use of short-term toxicity data or other indicators for toxicity

How to proceed when screening data indicate potential concern

- Test first P, then B, then T (reduce animal testing)

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PBT/vPvB Assessment

REACH

- is required for all substances for which a chemical safety assessment (CSA) must be conducted and reported in the chemical safety report (CSR).
- in general all substances M/I in amounts of ≥10 t/a that are not exempted from the registration requirement under REACH.
- exemptions apply as described in Article 14(2), e.g. for substances present in a preparation if the concentration is < 0.1 % weight by weight (w/w), for on-site or transported isolated intermediates, and for Product and Process Oriented Research and Development.

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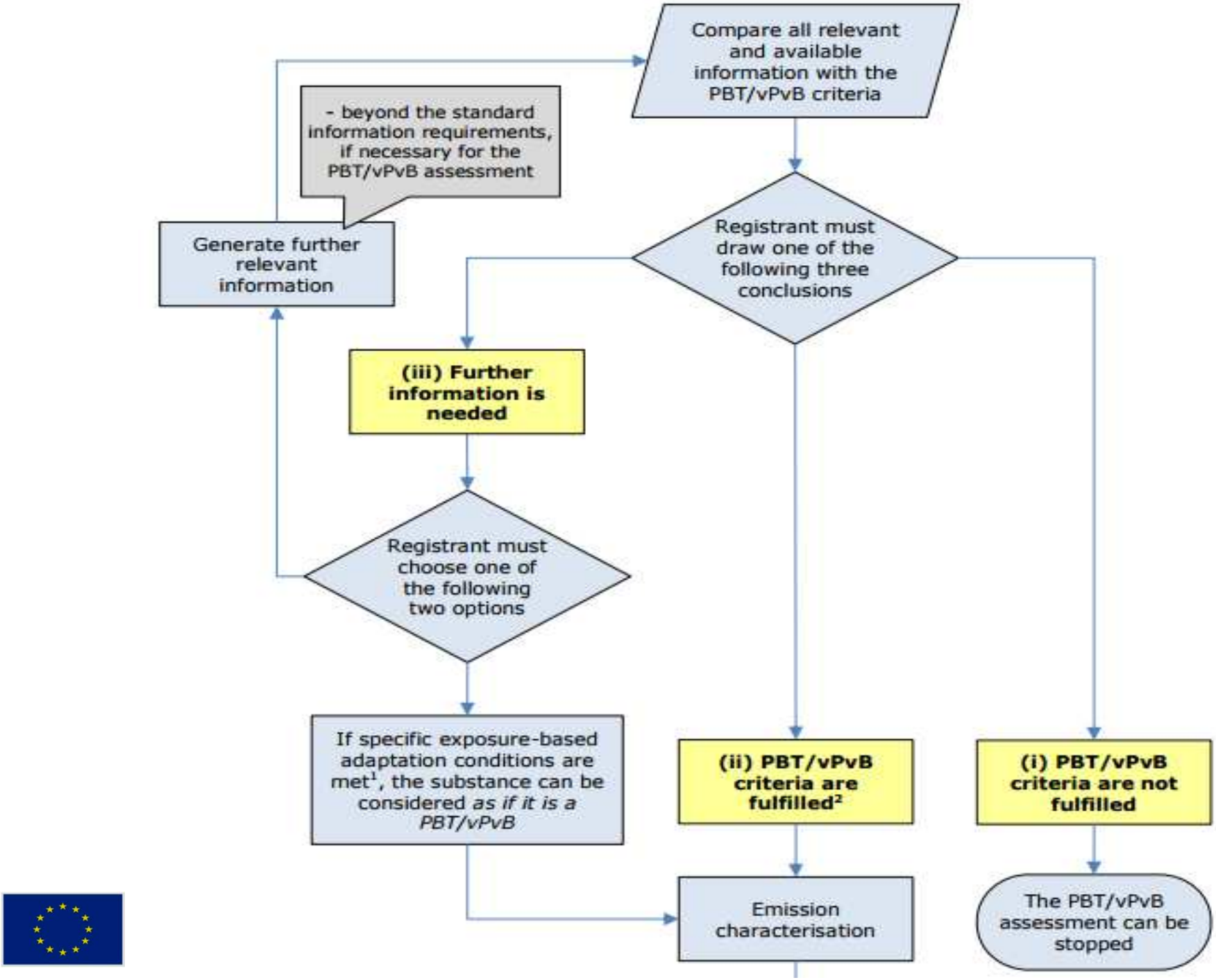
Compare all relevant and available information with the PBT/vPvB criteria
- beyond the standard information requirements, if necessary for the PBT/vPvB assessment
Generate further relevant information
Registrant must draw one of the following three conclusions
(iii) Further information is needed
Registrant must choose one of the following two options
If specific exposure-based adaptation conditions are met[1], the substance can be considered *as if it is a PBT/vPvB*
(ii) PBT/vPvB criteria are fulfilled[2]
(i) PBT/vPvB criteria are not fulfilled
Emission characterisation
The PBT/vPvB assessment can be stopped

The objective of PBT/vPvB Assessment

REACH

- to determine if the substance fulfils the criteria given in Annex XIII, and if so, to characterize the potential emissions of the substance to the different environmental compartments during all activities carried out by the registrant and all identified uses.
- In addition, it is necessary to identify the likely routes by which humans and the environment are exposed to the substance.
- **PBT substances** = substances that are persistent, bioaccumulative and toxic,
- **vPvB substances** = are characterised by a particular high persistency in combination with a high tendency to bio-accumulate, but not necessarily proven toxicity.

These properties are defined by the criteria laid down in Annex XIII of the REACH Regulation.

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PBT/vPvB Assessment - steps

REACH

- **Step 1:** Comparison with the criteria in Annex XIII
  - consider, on a case-by-case basis, other available evidence like monitoring data giving rise to an equivalent level of concern and
  - consider all information relevant for screening of the P, B and T properties of his substance.

- **Step 2:** Emission Characterization (EC)

- **Step 3:** Risk Characterization (RC)

Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment

This guidance describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment.

- Part C: PBT and vPvB Assessment (Chapter R.11)

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REACH PBT criteria

Persistence

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant. -

- T1/2 > 60 days in marine water, or
- T1/2 > 40 days in fresh- or estuarine water, or
- T1/2 > 180 days in marine sediment, or
- T1/2 > 120 days in fresh- or estuarine sediment, or
- T1/2 > 120 days in soil.

Bioaccumulation

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

- BCF > 2000 L/kg

Toxicity

- **NOEC (long-term) < 0.01 mg/L for marine or freshwater organisms, or**
- substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC. -

vPvB criteria

Persistence

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

- T1/2 > 60 days in marine, fresh- or estuarine water, or
- T1/2 > 180 days in marine, fresh- or estuarine sediment, or
- T1/2 > 180 days in soil.

Bioaccumulation

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

- BCF > 5000 L/kg

Table C.3-1: PBT and vPvB criteria according to Annex XIII to REACH

Property	PBT-criteria	vPvB-criteria
Persistence	A substance fulfils the persistence criterion (P) in **any** of the following situations: • $T_{1/2}$ > 60 days in marine water; • $T_{1/2}$ > 40 days in fresh- or estuarine water; • $T_{1/2}$ > 180 days in marine sediment; • $T_{1/2}$ > 120 days in fresh- or estuarine sediment; • $T_{1/2}$ > 120 days in soil.	A substance fulfils the "very persistent" criterion (vP) in **any** of the following situations: • $T_{1/2}$ > 60 days in marine, fresh- or estuarine water; • $T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment; • $T_{1/2}$ > 180 days in soil.
Bioaccumulation	A substance fulfils the bioaccumulation criterion (B) when: BCF > 2000	A substance fulfils the "very bioaccumulative" criterion (vB) when: BCF > 5000
Toxicity	A substance fulfils the toxicity criterion (T) in **any** of the following situations: • NOEC or EC_{10} < 0.01 mg/L for marine or freshwater organisms; • substance is classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2); • there is other evidence of chronic toxicity, as identified by the classifications: STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) according to the CLP Regulation.	-

Screening criteria

For many substances the available data may not allow a definitive conclusion on the PBT or vPvB properties. In this case so-called screening criteria may be used as surrogate information to decide whether a substance may potentially fulfil the PBT or vPvB criteria.

Persistence

Environment and Climate Regional Accession Network ECRAN

Type of data	Criterion	Screening assignment	See section
Persistence			R.11.1.3.1
Ready biodegradability test	readily biodegradable	Not P and not vP	
Enhanced ready biodegradability test	readily biodegradable	Not P and not vP	
Specified tests on inherent biodegradability			
Zahn-Wellens (OECD 302B)	≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum	Not P	
MITI II test (OECD 302C)	≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P	
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) **or** Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability < 0.5)[3] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2) **or** Does not biodegrade fast (probability < 0.5)[1] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2)	P P	

Bioacumulation and toxicity

Type of data	Criterion	Screening assignment	See section
Convincing evidence that a substance can biomagnify in the food chain (e.g. field data [4])	e.g. BMF > 1	B or vB, definitive assignment possible	R.11.1.3.2
Octanol-water partitioning coefficient (experimentally determined or estimated by valid QSAR)	Log Kow ≤ 4.5	Not B and not vB	
Toxicity			R.11.1.3.3
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.01 mg/L	T, criterion considered to be definitely fulfilled	
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.1 mg/L	T	
Avian toxicity (subchronic or chronic toxicity or toxic for reproduction)	NOEC < 30 mg/kg food	T	

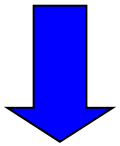
Guidance on information requirements and chemical safety assessment ,Chapter R.11: PBT Assessment

Outcomes from PBT/vPvB Assessment

1. The data show that **the properties of the substance meet the specific criteria**,

or

do not allow a direct comparison with all the criteria, but nevertheless indicate that the **substance is likely to have these properties**.



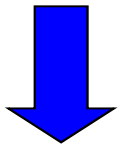
Emission and risk characterisation is required (i.e. characterisation of all emissions throughout the lifecycle of the substance and implementation, respectively recommendation of RMM and operational conditions (OC) that minimise exposure of humans and the environment).

Outcomes from PBT/vPvB Assessment

2. The data show that the properties of the substance **do not meet the specific criteria**

or

do not allow a direct comparison with all the criteria but nevertheless indicate that **the substance is not likely to have these properties** and, consequently, that **the substance is not considered a PBT/vPvB.**



The PBT/vPvB assessment stops.

Outcomes from PBT/vPvB Assessment

3. The data on the **properties of the substance do not allow a direct comparison with all the criteria and further information is needed**.

Registrant has two options:

- The registrant generates the required information (depending on the information needed, the submission of a testing proposal may be required) and concludes on the PBT/vPvB properties of the substance concerned once the lacking data are available (i.e. conclusion (1) or (2)); or
- The registrant refrains from generating further information and treats his substances as if it were a PBT/vPvB

Outcomes from PBT/vPvB Assessment

4. **Further information would be needed** to conclude on the PBT/vPvB properties of the substance. However, the registrant (for several reasons) has decided not to conduct confirmatory testing.

- If a clear decision on the properties of a substance cannot be made, either because it is not possible to characterise a substance, or since it is technically not possible to conduct testing, this lack of a clear decision does not obviate the requirement on a registrant to propose appropriate and proportionate RMMs and OCs.

Substances containing PBT/vPvB

- *A substance having a constituent with PBT or vPvB properties, which is present at a concentration of ≥80 % ;*
- *A substance having one or more constituents or impurities with PBT or vPvB properties in individual amounts equal or above 0.1 % (but less than 80%).*
- *If any constituent/impurity of a substance degrades, or is transformed into substances which have PBT or vPvB properties and if these transformation or degradation products are formed in individual amounts above 0.1% (of the weight of the initial substance). The percentage of degradation or transformation products may be indicated as for impurities or constituents with PBT- or vPvB- properties, if applicable.*

- RMM have to be considered as soon as a substance contains or degrades to PBT or vPvB substances above the threshold of 0.1%, irrespective of which of the three groups described above the substance belongs to.

EU Court confirms ECHA PBT assessment of substances

Helsinki, 08 March 2013 – ECHA welcomes the EU General Court's conclusions which confirm the Agency's approach in identifying PBTs and vPvBs as substances of very high concern.

The ruling confirms that ECHA's approach in identifying UVCB substances as well as other multi-constituent substances as PBTs[2] or vPvBs] on the basis of their constituent ingredients present in a concentration of 0.1% or more is lawful. The Court also upheld that ECHA's decisions were proportionate and did not breach the principle of equal treatment.

The Court further ruled that after a substance has been identified by ECHA as having PBT and/or vPvB properties, suppliers of these substances are legally required to update their safety data sheets with this information. It follows that all registrants of such substances will also need to update their chemical safety report with such information. It should be noted that according to the REACH Regulation, companies that have already concluded in their chemical safety assessment that a substance meets the criteria for identification as a PBT/vPvB are required to update their safety data sheet with this information even if ECHA has not yet formally identified such substances as PBTs/vPvBs and included them in the Candidate List.

anthracene oil, anthracene oil (low), anthracene oil (paste), and coal tar high pitch

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Recommendation of the European Chemicals Agency (ECHA)

of 1 June 2009

for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006

(4) ECHA has developed a paper presenting ECHA's approach for prioritising, pursuant to Article 58(3) of the REACH Regulation, substances for inclusion in Annex XIV[5]. On the basis of this approach ECHA has prioritised the following seven substances for inclusion in Annex XIV:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) **vPvB**
- 4,4'-Diaminodiphenylmethane (MDA)
- Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)
- Hexabromocyclododecane (HBCDD) **PBT**
- Bis(2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)

ECHA, industry, MSs

PBT Expert Group

The PBT Expert Group focuses on PBT substances, which are substances that are persistent, bioaccumulative and toxic, whereas vPvB substances are very persistent and very bioaccumulative.

These properties are further defined by the PBT/vPvB criteria in Annex XIII to the REACH Regulation.

- Management of PBT/vPvB substances under REACH
- Supporting activities

The PBT/vPvB concern

Establishment and role

Mandate

Overview of the 8th PBT Expert Group meeting (2-3 December 2014): substance outcome

Overview of the substance specific work of the PBT Expert Group

	Number of substances
Substances discussed in the 8th meeting (total)	17
-of these biocides	2
-of these REACH substances	15
-of these CoRAP substances	13
-of these other PBT assessments	2
Discussion outcomes (total)	17
Sufficient information is available - the substance is PBT/vPvB	1
"Not PBT/vPvB" based on present information	3
Refine assessment/More details on the available information needed/Testing or other new information needed	13

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EPA's PBT Criteria

Persistence		Bioaccumulation	Toxicity
Half-Life:		**BCF:**	**Fish ChronicValue:**
(Orange) Moderate	**(Red) High Concern**	**Moderate (Orange)**	**Moderate (Orange)**
Water: ≥ 2 months	**> 6 months**	**≥ 1,000**	**< 10 mg/L**
Soil: ≥ 2 months	**> 6 months**	**High Concern (Red)**	**High Concern (Red)**
Air: -	**> 2 days**	**≥ 5,000**	**< 0.1 mg/L**
Sed: ≥ 2 months	**> 6 months**		

Candidate List of Substances of Very High Concern for authorisation – PBT/vPvB substances

Name	EC Number	Reason for inclusion
Anthracene oil	292-602-7	Carcinogenic,PBT and vPvB
Anthracene oil, anthracene-low	292-604-8	Carcinogenic, mutagenic, PBT and vPvB
Anthracene oil, anthracene paste	292-603-2	Carcinogenic, mutagenic, PBT and vPvB
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	Carcinogenic, mutagenic, PBT and vPvB
Anthracene oil, anthracene paste,distn. lights	295-278-5	Carcinogenic, mutagenic, PBT and vPvB
Pitch, coal tar, high temp.	266-028-2	Carcinogenic, PBT and vPvB
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	vPvB
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	PBT and vPvB
Anthracene	204-371-1	PBT
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	247-148-4 and 221-695-9	PBT

The Exposure Scenario in General

- Format and content
- Major terms used in ESs
- Understanding ESs

Arnold van der Wielen

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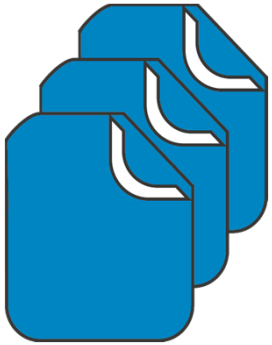
Project implemented by Human Dynamics Consortium

What is an Exposure Scenario?



The exposure scenario is a document generated by the registrant during REACH registration. The exposure scenario:

- Describes the conditions that ensure adequate control of risk when a substance is manufactured and used
- Addresses the risk to workers, consumers and the environment, as appropriate

Exposure Scenarios (ESs) are attached to the Safety Data Sheet (SDS)

e-SDS (extended Safety Data Sheet)

Exposure Scenario standard format

Exposure scenario format*
1. Title
2. Operational conditions and risk management measures
2.1 Control of workers exposure
2.2 Control of environmental exposure
2.3 Control of consumer exposure
3. Exposure estimation and reference to its source
4. Guidance to downstream user to check own conditions
Additional good practice advice beyond the REACH chemical safety assessment

* REACH does not define a specific format, but a standard format helps to streamline the communication in the supply chain.

What is in an Exposure Scenario?

- **Table of contents**
  - ✓ It helps to find the ES(s) related to a use/group of uses
- **Section 1 : Title**
  - ✓ Short title / Tasks & Activities covered (Use Descriptors)
- **Section 2: Conditions of Use affecting exposure**
  - ✓ Environment / Workers / Consumers - (Contributing Scenarios)
- **Section 3: Exposure estimation**
  - ✓ Method / Exposure estimates / Risk Characterisation Ratio
- **Section 4: Guidance to DU's**
  - ✓ How to verify that use is covered (Scaling Options)

Example for an industrial cleaner

Environment and Climate Regional Accession Network ECRAN

*Exposure Scenario Format (1) addressing uses carried out by **workers***	
1. Title	
Free short title	*Industrial Cleaner I*
Systematic title based on use descriptor	*SU3 (Industrial Manufacturing),, PROC4, PROC8 , PROC9, PROC10 ERC4*
Processes, tasks activities covered	*Metal cleaner (degreaser, descaler, etch); Manual process, Semi-Automatic process, Automatic process (according to A.I.S.E.)*
Assessment Method*	*ECETOC TRA, DPD +*
2. Operational conditions and risk management measures	
Brief description of overall operational conditions referring to process categories (PROC) and environmental release categories (ERC)	
*Number of sites using the substance supplied by the registrant (potentially required to demonstrate strictly controlled conditions, in order to justify waiving of information according to Annex XI of REACH) * *	
2.1 Control of workers exposure	
Product characteristic	
Amounts used	
Frequency and duration of use/exposure	
Human factors not influenced by risk management	
Other given operational conditions affecting workers exposure	
Technical conditions and measures at process level (source) to prevent release	
Technical conditions and measures to control dispersion from source towards the worker	
Organisational measures to prevent /limit releases, dispersion and exposure	
Conditions and measures related to personal protection, hygiene and health evaluation	

Use descriptors

1. **SU** – Sector of Use e.g. construction products
2. **PC** – Product Category e.g. adhesive
3. **PROC** – Process Category e.g. industrial spraying
4. **AC** – Article Category e.g. batteries
5. **ERCs** – Environmental Release Categories

- spERCs – sector specific Environmental Release Categories

Some use descriptors support identification of the suitable exposure estimation used in Tier 1 exposure estimation tool.

See ECHA Guidance Information requirements and CSA, Part D, Chap. 4.3.1, p. 25, + chapter R12 for an overview of Use Descriptors with standardized emission rates.0

Example for sectors of use

Environment and Climate Regional Accession Network ECRAN

Appendix R.0-1: Descriptor-list for sectors of use (SU)

	Key descriptor: Main user groups	
SU 3	Industrial uses: Uses of substances as such or in preparations* at industrial sites	
SU 21	Consumer uses: Private households (= general public = consumers)	
SU 22	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)	
	Supplementary descriptor: Sectors of end-use	**NACE[21] codes**
SU1	Agriculture, forestry, fishery	A
SU2a	Mining, (without offshore industries)	B
SU2b	Offshore industries	B 6
SU4	Manufacture of food products	C 10,11
SU5	Manufacture of textiles, leather, fur	C 13-15
SU6a	Manufacture of wood and wood products	C 16
SU6b	Manufacture of pulp, paper and paper products	C 17
SU7	Printing and reproduction of recorded media	C 18
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1
SU9	Manufacture of fine chemicals	C 20.2-20.6
SU 10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	C 20.3-20.5
SU11	Manufacture of rubber products	C 22.1
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23
SU14	Manufacture of basic metals, including alloys	C 24
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33
SU18	Manufacture of furniture	C 31
SU19	Building and construction work	F
SU20	Health services	Q 86
SU23	Electricity, steam, gas water supply and sewage treatment	C 35-37
SU24	Scientific research and development	C72
SU0	Other	

How to read exposure scenarios

Know what should be in there

- The key information is the operational conditions and risk management measures

Learn how to find it

- A table of contents helps to search quickly
- Formats are being harmonised

Understand Use Descriptors

- These are codes to describe tasks and activities (PROCs, ERCs etc.)

When exposure scenarios required

When a chemical safety assessment with exposure assessment has been prepared, namely:

When it is a substance

- For mixtures, the supplier may forward the information from exposure scenarios for the ingredient substances in other ways

...and registered > 10 tonnes/year

- A chemical safety assessment is not required for quantities <10 tonnes / year

...and it is hazardous

- Exposure scenarios are generated only for hazardous substances

"Hazardous",
if the substance meets the criteria for classification as dangerous,
or is assessed to be a PBT/vPvB

Check that company's use and customer use is covered in ES

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What to do when ES(s) present

It seems like a lot of information, but the key information is the operational conditions and risk management measures

Check that company's use and customer use is covered in ES

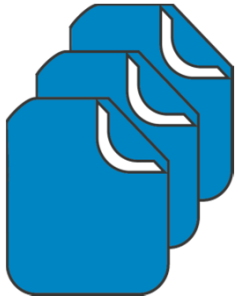
Check that the conditions match the actual conditions

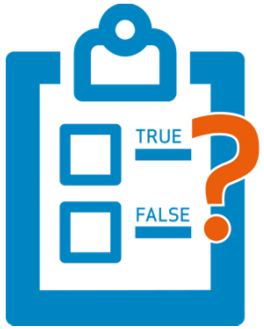
Check that necessary actions have been taken / recommended

DUs with data indicating that applying Exposure Scenario leads to unsafe use, shall inform the supplier and shall take actions to control the risks

Checking uses and conditions of use

The exposure scenario should be checked by DUs for their own use and any foreseeable customer use





Uses described by supplier = Actual use

- SDS Section 1.2
  - Identified uses
- ES Section 1 - Title
  - Identified uses
  - Processes/activities covered
- ES Section 2
  - Conditions of safe use

- Own/customer site
  - Processes/activities
  - Conditions of use
- Own /Customer products
  - Product category
  - Article category

Understand use descriptors

This Project is funded by the European Union

ES – check if company's use is covered in the title section

Title section: use name	• Are all uses and foreseeable uses of a product by customers identified in the title section of one or more of the exposure scenarios? • Is the use title applicable to these uses?
Title section: scope	• Do the contributing exposure scenarios cover all tasks or processes relevant for own uses in the contributing scenarios? (matching PROCs/ERCs)

ES –Check if the technical measures in section 2 will match

Section 2:

Operational conditions.

Technical measures

- Do the product/substance characteristics (such as form [liquid/powder/-granular/pellet], volatility and viscosity, concentration of substance in mixture) match those specified in the exposure scenario?

- Are the processes, technologies and the conditions which control the release of the substance into the working environment (such as amount used, transfer system, containment, frequency and duration of use,) in line with the recommendations in the exposure scenario?

ES – Check if the organisational measures in section 2 will match

Section 2:

Operational conditions.

Organisational measures

- Are organisational measures (such as training and supervision) specified in the exposure scenario included at the location?
- Is training provided as required?
- Is equipment maintained?

- Are measures recommended as a 'good practice' incorporated into the implemented work practices?

ES – check if the RMM in section 2 will match

Section 2:

Risk management measures

- Are general ventilation conditions (air change rate, room volume, indoor/outdoor) met?

- Are the risk management measures indicated in the exposure scenarios used?
- Is the effectiveness / type of RMM in line with exposure scenario requirements?

Outcome of the ES check

1. Use and conditions of use are covered
   - No action needed.

2. Conditions of use slightly differ
   - Check if conditions of use may be covered by similar use of broader scope (by scaling, if applicable)

3. Use and/or conditions not covered
   - Company needs to take actions!

2. Conditions slightly differ

Has the company its conditions of use covered by using "scaling".

- Scaling is a mathematical method to show that the substance is used under use conditions described in the ES, but some parameters are slightly different
- It can be used when:
  - There is an exposure limit (DNEL/PNEC)
  - the supplier (registrant or DU) has used an exposure model for the assessment
  - the supplier provides information for scaling

Outcome from the scaling

Scaling shows that the use is covered

- No further actions required.

Scaling shows that use is not covered e.g.

- ✓ $RCR_{scaling} > RCR_{ES}$ or
- ✓ parameters are not scalable or
- ✓ scaling is not foreseen as an option

- Have actions been taken for uses not covered

3. Use/conditions not covered

Has the company taken any of the following options?

1. Contact supplier to have the ES updated with use covered
2. Change process to implement the ES
3. Substitute with another substance or process, or stop the activity
4. Find a supplier providing ES that covers company's conditions
5. Prepared a downstream user chemical safety report (DU CSR) to establish safe conditions for the use not covered in ES and reported unsupported use to ECHA

DU Chemical Safety Report (CSR)

What it's not

As extensive as a registrant chemical safety report

What it is

A report of the chemical safety assessment for the use not covered. The hazard assessment of the registrant (DNEL's/PNEC's etc.) may be used.

Exemptions from DU CSR

- The total use is less than 1 tonne/year
- The substance is used for Process and Product Oriented Research & Development (PPORD)

No need to prepare DU Chemical Safety Report?

…. however, use needs to be reported to ECHA

Restriction under REACH

History, structure of REACH Annex XVII
Overlap by other legislation
Challenges in enforcement
Example: Consumer product for repairing bicycles

Arnold van der Wielen

This Project is funded by the European Union

Project implemented by Human Dynamics Consortium

History

- **Originally:**
  - Directive 76/769: “Marketing & Use Directive on Dangerous Substances and Preparations”
- **Integrated in REACH (Regulation 1907/2006):**
  - Title VIII: Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles
  - Annex XVII: [same title]

Structure of Annex XVII (1/2)

- **Part 1: List of banned and severely restricted substances and mixture including conditions of restrictions**
  - Since 2006, already 11 amendments of part 1 of Annex XVII
  - At this moment 64 entries
- **Part 2: entries 28, 29 and 30: list of identified CMRs**
  - Entry 28, Appendices 1 and 2: list of carcinogens cat. 1A (new 1) and 1B (new 2)
  - Entry 29, Appendices 3 and 4: list of mutagens cat. 1A(new 1: none identified) and 1B (new 2)
  - Entry 30, Appendices 5 and 6: list of reprotoxic substances cat. 1A (new 1) and 1B (new 2)

Structure of Annex XVII (2/2)

- **Part 3: labelling of articles containing asbestos (appendix 7)**
- **Part 4: entry 43 azocolorants**
  - Appendix 8, list of aromatic amines
  - Appendix 9, list of azodyes
  - Appendix 10, list of testing methods for determining azocolorants
- **Part 5: entries 28 to 30, Derogations for specific substances**

General conditions of restriction

- **Part 1 regards specified conditions of restriction in manufacture and or use of specified substances/mixtures**

- **Part 2 regards CMRs with the general restriction not to be placed on the market for consumer use. For mixture max. conc. <= 0,01% or otherwise specified.**

In this presentation focus is on part 1 restrictions

Well-known substances subjected to restrictions (list not complete)

- Benzene, toluene, trichlorobenzene, dichlorobenzene
- Asbestos
- PBBs, PCTs
- 2-Naphthylamine, benzidine, 4-nitrobiphenyl, 4-aminobiphenyl xenylamine
- Lead carbonates, sulphates
- Lead and its compounds
- Mercury and its compounds
- Cadmium and its compounds
- Nickel and its compounds
- Chromium-VI compounds
- Arsenic compounds
- Organostannic compounds
- Pentachlorophenol
- Creosotes, coal tar, anthracene oil, etc.
- Azocolourants and azodyes
- Nonylphenol and nonylphenol ethoxylates
- PAHs
- Phalates (DEHP, DBP, BBP, DINP, DIDP, DNOP)
- DEGBE and DEGME
- MDI and its isomers
- Cyclohexane
- Ammonium nitrate
- Chloroform, tri-, tetra-, penta- and hexachloroethane, dichloroethene
- Dichloromethane
- Acrylamide
- Dimethylfumarate

Legal issues regarding enforcement of REACH restrictions

- Misunderstanding scope of legislation on cosmetics, medical devices, human and veterinary drugs, pesticides and biocides
  - Within the scope of REACH:
    - Ingredients of cosmetics
    - Precursors of end-use substances in medical devices, human and veterinary drugs
    - Precursors of active ingredients for pesticides and biocides

- Overlap with ROHS (Restrictions of use of certain hazardous substances in electrical and electronic equipment (EEE))

- Waste is outside the scope of REACH (only included in CSR as follow-up of a substance), but recycled products placed on the market are included in REACH; should comply with restrictions

Overlap by other legislation (1/2)

- **Overlap with ROHS (Restriction of Hazardous Substances in electric and electronic equipment)**
  - Regulation 2002/95, last amended 2011/65
  - Substances showing overlap:
    - Mercury in lamps for lighting, etc.
    - Lead in glass of tubes (cathode ray, fluorescent), as alloying element, in solders, in ceramics, etc.
    - Cadmium in electrical contacts, Cd-alloys in solder joints, etc.
    - Cr-VI in absorption refrigators

Overlap by other legislation (2/3)

- Scope of REACH partially overlaps scope of ROHS
- COM proposed in 2014 a working procedure for preventing conflicts between ROHS and REACH, but not the case for already defined restrictions and exemptions in ROHS and REACH
- ROHS considers electric & electronic equipment including waste management, but no exemption/exclusion of electronic equipment in REACH

Conclusion:

Possibility for conflicts in restrictions btween REACH and ROHS regarding control of electric & electronic equipment on the market

Illustrative example: cadmium

Example Cadmium

REACH

- Not to be used in mixtures and articles produced from specific synthetic organic polymers,
- not be placed on the market if conc. >= 0,01%
- Not to be used in paints
- Painted articles not be placed on the market if conc. >=0,1% in paint; exemption if for safety reasons
- Jewels, etc. max conc. 0,01%
- Many other articles specified and exemptions.
- Recovered PVC max. conc. 0,1% used for specified applications
- Cd-plating not allowed in specified applications, but with exemptions, a.o. electrical contacts if necessary

ROHS

Cd max 0,01% in homogeneous material, but exempted if

- In electrical contacts
- In filter glasses and reflextants
- In printing inkt for enamels on glasses
- Cd-alloys as solder joints in specific high-power loadspeakers
- In film pastes used on Aluminium-bonded beryllium oxide

Observation:
Glass, inkt for enamels, solder and alloys as specified in ROHS are not specifically defined as exemption in REACH

Case study:
Consumer product for repairing bicycles

During inspection in retail store found in sport departement

10 ml glue; marked with
Label contains
model number, bar code
and name importer
No label on blister package

Sample taken and analysed:
Benzene (14,7% and
toluene (1,1%)

Observation on composition:

Sample taken and analysed, mixture flash point 28 °C, boiling point 58 °C

Composition	Conc. (%)	Classif. CLP	Classif. DSD
Benzene	14,7	Flam. Liq. 2, H225 Carc. 1A , H350 Muta. 1B , H340 STOT RE 1, H372 Asp. Tox. 1. H304 Eye Irrit. 2, H319 Skin Irrit. 2, H315	F; R11 Carc. Cat. 1;R45 Muta. Cat. 2;R46 T; R48/23/24/25 Xn; R65 Xi; R36/38
Toluene	1,1	Flam. Liq. 2, H225 Repr. 2, H361d Asp. Tox. 1, H304 STOT RE 2* H373 Skin Irrit. 2 H315 STOT SE 3 H336	F; R11 Repr. Cat. 3;R63 Xn; R48/20-65 Xi; R38 R67

Observation on labelling

- Classification of mixture shall be
  - Carc 1A, H350 May cause cancer
  - Muta 1B, H340 May cause genetic defects
  - STOT RE 1; H372 Causes damage to organs through prolonged exposure
  - Asp Tox 1; H304 May be fatal if swallowed and enters airways

  And in addition
  - Eye Irr 2 ; H319 Causes serious eye irritation
  - Skin Irr 2, H315 Causes skin irritation
  - Flam Liq 2 H225 Highly flammable liquid and vapour.

Observation on labelling

Labelling shall contain

- Name, address and telephone number of the supplier;
- The nominal quantity of mixture in the package where this is being made available to the general public, unless this quantity is specified elsewhere on the package;
- Product identifiers;
- Hazard pictograms, where applicable;
- The relevant signal word, where applicable;
- Hazard statements, where applicable;
- Appropriate precautionary statements where applicable;
- A section for supplemental information, where applicable.

Blister package also need to carry a CLP label

CONCLUSION: C&L shall be modified

Annex XVII: Benzene and toluene

5. Benzene CAS No 71-43-2 EC No 200-753-7	1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy. 2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market, or used, — as a substance, — as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight. 4. However, paragraph 3 shall not apply to: (a) motor fuels which are covered by Directive 98/70/EC; (b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation.
48. Toluene CAS No 108-88-3 EC No 203-625-9	Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.

Observation regarding presence on the market

REACH Annex XVII:

- According to Annex XVII, entry 5 (benzene) mixture not allowed on the market for consumer use in conc. ≥ 0,1%
- According to Annex XVII, entry 48 (toluene) mixture not allowed on the market for consumer use in conc. ≥ 0,1%

FINAL CONCLUSION:

- **Product shall be taken from the market**
- **If solely for professional use: C&L shall be modified**

T.C.
ÇEVRE VE ŞEHİRCİLİK
BAKANLIĞI

Overview of current Turkish legal framework for chemical management legislation

Ahu ÇEKİM

Expert
Ministry of Environment and Urbanization

December 2015

INSTITUTIONAL FRAMEWORK

INSTITUTION	TASK
Ministry of Environment and Urbanization	industrial chemicals and coordination
Ministry of Health	biocidal products
Ministry of Food, Agriculture and Livestock	plant protection products
Ministry of Labour and Social Security	health and safety in workplace
Ministry of Transport Maritime and Communication	transportation of chemicals
Ministry of Science, Industry and Technology	chemical weapons
Ministry of Economy	import and export of chemicals
Ministry of Customs and Trade	control of chemicals at customs and detergents, some cleaning products, poolchemicals

EU-DIR./REGULATION	TURKISH REGULATION
67/548/EC Dir. 99/45/EC .Dir.	By-law On Classification, Packaging And Labelling Of Dangerous Substances And Preparations (26.12.2008/27092) (CPL By-law)
1272/2008/EC CLP Reg.	By-law On The Classification, Labelling And Packaging Of Substances And Mixtures (11.12.2013/28848) (CLP By-law)
91/155/EC Dir.-REACH Annex II	By-law On The Preparation And Distribution Of Safety Data Sheets (26.12.2008/27092)
İn parallel to REACH Annex II	By-law on the Safety Data Sheets of Hazardous Substances and Mixtures (13.12.2014/29204)
In parallel to REACH Annex XVII	By-law On Restrictions And Prohibitions Of Hazardous Substances And Mixtures (26.12.2008/27092; last rev. 27.11.2014/29182)
440/2008/EC Dir.	By-law On Test Methods Applied For Determining The Physicochemical Toxicological And Ecotoxicological Properties Of The Substances And Mixtures (11.12.2013/28848)

By Law on Inventory and Control of Chemicals (26.12.2008/27092)
(in parallel to 793/93/EEC) NATIONAL NEEDS

BY LAW ON INVENTORY AND CONTROL OF CHEMICALS

Aim is to constitute Turkish Chemicals Inventory in order to apply better chemicals management

Turkish manufacturers or importers of substances, on its own or in a preparation **in quantities of**

- one thousand tonnes per year or more

- one tonne or more but less than one thousand tonnes

Is not applied to:

- substances in transit
- subtances manufactured or imported for military purposes

No Submission Fee

Available Data

Could be done by an representative in TURKEY

Data To Be Submitted

- **Substance Name, EC number ve CAS number**
- **The quantity of the substance produced or imported**
- **Classification**
- **Information on the reasonably foreseeable uses**

- **physico-chemical properties**
- **pathways and environmental fate**
- **ecotoxicity**
- **acute and subacute toxicity**
- **carcinogenicity, mutagenicity and/or toxicity for reproduction (CMR)**
- **any other information relevant to the risk evaluation**

≥ 1t<1000

Annex-III

≥ 1000 t

Annex-II

UPDATING OF DATA

New uses of the substance which substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance

New data on the physico-chemical properties, toxicological or ecotoxicological effects

Any change in the provisional classification under By-law on Classification, Packaging and Labelling of Dangerous Substances and Preparations

New information obtained about a substance which may present a serious risk to man or the environment

within 1 month

manufacture and import **volumes**  every three years

MAIN OUTPUTS

Appr. 12000 entries for substances manufactured or imported ≥1 t/pa

Published Lists;

- List of substances on its own or in a preparation, in quantities exceeding 1 tonnes per year in Turkish market
- List of High Production Volume (HPV) Chemicals
- List of priority substances or groups of substances (131 substances)

TONNAGE RANGE	NUMBER OF ENTRIES
1-10	5986
10-100	3687
100-1000	1563
1000-	891
	12127
Total 3000 different substances	

BY-LAW ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES

Aim is to Protect human health & the environment and defining rules and principles for classification labelling and packaging

DIFFERERENCE BETWEEN CLP BY-LAW AND EU CLP REG.

- ✓ Some Boron Derivatives are excluded from Annex VI
- ✓ in accordance to 3rd ATP
- ✓ MoEU /ECHA
- ✓ 4 additional annexes

Annex VIII	CONDITIONALATIES REGARDING CLASSIFICATION AND NOTIFICATION OF SUBSTANCES
Annex IX	GENERAL PROVISIONS FOR ADAPTATION OF THE STANDARD TESTING REGIMES
Annex X	INFORMATION PRESENTED TO PUBLIC ACCESS
Annex XI	HAZARD ASSESSMENT AND FORM FOR SUBMITTİNG HARMONISED CLASSIFICATION

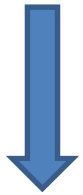
	Classification	Labelling	Packaging	Notification	Keep information for 10 years
Manufacturer	✓	✓	✓	✓	✓
Importer	✓	✓	✓	✓	✓
Downstream User	✓ *	✓	✓	x	✓
Distributer	x***	✓	✓	x	✓

- Could use that of supplier if chemically not changed
- *** Could use any classification of another actor

NOTIFICATION (Article 41)

- Same inputs as in EU CLP

- substances placed on the market before 1/6/2015 has been notified between 1/6/2014 and 1/6/2015



currently 539 companies 28’005 notification

The obligations on notification of importers could be performed through a representative that is established in Turkey (appointed with an agreement determined by the natural or legal persons settled abroad).

TRANSITIONAL PROVISIONS

- **From 1 June 2015** substances shall be classified and labelled in accordance with CLP By-Law

- **Untill 1 June 2016 mixtures** shall be classified, labelled and packaged in accordance with CPL By-Law; voluntarily in acoording to CLP

- **Repeal** of CPL By-Law with effect from 1 June 2016

<u>Exemptions from transitional provisions:</u>

Substances and mixtures placed on the market before 1 June 2015/1 June 2016 and classified, labelled and packaged according to CPL

Not relabeled and repackaged in accordance with CLP By-Law untill

- ❖ 1 January 2017 for substances
- ❖ 1 June 2018 for mixtures

BY-LAW ON THE SAFETY DATA SHEETS OF HAZARDOUS SUBSTANCES AND MIXTURES

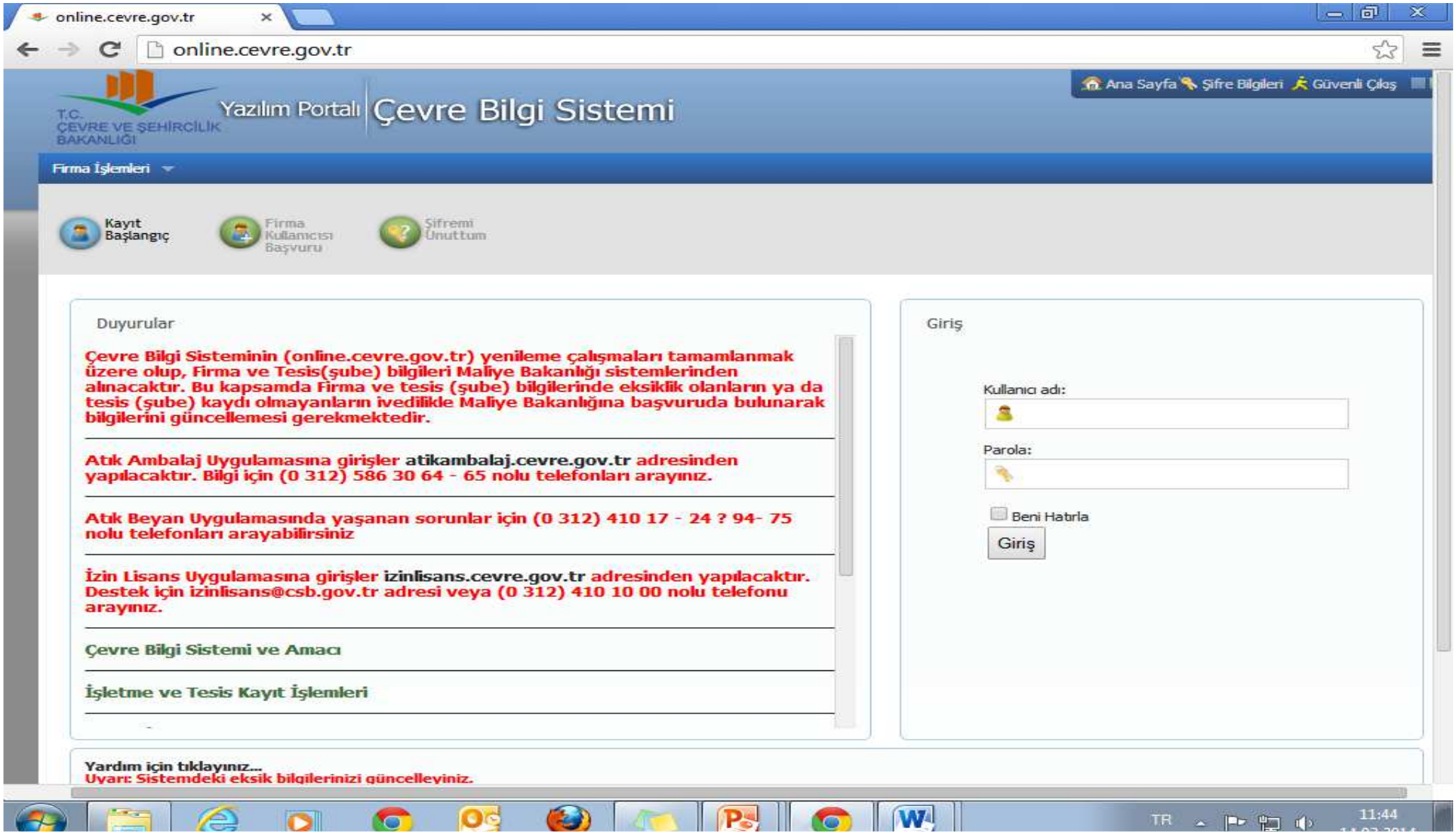
Aim is to determine the principles and procedures related with compilation and distribution of safety data sheets

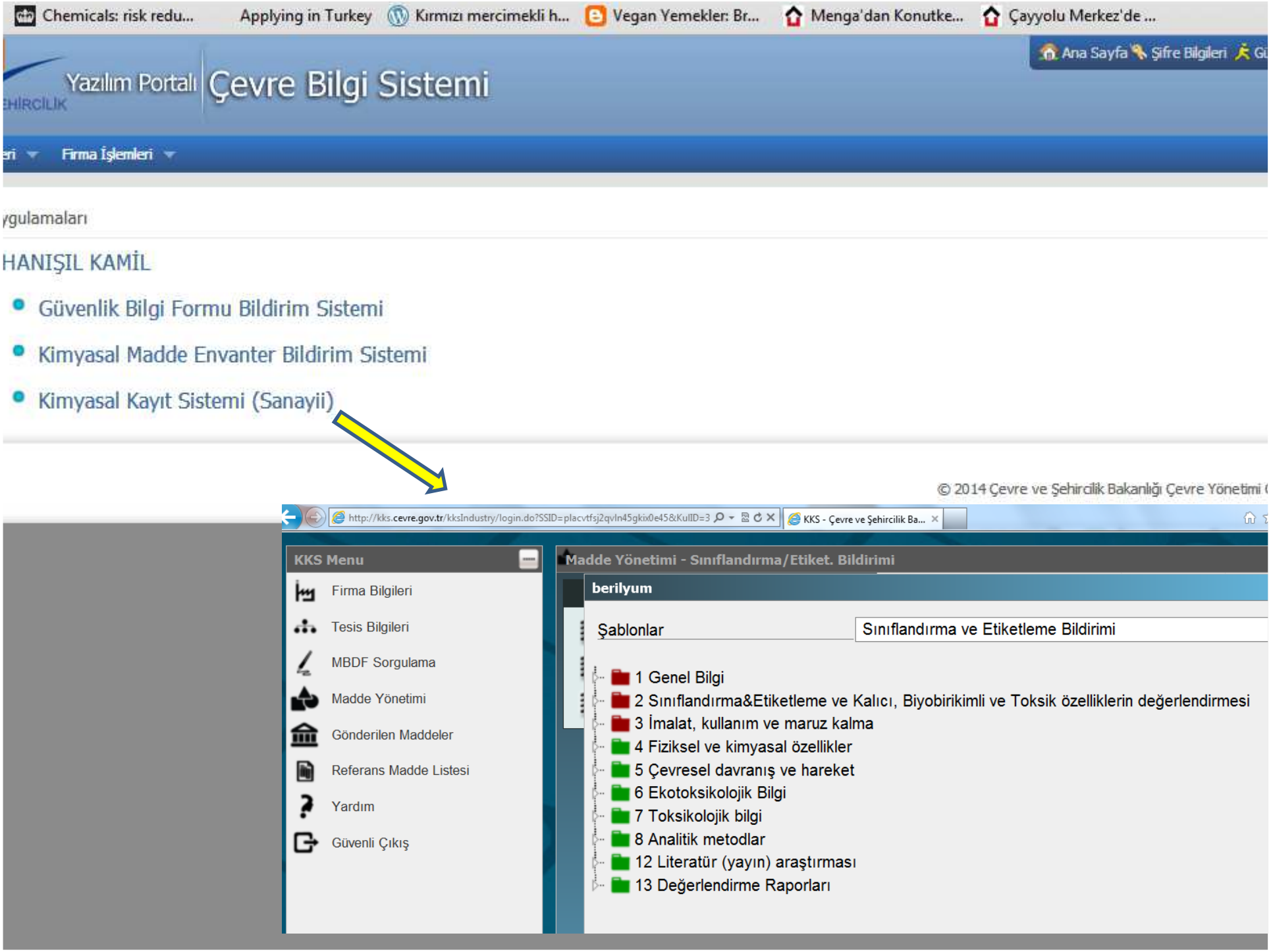
Manufacturer, importer and distributor responsible with the placing on the market of the dangerous substance or preparation has to provides the professional user of this dangerous substance or preparation a safety data sheet

- ✓ Feeless
- ✓ Turkish
- ✓ Supplied via paper or electronically
- ✓ A copy to relevant inst. and electronic copy to MoEU
- ✓ **Prepared by persons certified** by institutions which are acredited about certification of persons

CHEMICALS REGISTERING SYSTEM

http://online.cevre.gov.tr




Chemicals: risk redu...
Applying in Turkey
Kırmızı mercimekli h...
Vegan Yemekler: Br...
Menga'dan Konutke...
Çayyolu Merkez'de ...
Yazılım Portalı
Çevre Bilgi Sistemi
Ana Sayfa
Şifre Bilgileri
Firma İşlemleri
ygulamaları
HANIŞIL KAMİL
Güvenlik Bilgi Formu Bildirim Sistemi
Kimyasal Madde Envanter Bildirim Sistemi
Kimyasal Kayıt Sistemi (Sanayii)
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http://kks.cevre.gov.tr/kksIndustry/login.do?SSID=placvtfsj2qvln45gkix0e45&KullD=3
KKS - Çevre ve Şehircilik Ba...
KKS Menu
Firma Bilgileri
Tesis Bilgileri
MBDF Sorgulama
Madde Yönetimi
Gönderilen Maddeler
Referans Madde Listesi
Yardım
Güvenli Çıkış
Madde Yönetimi - Sınıflandırma/Etiket. Bildirimi
berilyum
Şablonlar
Sınıflandırma ve Etiketleme Bildirimi
1 Genel Bilgi
2 Sınıflandırma&Etiketleme ve Kalıcı, Biyobirikimli ve Toksik özelliklerin değerlendirmesi
3 İmalat, kullanım ve maruz kalma
4 Fiziksel ve kimyasal özellikler
5 Çevresel davranış ve hareket
6 Ekotoksikolojik Bilgi
7 Toksikolojik bilgi
8 Analitik metodlar
12 Literatür (yayın) araştırması
13 Değerlendirme Raporları

BY-LAW ON RESTRICTIONS AND PROHIBITIONS OF HAZARDOUS SUBSTANCES AND MIXTURES

Asbestos
Polychlorinated terphenyls (PCT)
Polychlorinated biphenyls (PCB)
Polybromobiphenyls (PBBs)

can not be
manufactured
used
placed on the market

Azo colourants & Azo dyes
Some Phytalates(DEHP/DBP/BBP/DINP/DIDP/DNOP)
Tris (2,3 dibromopropyl) phosphate
Tris (aziridinyl) phosphine oxide
Mercury, Cadmıum and Nickel and their compounds
Lead Carbonates, Lead Sulphates
Arcenic Compounds
Organostannic Compounds
Pentachlorophenol
PFOS
Nonylphenol

RESTRICTED

IMPLEMENTATION OF EU REACH REGULATION

Seminars/Guidelines/CARACAL

REACH Advisory Group (6 Ministries&12 Industrial Organizations)

REACH Chemicals Project 2011-2013 (IPA Project)

- Awareness of major groups (manufacturers, importers, downstream users of chemicals) and decision makers has been raised.
- Chemicals Helpdesk & Chemicals Registering System has been established
- Draft legislation (KKDİK By-Law) and guidelines on REACH has been prepared.

CHEMICALS HELPDESK

https://kimyasallar.csb.gov.tr

KKDIK BY-LAW

- Scope
- Exemptions
- Registration
- Evaluation
- Athorization (31.12.2020)
- Restriction

REGISTRATION (31.12.2018-31.12.2020)

- Own Registration System (KKS)
- Pre- SIEF (deadline 31/12/2018)
- Same registration deadline for all tonnage ranges (between 31/12/2018-31/12/2020)
- Fee policy likewise REACH

Annex XVII

- Currenty 20 substances and substance groups (s&sg) in Restr. By-Law
- 18 s&sg 6 months after the date of publication
- 20 s&sg in 31/12/2017
- 1 substance in 31/12/2019

- 2 substances added to the By-Law on the reduction of Ozone Deplating Substances
- 3 substances added in the By-law that harmonizes EU POPs Reg.

THANK YOU FOR YOUR ATTENTION

Ahu ÇEKİM
Expert
Chemicals Management Department
Ministry of Environment and Urbanization

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REACH & CLP: CROATIAN EXPERIENCE AND ACCESSION ISSUES

Sandra Pezelj Mestric, senior environmental protection inspector, Ministry for Environmental and Nature Protection

Content

- REACH & CLP timeline – short overview
- Croatia's road to EU membership
- Transfer of rights and obligations from OR to a (new) EU manufacturer
- Environmental professionals, REACH & CLP

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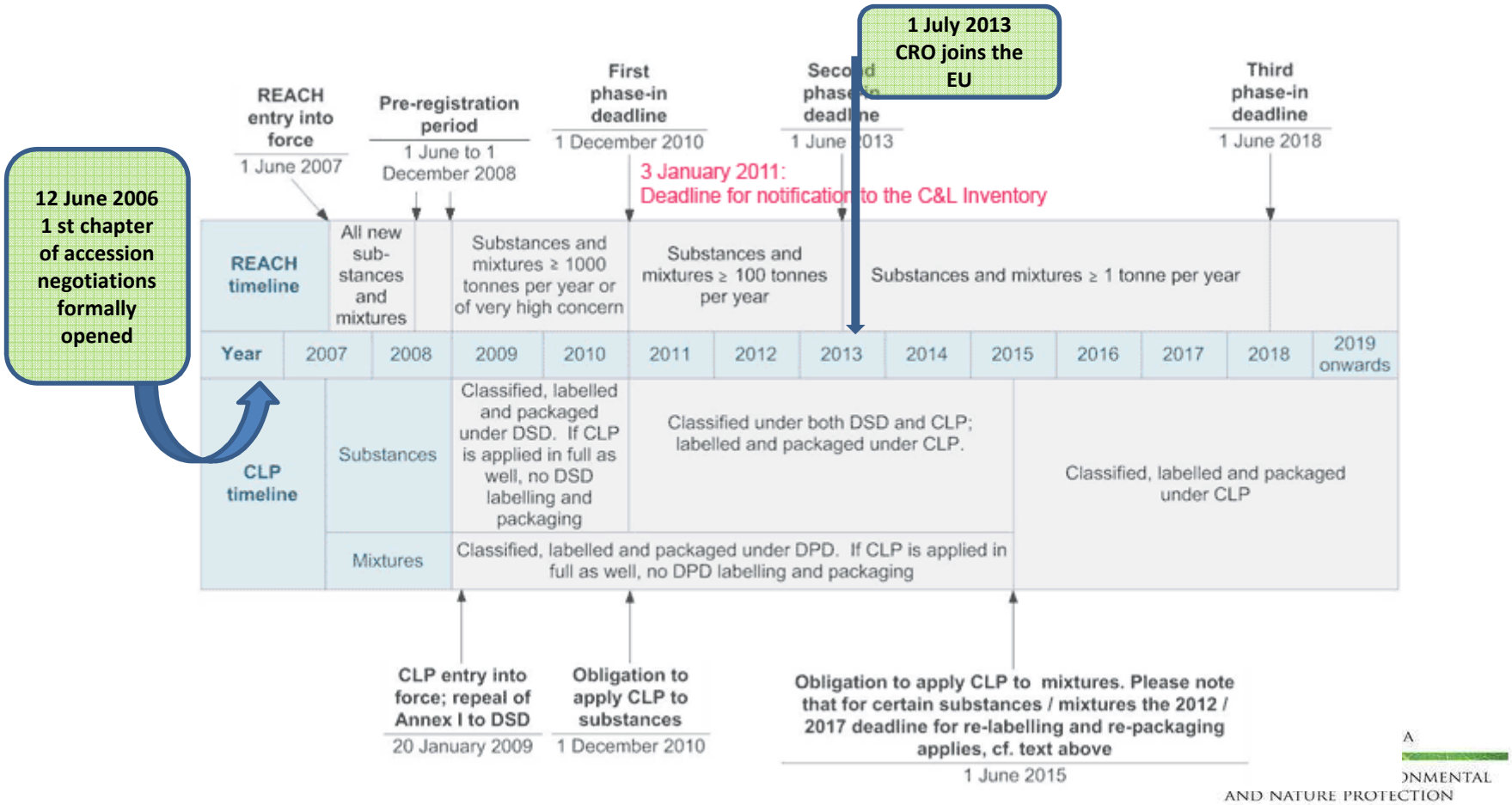
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

REACH & CLP TIMELINE



Croatia: Situation on 30 June 2013

NON – EU

CRO MANUFACTURER

- Production site
- Exports to EU
- Contract with EU OR
- Not present in ECHA
- National HELP-desk

EU

ONLY REPRESENTATIVE

- Office
- -Contract with non-EU manufacturer
- Responsible for documents
- Responsible for legal issues
- Officialy contacts DU within EU

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MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

Croatia: Situation on 1 July 2013

- CRO becomes the 28th EU member
- NON-EU manufacturer ⟶ EU manufacturer = **NEW LEGAL ENTITY !**

» Contact ECHA
» Register substances
» Contact DUs
» OR status?
» **FEES?**

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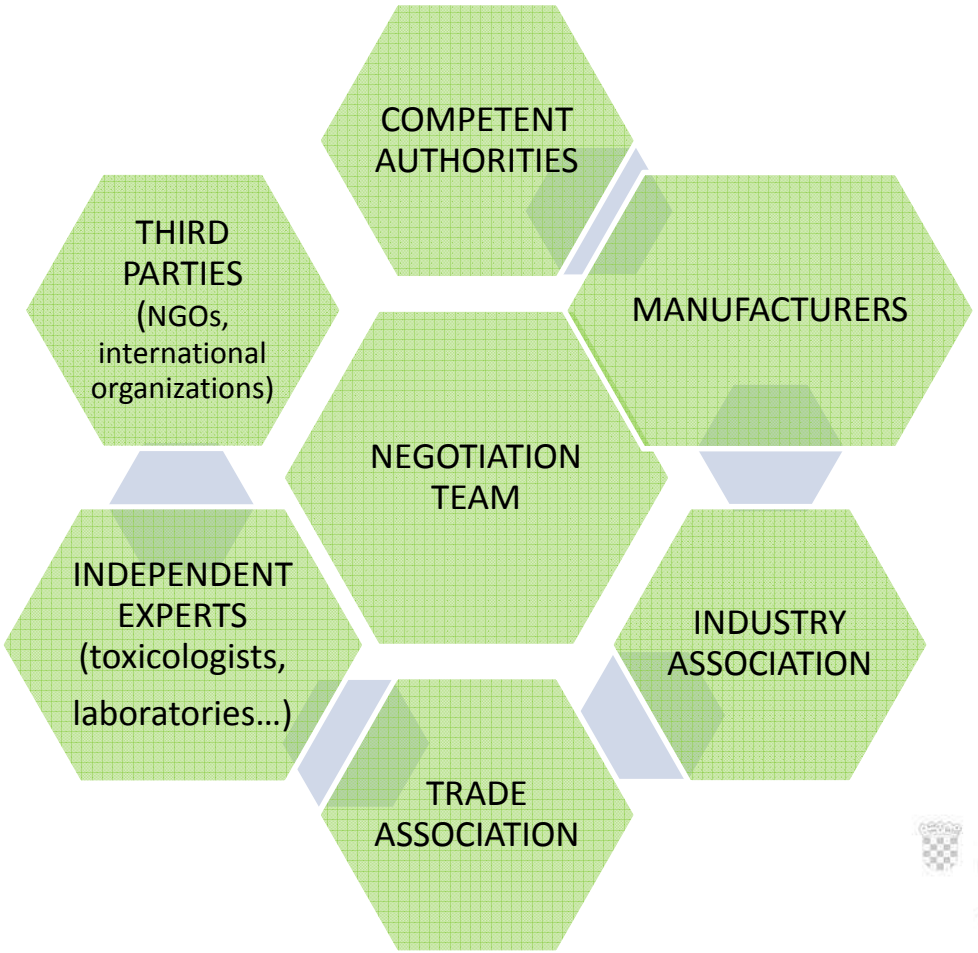
Recommendations (1): transparent communication within the candidate country



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Recommendations (2):

- Allocation of responsibilities from OR to manufacturer – to be defined in the contract (include all obligations, costs,…)
- Lessons learnt and best practices from previous integration processes
- Well informed and prepared negotiation team (problematic issues, longer implementation period, other,…)

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Croatia: results of negotiations

- REACH - part of Chapter 27: Environment
- Direct allocation of responsibilities from OR to manufacturer without additional costs
- 6 months delay for second phase-in deadline

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Environmental professionals, REACH & CLP

- Permitting
- Waste
- SEVESO – exposure scenario, risk assessment

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Why? How?

WASTE:

- completely excluded from REACH
- waste is not considered to be a substance, mixture or article under CLP, waste treatment operators are not considered as downstream users
- SDS FOR WASTE?!

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WASTE - BASIC CHARACTERISATION & SDS

Gather all available information

- Substance / mixture identity
- Details of impurities, additives
- Assess the hazardous properties of the waste

SDS section 13: disposal considerations

(see: ECHA GUIDANCE ON THE COMPILATION OF SDS, November 2015)

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Example – SDS chapter 13

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
- 13.1.1 Product / Packaging disposal

Waste codes / waste designations according to LoW

- 13.1.2 Waste treatment-relevant information
- 13.1.3 Sewage disposal-relevant information
- 13.1.4 Other disposal recommendations

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WASTE & CLP

- Waste Framework Directive: classification of waste must be based on EU chemical classification legislation

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Weak spots and potentional improvment

- SMEs (non-EU manufacturers)– building capacities through professional institutions, chambers of economy
- Stronger REACH&CLP enforcement in non-production domain (waste, product labelling,…)

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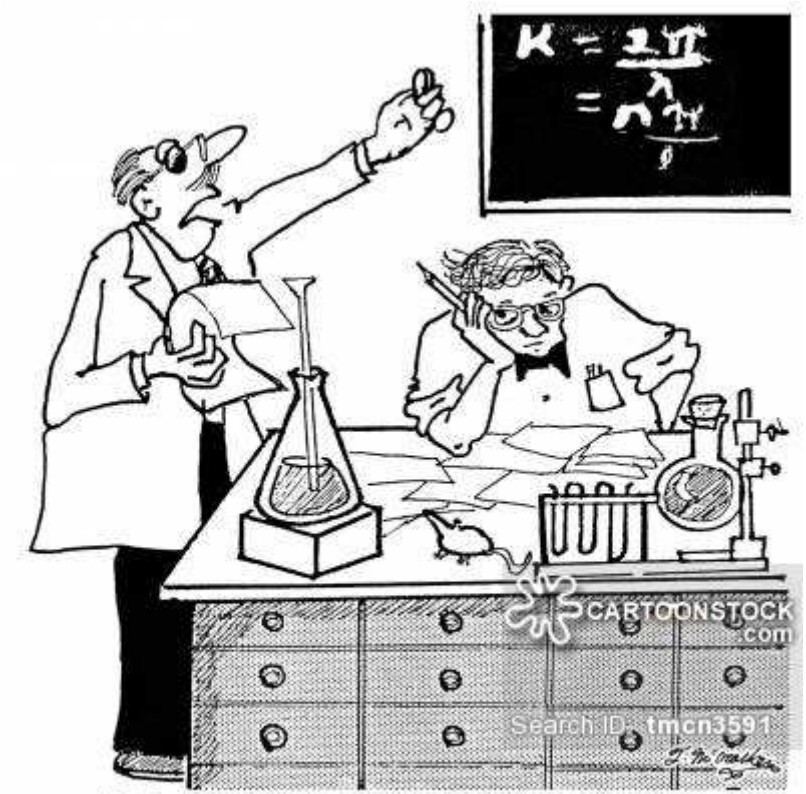
Use the information reasonably!



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Questions?

THANK YOU FOR YOUR ATTENTION!

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Directorate for inspection
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TAIEX-ECRAN

ECRAN Capacity buliding on compliance with chemicals legislation

Implementation of Chemical Legislation in Croatia – Enforcement Aspects

Istanbul, Turkey, 8 – 10 December, 2015

Miljenka Kliček, senior environmental protection inspector,
Ministry for Environmental and Nature Protection,
REPUBLIC OF CROATIA

Content

- LEGAL FRAMEWORK
- ENFORCEMENT STRATEGIES
- RELATION TO OTHER LEGISLATION – SEVESO III
- COOPERATION AND COORDINATION BETWEEN ENFORCEMENT AUTHORITIES
- MINIMUM CRITERIA FOR INSPECTIONS
- CONCLUSION

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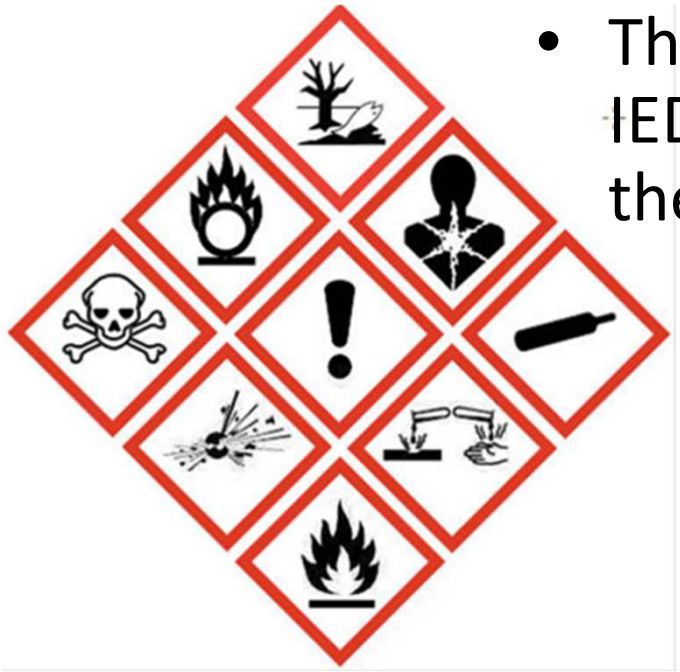
LEGAL FRAMEWERK



- REACH and CLP are regulations and are directly applicable to national law
- There are linkages of REACH/CLP with IED, SEVESO and Waste management in the national Croatian legislation
  - Evironmental Protection Act, O.G.80/13, 153/13 and 78/15
  - Act on sustainable waste management, O.G. 94/13

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CONDITIONS FOR ENFORCEMENT

Effective implementation of legislation can be guaranteed only if its requirements are enforced in an appropriate and effective way.

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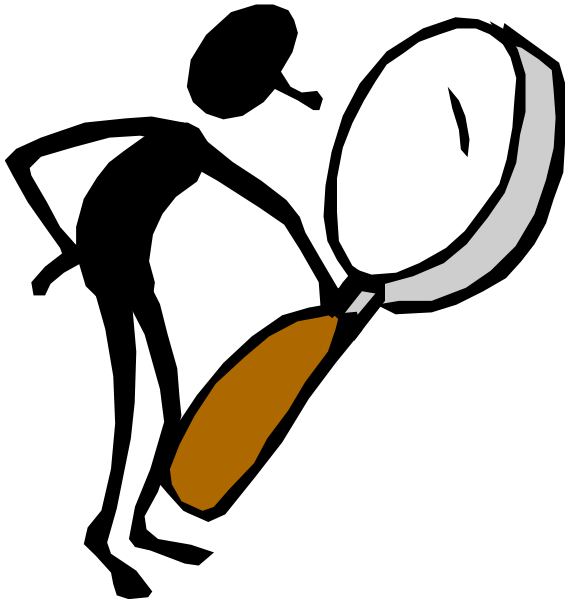
WHY TO ENFORCE?



Inspection and enforcement approaches often aim to achieve one or more of the following:

- Return violators to compliance
- Impose a sanction to prevent future violations
- Remove economic benefit of non-compliance
- Correct environmental damages
- **Ensure safety of man and environment**
- Correct internal company management problems

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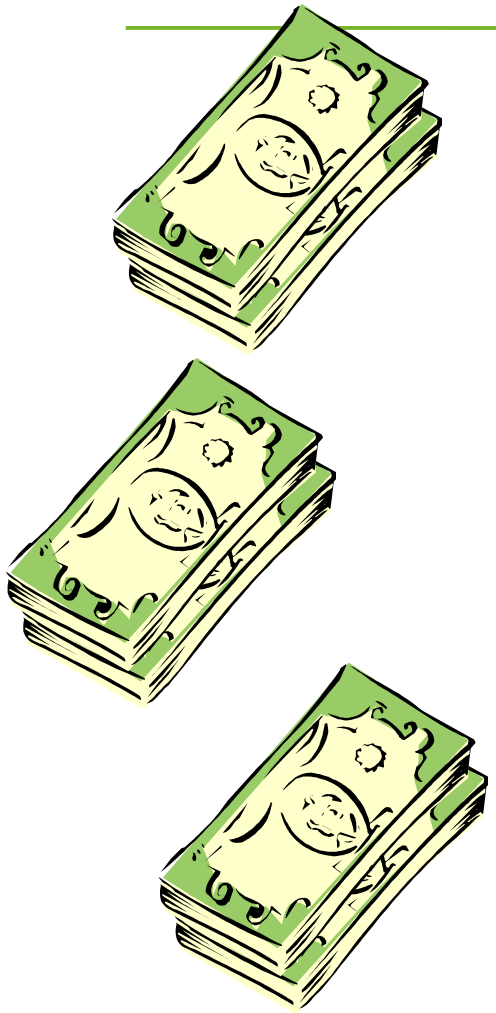
REMOVE ECONOMIC BENEFIT OF NON-COMPLIANCE



- A base set notification costs about €120,000 to €170,000 and one needs about one year to collect all data required.
- A company that does not notify/register has an unfair advantage in competition.
- Therefore chemical industry is interested in compliance monitoring by the authorities to ensure the same market conditions for all companies in Europe.

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ENSURE SAFETY OF MAN AND ENVIRONMENT

Downstream useage of chemicals:
Storage of big/small amounts of chemicals

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ENSURE SAFETY OF MAN AND ENVIRONMENT

Downstream use of chemicals:
Storage of gaseous substances /liquide chemicals

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ENSURE SAFETY OF MAN AND ENVIRONMENT

Downstream usege of chemicals:

- toxic gas - chlorine
- ozon layer depleting substances

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ENSURE SAFETY OF MAN AND ENVIRONMENT

PROCESS INDUSTRY

Major hazard sites are industrial sites that manufacture, process or store dangerous chemicals and substances in quantities that could pose a risk to workers, people in the vicinity of the site, and the environment in the event of a major accident.

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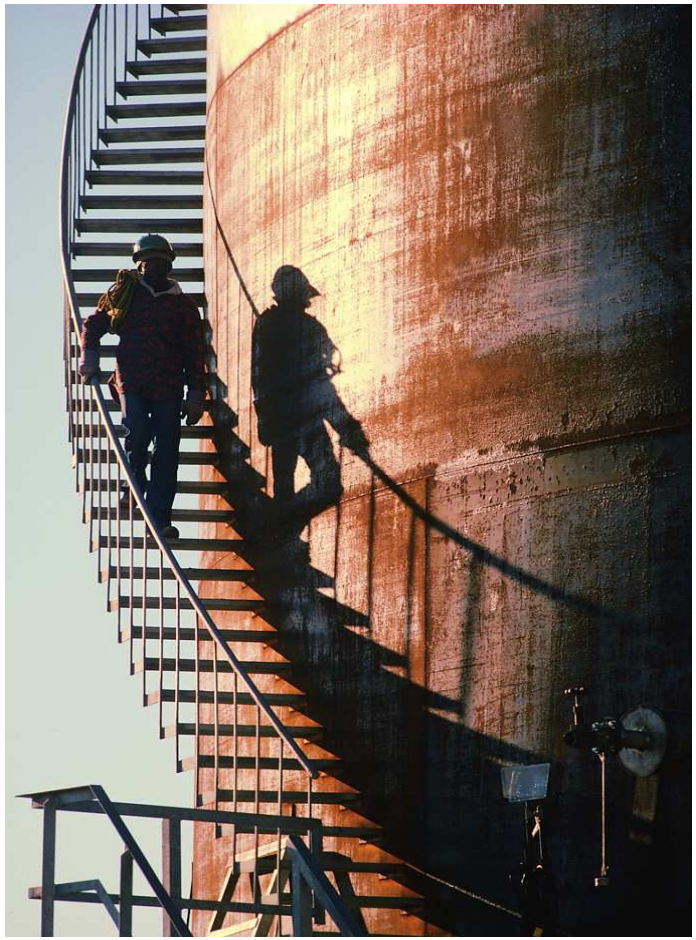
RELATION TO SEVESO III



Article 1

Subject matter

This Directive lays down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to ensuring a high level of protection throughout the Union in a consistent and effective manner.

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MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

RELATION TO SEVESO III
IDENTIFICATION OF DANGEROUS SUBSTANCES

DIRECTIVE 2012/18/EU
art.3., point 12

'presence of dangerous substances' means the actual or anticipated presence of dangerous substances in the establishment, or of dangerous substances which it is reasonable to foresee may be generated during loss of control of the processes, including storage activities, in any installation within the establishment, in quantities equal to or exceeding the qualifying quantities set out in Part 1 or Part 2 of Annex I;

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MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

IDENTIFICATION OF DANGEROUS SUBSTANCES

KOMERCIJALNO IME	SASTOJCI KOJI PRIDONOSE OPASNOSTI PROIZVODA	EINECS / CAS BROJ	IZGLED	OZNAČAVANJE			TRANSPORT / SKLADIŠTENJE
				ZNAK OPASNOSTI	OZNAKA UPOZORENJA "R"	OZNAKA OBAVIJESTI "S"	
Acetilen	acetilen	200-816-9 / 74-86-2	plin	F+	5, 6, 12	7, 9, 16, 33	boce pod tlakom
Amonijak - bezvodni	amonijak	231-635-3/ 7664-41-7	plin	T,N	10, 23, 34, 50	9, 16, 26, 36/37/39, 45, 61	boce pod tlakom
Dizelsko gorivo	smjesa ugljikovodika	269-822-7 / 68334-30-5	Žućkasta tekućina	Xn	40	36/37	cist / spr. / bačve
Dowtherm G	(eter, oksid, fenol)	8004-13-5	Smeđa tekućina	Xn	20/21/22	23, 24/25 36/37/39	spremnik
Dušik, tekući*	dušik	231-783-9/ 7727-37-9	ukapljeni plin, bez boje			7, 9, 16, 36/37/39	spremnik
EC6210A	-etilen glikol (30-60% -sol masnog amina	-	Jantarna tekućina	Xn, N	22, 38, 41, 51/53	24725, 26, 36/37/39, 46	bačve
Etilen	etilen	200-815-3 / 74-85-1	ukapljeni plin, bez boje	F+	12, 67	9, 16, 33, 36/37/39	brod/ spremnik
Etilen diklorid	1,2 dikloretan	203-451-1 /107-06-2	Bezbojna tekućina	T, F	11, 22, 45, 36/37/38	45, 53	brod/ spremnik
Etilen glikol	Etilen glikol	203-473-3 /107-21-1	Bezbojna uljasta tekućina	Xn	22	20, 24, 25, 36/37/39, 45	spremnik
Fuelsolv OMG 2562	-plinsko ulje (30-60% -loživo ulje br.2 (10-30%)	-	crveno-smeđa tekućina	Xn, N	40, 66, 51/53	26, 28, 36/37/39, 61	bačve
INA Antifriz AI 40	etilen-glikol	203-473-3 / 107-21-1	bezbojna uljasta tekućina	Xn	22	20, 24, 25, 36/37/39, 45	bačve
Izododekan	2,2,4,6,6-pentametilheptan	297-629-81/ 93685-81-5	Bezbojna tekućina	Xn	10, 65	23, 24, 62,	Cisterna /spremnik
Vodikov klorid		231-595-7 /7647-01-0	Bezbojan plin	T,C	23, 35	9, 26, 36/37/39, 45	spremnik
Kisik	O_2	231-956-9/ 7782-44-7	Bezbojan ukapljeni plin	O	8	7, 9, 16, 17, 36/37/39	spremnik

ANNEX 1:

PART 1

Categories of dangerous substances

This Part covers all dangerous substances falling under the hazard categories listed in Column 1:

Column 1	Column 2	Column 3
Hazard categories in accordance with Regulation (EC) No 1272/2008	Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	
	Lower-tier requirements	Upper-tier requirements
Section 'H' – HEALTH HAZARDS		
H1 ACUTE TOXIC Category 1, all exposure routes	5	20
H2 ACUTE TOXIC — Category 2, all exposure routes — Category 3, inhalation exposure *route* (see note 7)	50	200
H3 STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE STOT SE Category 1	50	200
Section 'P' – PHYSICAL HAZARDS		

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SDS-HAZARD identification

EXAMPLE: METHANOL

SECTION 2. HAZARDS IDENTIFICATION

Classification ***(EC 1272/2008)***	2.6 — Flammable liquids, Hazard Category 2 3.8 — Specific target organ toxicity — single exposure, Hazard Category 1 3.1 — Acute toxicity (inhal.), Hazard Category 3 3.1 — Acute toxicity (dermal), Hazard Category 3 3.1 — Acute toxicity (oral), Hazard Category 3	
Classification ***(67/548/EEC)***	HIGHLY FLAMMABLE TOXIC	R11 R23/24/25, 39/23/24/25
Label Elements:		
Signal Word	**DANGER**	
Hazard Statements	H225 H331 H311 H301 H370	Highly flammable liquid and vapour. Toxic if inhaled. Toxic in contact with skin. Toxic if swallowed. Causes damage to organs.
Precautionary Statements	P210 P233 P280 P307+P311	Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Keep container tightly closed. Wear protective gloves/protective clothing. IF exposed: Call a POISON CENTER or doctor/physician.
Supplemental information	Not applicable	
Other hazards	Risk of blindness if product is swallowed. Not classified as PBT or vPvB, based on the assessment carried out according to Annex XIII of REACH Regulation.	

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SDS-HAZARD identification

ODJELJAK 2. IDENTIFIKACIJA OPASNOSTI		
2.1.	Razvrstavanje tvari ili smjese	
2.1.1.	Razvrstavanje prema uredbi (EZ-a) br. 1272/2008 (CLP)	
	Razred (klasa) opasnosti i kod kategorije:	Oznaka upozorenja*:
	Zap. tek. 2 Ak. toks. 3 Ak. toks. 3 Ak. toks. 3 TCOJ 1	H225 Lako zapaljiva tekućina i para. H301 Otrovno ako se proguta. H311 Otrovno u dodiru s kožom. H331 Otrovno ako se udiše. H370 Uzrokuje oštećenje organa.
2.1.2.	Dodatne obavijesti	
	Klasifikacija odgovara aktualnim propisima EU. Ista je međutim dopunjena podacima iz stručne literature i podacima poduzeća.	
*Puni tekst H i EUH oznaka dan je u Odjeljku 16.		
2.2.	Elementi označavanja prema direktivi 1999/45/EZ ili uredbi (EZ-a) br. 1272/2008 CLP)	
	Identifikacija proizvoda:	**Metanol**
	Indeksni broj:	-
	Broj autorizacije:	-
	Piktogrami:	
	Oznaka opasnosti:	OPASNOST
	Oznake upozorenja:	H225 Lako zapaljiva tekućina i para. H301 Otrovno ako se proguta. H311 Otrovno u dodiru s kožom. H331 Otrovno ako se udiše. H370 Uzrokuje oštećenje organa.
	Oznake obavijesti:	P210 Čuvati odvojeno od topline/iskre/otvorenog plamena/vrućih površina – Ne pušiti. P233 Čuvati u dobro zatvorenom spremniku. P280 Nositi zaštitne rukavice/zaštitno odjelo/zaštitu za oči/zaštitu za lice. P308+P311 U SLUČAJU izloženosti ili sumnje na izloženost: nazvati CENTAR ZA KONTROLU OTROVANJA/liječnika. P501 Odložiti sadržaj/spremnik u skladu s Zakonom o otpadu-predati tvrtki ovlaštenoj za zbrinjavanje otpada.
	Dodatni podaci o opasnostima:	-
2.3.	Ostale opasnosti	
	-	

EXAMPLE: METHANOL
Translation obligatory

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MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

RELATION TO SEVESO III
SAFETY REPORT

DIRECTIVE 2012/18/EU
introduction, point 15

„That **safety report** should contain details of the establishment, the dangerous substances present, the installation or storage facilities, possible major- accident scenarios and risk analysis, prevention and intervention measures and the management systems available, in order to prevent and reduce the risk of major accidents and to enable the necessary steps to be taken to limit the consequences thereof."

SDS content

- SECTION 4. First aid measures
- SECTION 5. Fire fighting measures
- SECTION 6. Accidental release measures
- SECTION 7. Handling and storage
- SECTION 8. Exposure controls/personal protection
- SECTION 9. Physical and chemical properties
- SECTION 10. Stability and reactivity

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RELATION TO SEVESO III
MAJOR ACCIDENT PREVENTION

Major accident means an occurence such as a major emission, fire or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by Directive , and leading to serious danger to human health or the environment, immediate or delayed, inside or outside an establishment, involving one or more dangerous substances.

Bhopal plant, 1984

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MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

ENFORCEMENT IS NATIONAL RESPONSABILITY

INSPECTION

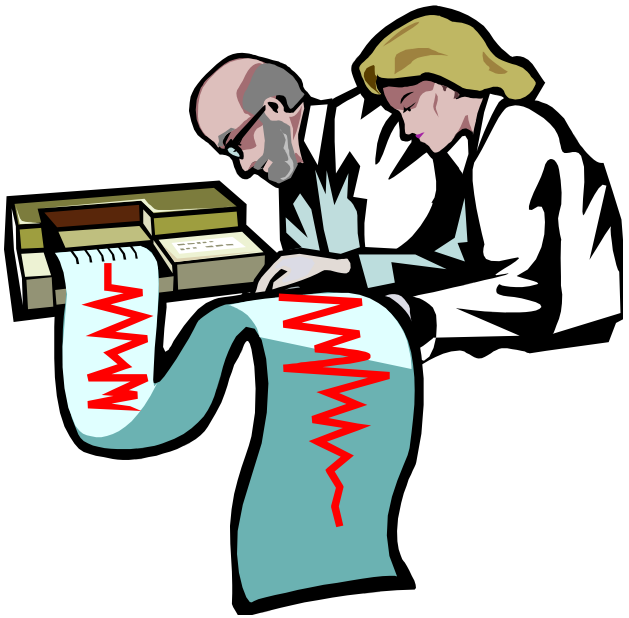
- Preventative side of the inspector's work
- Checking the compliance with the rules

ENOFRCEMENT

- Repressive by nature
- 'Lead' the offender back to compliance

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

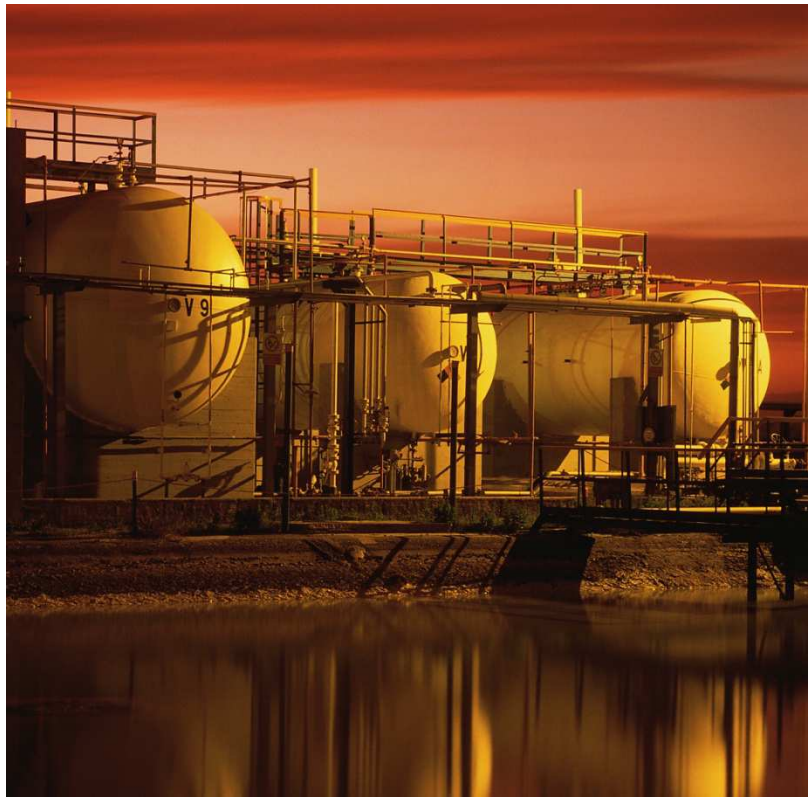
ENFORCEMENT STRATEGIES



- a range of actions that national authorities initiate to verify the compliance with REACH and CLP Regulations
- the principles that will be followed:
  - priority setting,
  - frequencies of inspections,
  - how to deal with inspection outcomes,
  - which quantitative and qualitative resources are needed,
  - which inspection and enforcement tools are needed and how to apply them

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

INTEGRATED APPROACH



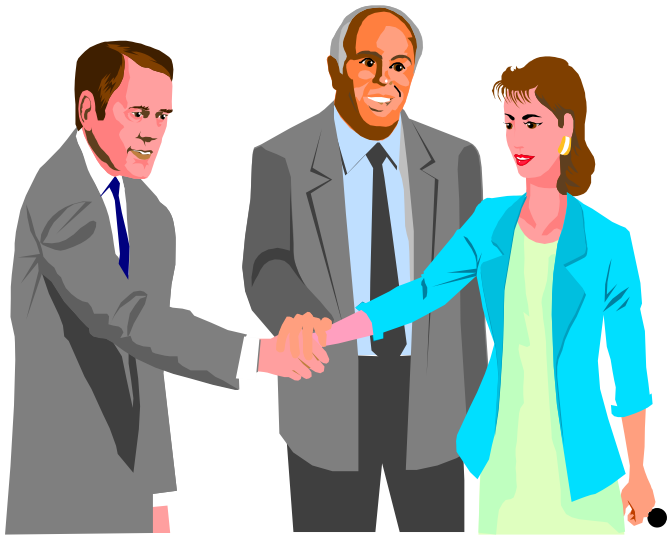
Principle of Integrated Approach

(Environmental protection act, OG 80/13, 153/13, 78/15; Article 14.)

The purpose of the principle of integrated approach is the prevention of environmental risk and/or the reduction of environmental risk to a minimum risk to the environment as a whole.

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

COOPERATION AND COORDINATION BETWEEN ENFORCEMENT AUTHORITIES



- Agreement on co-opertaion between inspection services in the field of environment, from 5. Jun 2008.
  - Co-ordinated inspection controls of IED and SEVESO instalations
  - Annual plan, submited report on co-ordinated inspection available on web
- The environmental inspectorate play a coordinating role.

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

MINIMUM CRITERIA FOR INSPECTIONS - INSPECTION PERFORMANCE

- PLANNING THE INSPECTION
- PREPARING THE INSPECTION
- ON SITE VISIT
- REPORTING
- LEGAL ACTION
- FOLLOW UP INSPECTION

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

ANNUAL PLAN – EXTRACT FOR OCTOBER 2015

listopad

49.	C.I.A.K. d.o.o., Zabok skladište opasnog otpada Zabok www.ciak.hr	2.5.(a) 5.1. (c)	• Vodopravna- Mirjana Tuđak • MUP • Sanitarna - Danica Matek • Elektroenergetska- Božidar Bradač • Oprema pod tlakom -Božidar Borovec • Zaštita na radu • DUZS - Nevenka Sugnetić	5. - 9.	Zora Jelić
50.	JANAF d.d. - Terminal Omišalj www.janaf.hr	SEVESO	• Vodopravna- Dženan Avdić • MUP (nadležna Policijska uprava) • Sanitarna - Dražen Nalis • Elektroenergetska - Zlatko Jurković • Oprema pod tlakom - Eol Bulić • Zaštita na radu • DUZS - Nevenka Sugnetić	5. - 9.	Miljenka Kliček
51.	OMIAL NOVI d.o.o., Omiš proizvodnja oplemenjenih folija www.omial.hr	6.7.	• Vodopravna- Slavica Čikotić • MUP (nadležna Policijska uprava) • Sanitarna - Anđa Puljiz • Elektroenergetska- Kaarija Tomić • Oprema pod tlakom - Vesna Perić • Zaštita na radu	12. - 16.	Ante Belamarić
52.	HEP-PROIZVODNJA d.o.o., Pogon EL-TO Zagreb proizvodnja toplinske i električne energije www.hep.hr	1.1.	• Vodopravna- Zvonimir Mayer • MUP (nadležna Policijska uprava) • Sanitarna - Zvonimir Kramarić i Mirjana Brkić • Elektroenerg.– Zvonko Harže-Hanđin • Oprema pod tlakom – Ivan Sačinec • Zaštita na radu	12. - 16.	Snježana Šimunić
53.	DUKAT d.d., Tvornica Sirela Bjelovar proizvodnja mlijeka www.dukat.hr	6.4.(c)	• Vodopravna- Natalija Vodopija • MUP (nadležna Policijska uprava) • Sanitarna - Valentina Zoretić- Rubes i Katica Mršić • Elektroenerget. – Mirjana Pedovan • Oprema pod tlakom – Ivan Sačinec • Zaštita na radu • Veterinarska -Tatjana Karačić	19. - 23.	Renata Miletić
54.	DINA Petrokemija d.d. - Proizvodnja, terminali i servisi iz Omišlja	SEVESO	• Vodopravna- Dženan Avdić • MUP (nadležna Policijska uprava) • Sanitarna - Dražen Nalis • Elektroenergetska - Zlatko Jurković • Oprema pod tlakom - Eol Bulić • Zaštita na radu • DUZS - Nevenka Sugnetić	26. - 30.	Miljenka Kliček
55.	TUP d.d., Dubrovnik Proizvođač ugljenih poluproizvoda i elektrografitnih industrijskih dijelova www.tup-carbon-graphite.eu/hr	6.8.	• Vodopravna – Ante Krstičević • MUP (nadležna Policijska uprava) • Sanitarna - Dubravka Marija Kreković • Elektroenergetska- Srđan Vukičević • Oprema pod tlakom - Vesna Perić • Zaštita na radu	26. - 30.	Diana Rački

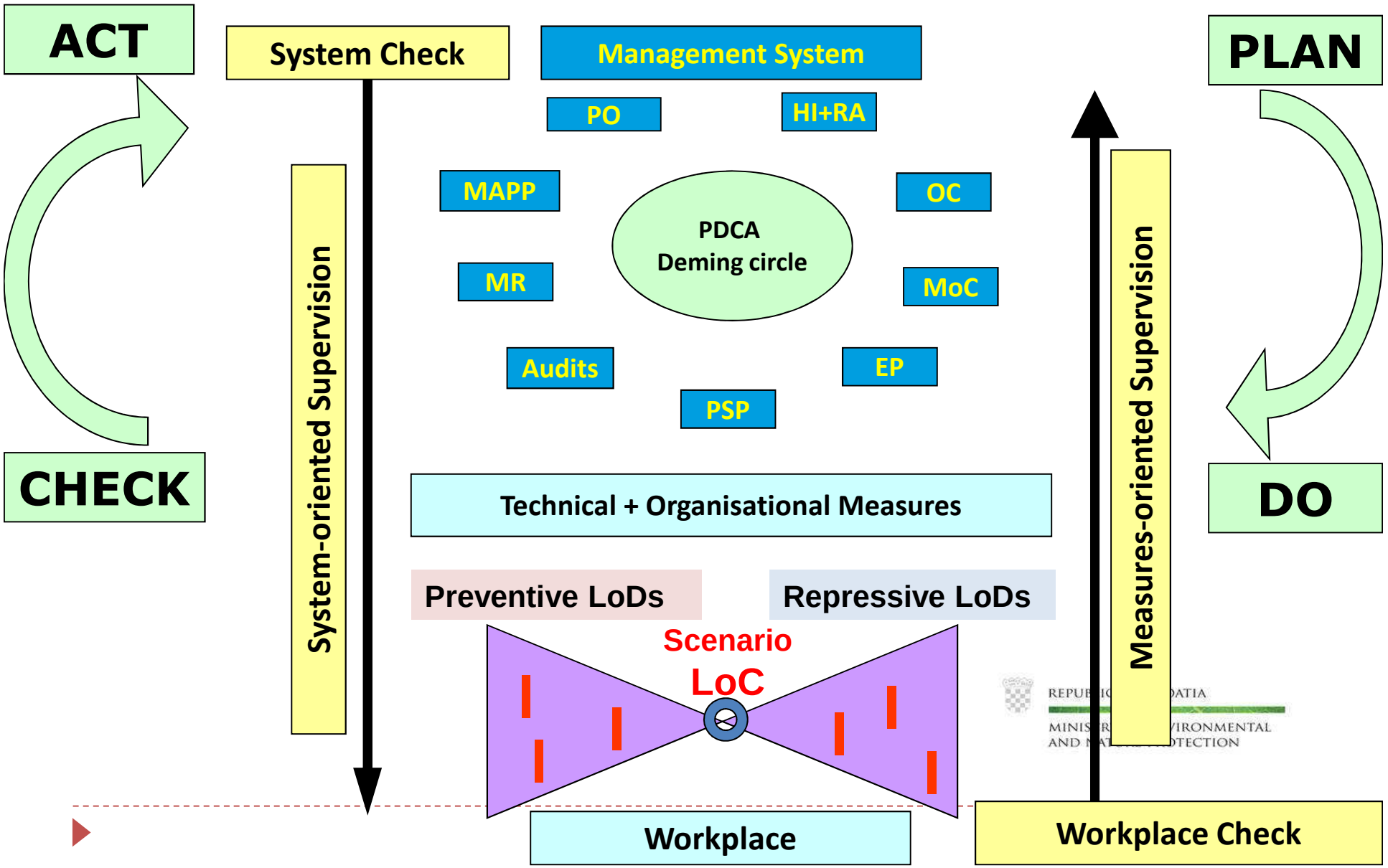
REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

PREPARING THE INSPECTION

- ANNOUCEMENT LETTER TO THE OPERATOR
- COORDINATION WITH OTHER INSPECTORS
- PREPARATORY MEETING
- CLOSE UP MEETING WITH OPERATOR

Red.br.	Datum nadzora	Nadležno tijelo	Ime inspektora	Predmet nadzora
1.	3.11.2014.	Ministarstvo zaštite okoliša i prirode – Inspekcija zaštite okoliša	Miljenka Kliček	UVODNI SASTANAK, Postupanje prema uvjetima iz Rješenja o objedinjenim uvjetima zaštite okoliša; postupanje s otpadom, zaštita zraka – mjerenje emisija; prijave u registar onečišćavanja okoliša
3.	3.11.2014	Ministarstvo rada i mirovinskog sustava - Inspekcija rada	Marinka Golubar	Procjena opasnosti, osobito za rad s kemikalijama, ispravnost strojeva i uređaja s povećanim rizikom
4.	4.11.2014.	Ministarstvo zdravlja – Sanitarna inspekcija	Žaklina Premec	Kemikalije – udovoljavanje uvjetima za skladištenje i uporabu kemikalija, osposobljenost zaposlenih i rukovoditelja iz toksikologije; buka
5.	4.11.2014.	elektroenergetska inspekcija	Zvonko Hanže-Hanzlin	Ispravnost električnih instalacija, gromobranskih instalacija, obveze u svezi protueksplozijske zaštite
6.	5.11.2014.	elektroenergetska inspekcija	Zvonko Hanže-Hanzlin	Ispravnost električnih instalacija, gromobranskih instalacija, obveze u svezi protueksplozijske zaštite
7.	6.11.2014.	Ministarstvo poljoprivrede, Uprava za vodno gospodarstvo, Vodopravna inspekcija		Udovoljavanje uvjetima iz Rješenja o objedinjenim uvjetima zaštite okoliša– Obvezujućeg vodopravnog mišljenja, iznenadna onečišćenja voda (ako ih je bilo), potrošnja vode, obrada i kontrola kakvoće otpadnih voda; obveze po ekonomskim instrumentima zaštite okoliša koji se odnose na vode
2.	6.11.2014	Ministarstvo unutarnjih poslova – Inspekcija zaštite od požara	Danijel Godinić	Ispunjavanje obveza iz Rješenja o kategorizaciji objekata prema ugroženosti od požara, Ispravnost sustava za dojavu i gašenje požara i sustava za dojavu prisutnosti zapaljivih plinova i para
8.	7.11.2014.	Inspekcija za posude pod tlakom	Borovec Božidar	Identifikacija posuda i instalacija pod tlakom, ispravnost istih - pregled opreme i dokumentacije o opremi
	11.11.2014.	Ministarstvo zaštite okoliša i prirode – Inspekcija zaštite okoliša	Svi (po mogućnosti)	Završni sastank s operaterom

Seveso Inspection Methodology



ON SITE VISIT

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

SITE VISIT – THE ROLE OF INSPECTOR

- **Inspector should be able to professionally handle unforeseen situations and should have a high level of technical, legal and administrative knowledge.**
- **Inspector should be familiar with a range of communication techniques, such as human interaction, interviewing techniques, negotiation techniques, conflict handling techniques and even interrogation techniques.**

Quote from: MANUAL FOR IPPC INSPECTIONS, March 2009

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

EXAMPLE – INSPECTION REPORT

INSPECTION REPORT ON COORDINATED SEVESO INSPECTION IN PETROCHEMICAL ISTALLATION

- IZVJEŠĆE izvanredni koordinirani DINA PETROKEMIJA d.d. 2014.doc

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

REPORT EXTRACT FOR MAY/JUNE 2015

br.	Naziv i lokacija nadziranog subjekta	Datum nadzora	Djelatnost	izo	vod	zp	san	polj	el	opt	znr	vet	rud	sto	izs
24.	LTH METALNI LIJEV d.o.o., Benkovac	11. - 15. svibnja	2.5.(b)	*	*		*								
25.	BIOTRON d.o.o., pogon Ozalj	18. - 22. svibnja	4.1. (b) SEVESO[2] niži razred			*			*						*
26.	Calucem d.o.o. Pula	18. - 22. svibnja	3.1.	☑	*										
27.	HEP-PROIZVODNJA d.o.o., Pogon Plomin 1&2	25. – 29. svibnja	1.1.	☑		☑									
28.	PAN tvornica papira Zagreb, Zagreb	25. – 29. svibnja	6.1.(b)	*			☑		*	☑					
29.	Brodograđevna industrija 3. Maj d.d., Rijeka	1.-5. lipnja	6.7.			*									

Legenda:

- Nadzorima nisu utvrđene povrede propisa
- * Nadzorima su utvrđene povrede propisa (izdano rješenje ili zapisnički naređene mjere) *kontrolni nadzor nije obavljen ili je stranka još u ostavljenom roku*
- ☑ Nadzorima su utvrđene povrede propisa, *ali su nepravilnosti otklonjene* – utvrđeno u kontrolnom nadzoru
- ☒ Nadzorima su utvrđene povrede propisa, *ali nepravilnosti nisu otklonjene* – utvrđeno u kontrolnom nadzoru
- Koordinirani nadzor je proveden, ali nije dostavljen izvještaj
- Koordinirani nadzor nije proveden prema planu rada
- Koordiniranim nadzorom nije predviđeno sudjelovanje suradne inspekcije

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

ANNUAL REPORT

VLADA REPUBLIKE HRVATSKE

Na temelju članka 31. stavka 3. Zakona o Vladi Republike Hrvatske (Narodne novine, br. 150/2011 i 119/2014), a u vezi s člankom 256. stavkom 3. Zakona o zaštiti okoliša (Narodne novine, br. 80/2013 i 153/2013), Vlada Republike Hrvatske je na sjednici održanoj 23. srpnja 2015. godine donijela

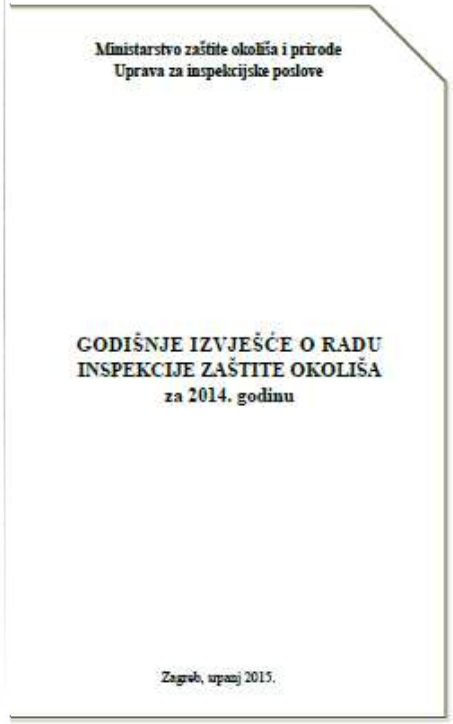
ZAKLJUČAK

Prihvaća se Godišnje izvješće o radu inspekcije zaštite okoliša za 2014. godinu, u tekstu koji je Vladi Republike Hrvatske dostavilo Ministarstvo zaštite okoliša i prirode aktom, klase: 351-02/15-20/130, urbroja: 517-15-8, od 20. srpnja 2015. godine.

Klasa: 022-03/15-07/257
Urbroj: 50301-05/25-15-3

Zagreb, 23. srpnja 2015.

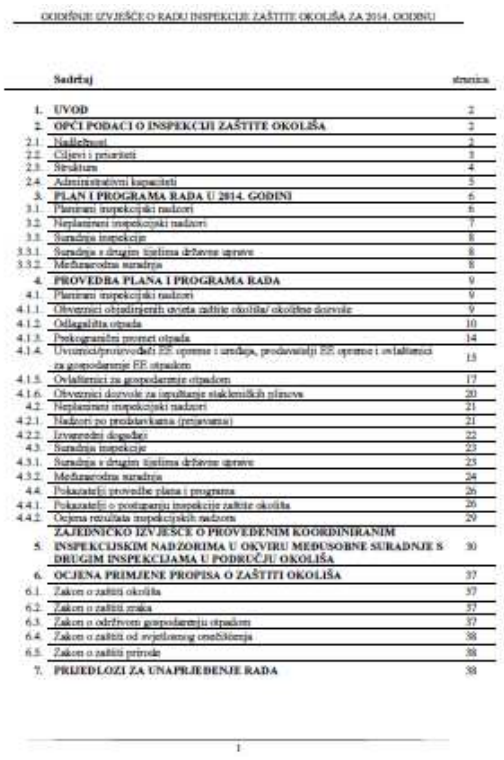
PREDSJEDNIK
Zoran Milanović



Ministarstvo zaštite okoliša i prirode
Uprava za inspekcijske poslove

GODIŠNJE IZVJEŠĆE O RADU INSPEKCIJE ZAŠTITE OKOLIŠA za 2014. godinu

Zagreb, ujanj 2015.



GODIŠNJE IZVJEŠĆE O RADU INSPEKCIJE ZAŠTITE OKOLIŠA ZA 2014. GODINU

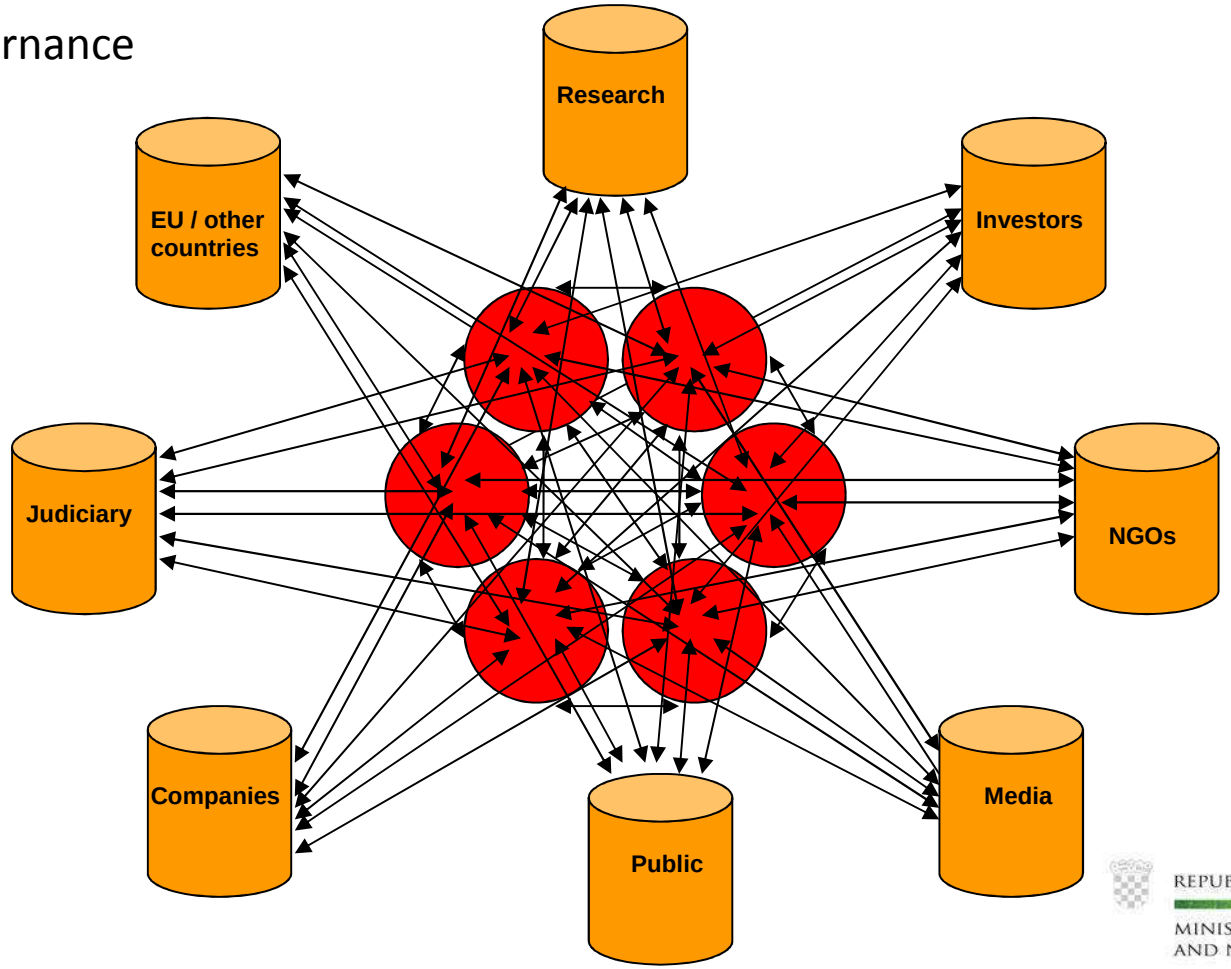
Sadržaj

1

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

CONCLUSION

Good governance



REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

THAK YOU FOR YOUR ATTENTION

Croatian orchid (Hrvatska orhideja)
Dactylorhiza majalis (Kaćunak)

MILJENKA KLIČEK
senior environmental protection inspector
miljenka.klicek@mzoip.hr
00385 91 28 77 176
00385 42 301 681

REPUBLIC OF CROATIA
MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION

THE SEVESO DIRECTIVE

Ike van der Putte

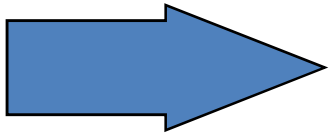
Source: RPS/EC, DG Environment/ECENA

This Project is funded by the European Union

Project implemented by Human Dynamics Consortium

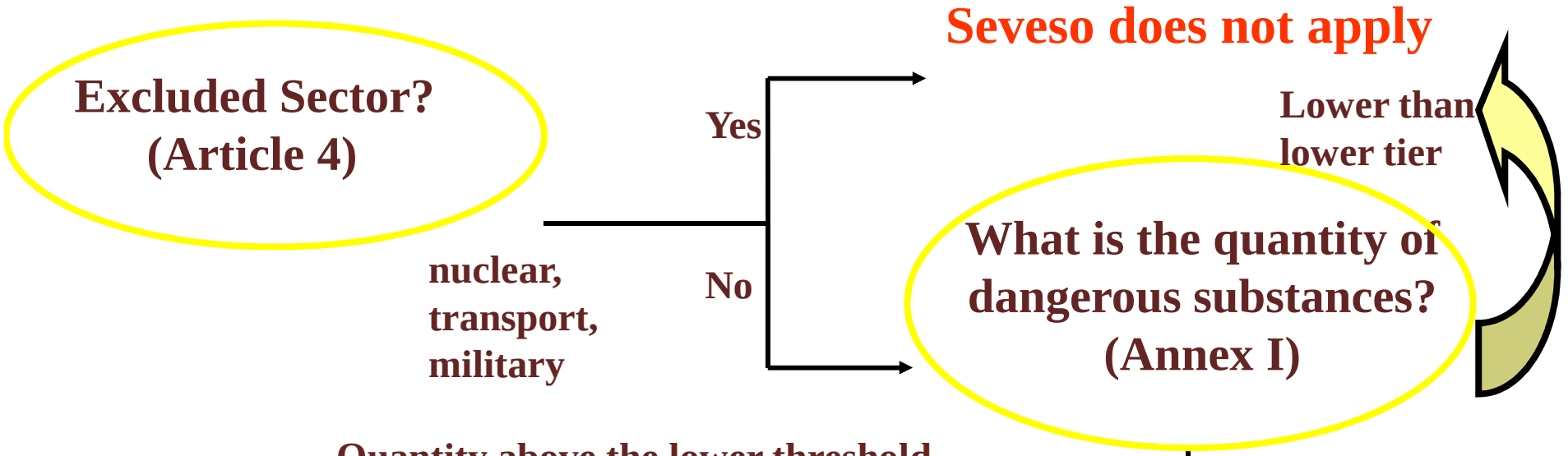
Seveso II Directive - Aim

- **prevention** of major accidents involving dangerous substances
- **limitation of the consequences** of accidents on man and the environment



high level of protection for man and the environment throughout the European Union

Seveso Directive – Scope & main obligations



- Notification
- Major Accident Prevention Policy (MAPP)
- Domino Effects
- Land-use planning
- Inspection

Quantity above the higher threshold

Additionally:

- Safety report (including MAPP and Safety Management System)
- Emergency plans (internal and external)
- Information to the public

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Project implemented by Human Dynamics Consortium

Seveso Directive – Scope, Methods

- ~ 4000 upper + ~ 4000 lower tier establishments storing dangerous substances -EU
- Mainly chemical and petrochemical industry, storage, big industrial production and energy installations
- Criteria: Hazard: Quantity of dangerous substances present

- .. the Seveso II Directive contains no detailed procedures and guidelines for risk assessment and management.

- A variety of such procedures is currently in use, employing different terminologies and underlying philosophies, making cross-comparison of results difficult.

Seveso Directive – Control measures aimed at Prevention

Upper and lower tier:

- General obligations
- Notification
- Major Accident Prevention Policy
- Domino Effects
- Inspection by Competent Authorities

For upper tier only:

- Safety Report
- Safety Management System

Seveso Directive – Control measures aimed at limitation of the consequences

Upper and lower tier:

- General obligations
- Land-Use Planning
- Information to the Public

For upper tier only:

- Emergency Planning
- More information to the Public on MAH

2015 – Seveso III

As a result of the review process, on 21 December 2010 the Commission adopted a proposal for a new Directive, replacing the current SEVESO II Directive by 1 June 2015.

- to align Annex I to the Directive to changes to the EU system of classification of dangerous substances (CLP)
- to include corrective mechanisms to adapt Annex I in the future
- to strengthen the provisions relating to public access to safety information, participation in decision-making and access to justice,
- to introduce stricter standards for inspections of installations to ensure the effective implementation and enforcement of safety rules.
- Stricter Landuse planning requirements

CORRELATION WITH OTHER EU LEGISLATION

- CLP Directives
  - Definition of Hazardous Substances & Preparations
- REACH
  - Chemical Safety reports
  - New Studies on Chemicals – New Classification possible
- GHS
  - New Classification Rules – Downstream Effect
- Labour safety
  - Complementary to each other

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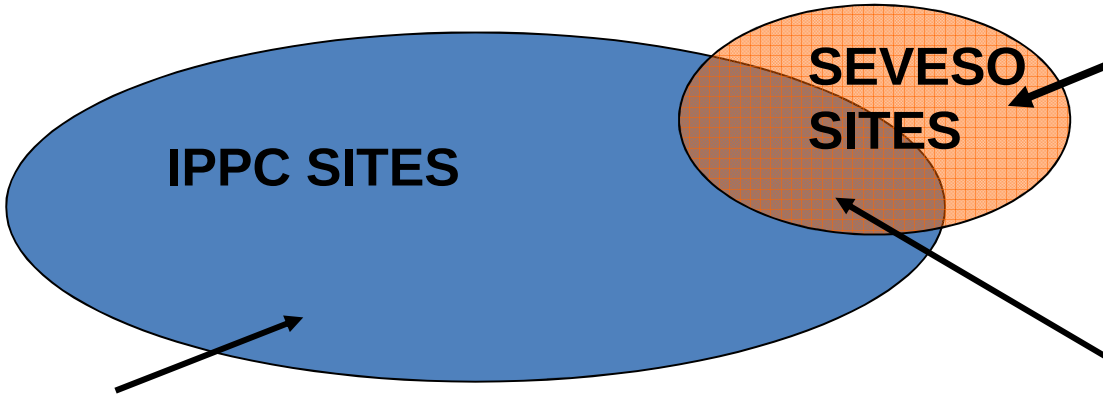
CORRELATION WITH OTHER EU LEGISLATION

IPPC Directive - Different scope



SEVESO SITES ONLY

Major Accidents

IPPC SITES ONLY

Minor and Major Accidents

IPPC/SEVESO SITES

Minor Accidents/Spills IPPC

Major Accidents Seveso

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CORRELATION WITH OTHER EU LEGISLATION

IPPC Directive

- **Synergies**
  - Use of management systems
  - Use of less hazardous materials at the site
  - Reduction in the volume of hazardous material stored at the site
- **Differences**
  - **Seveso** - protection of human health and environment from the negative effects of major accidents through prevention of major accidents using SMS
  - **IPPC** - protecting environment and human health on a long term basis by preventing and minimising pollution through use of BAT and EMS
- **Potential Conflicts**
  - Safety over Environment ?
  - Siting of establishments
  - Technical measures

REACH/CLP → **IPPC/SEVESO ?**

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Project implemented by Human Dynamics Consortium

REFERENCES

1. Chemical Accidents (Seveso I, II and III) - Prevention, Preparedness and Response
http://ec.europa.eu/environment/seveso/

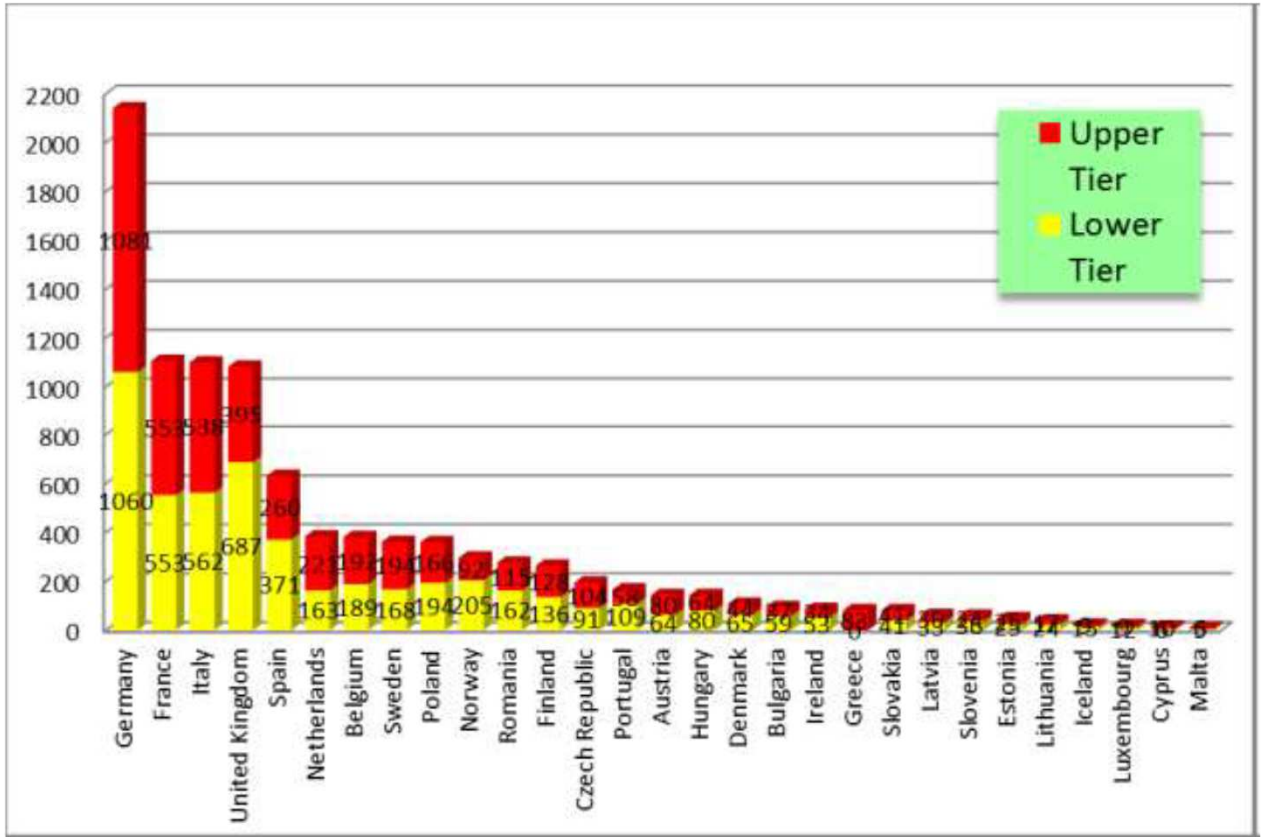
2. **I.van der Putte. RENA- Working Group 4- ECENA**
http://www.renanetwork.org

3. Report on the Application in the Member States of Directive 96/82/EC on the control of major-accident hazards involving dangerous substances for the period 2009-2011 .Final REPORT FROM THE COMMISSION
Brussels, 28.6.2013 C(2013) 4035

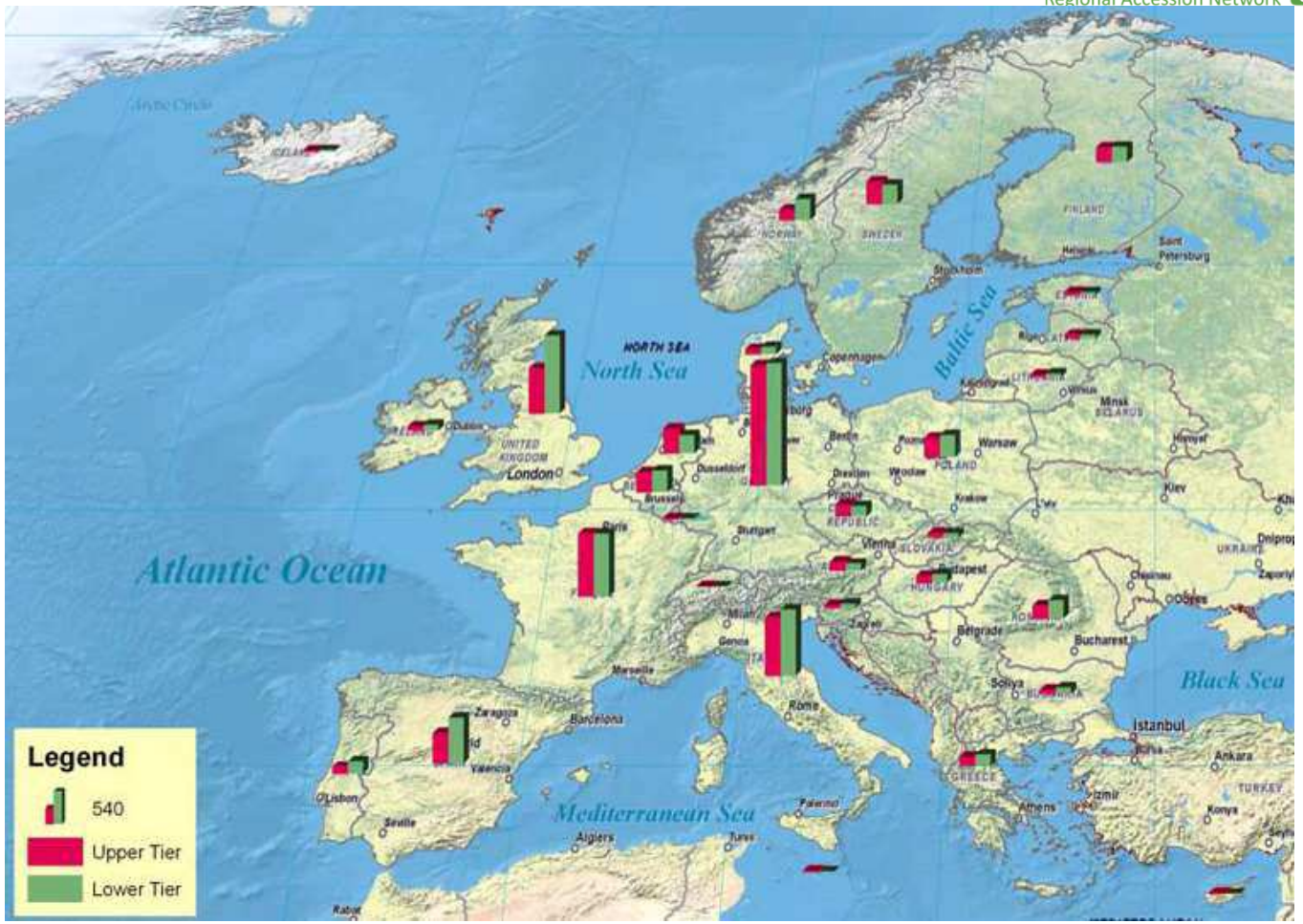
To whom does SEVESO apply

SEVESO Examples Tier approach

- Two Tier approach is used
- Maximum quantities of dangerous substances (existing or anticipated) are considered
- Compared against threshhold quantities



Upper tier and lower tier establishments per country in ranked order (Source: EC-JRC-MAHB 2012)



Mapped illustration of upper and lower tier Seveso establishments per country (EU and EEA) order (Source: EC-JRC-MAHB, 2012)

PRELIMINARY LIST OF SEVESO PLANTS SERBIA

Enviroment and Climate Regional Accession Network ECRAN

In total approx. 105 installations

Lower tier plants: 59 installations

Upper tier plants: 46 installations

Accident prevention policy Notification

Safety report Accidents protection plan

Ref. Ljiljana Stanojevic 2012

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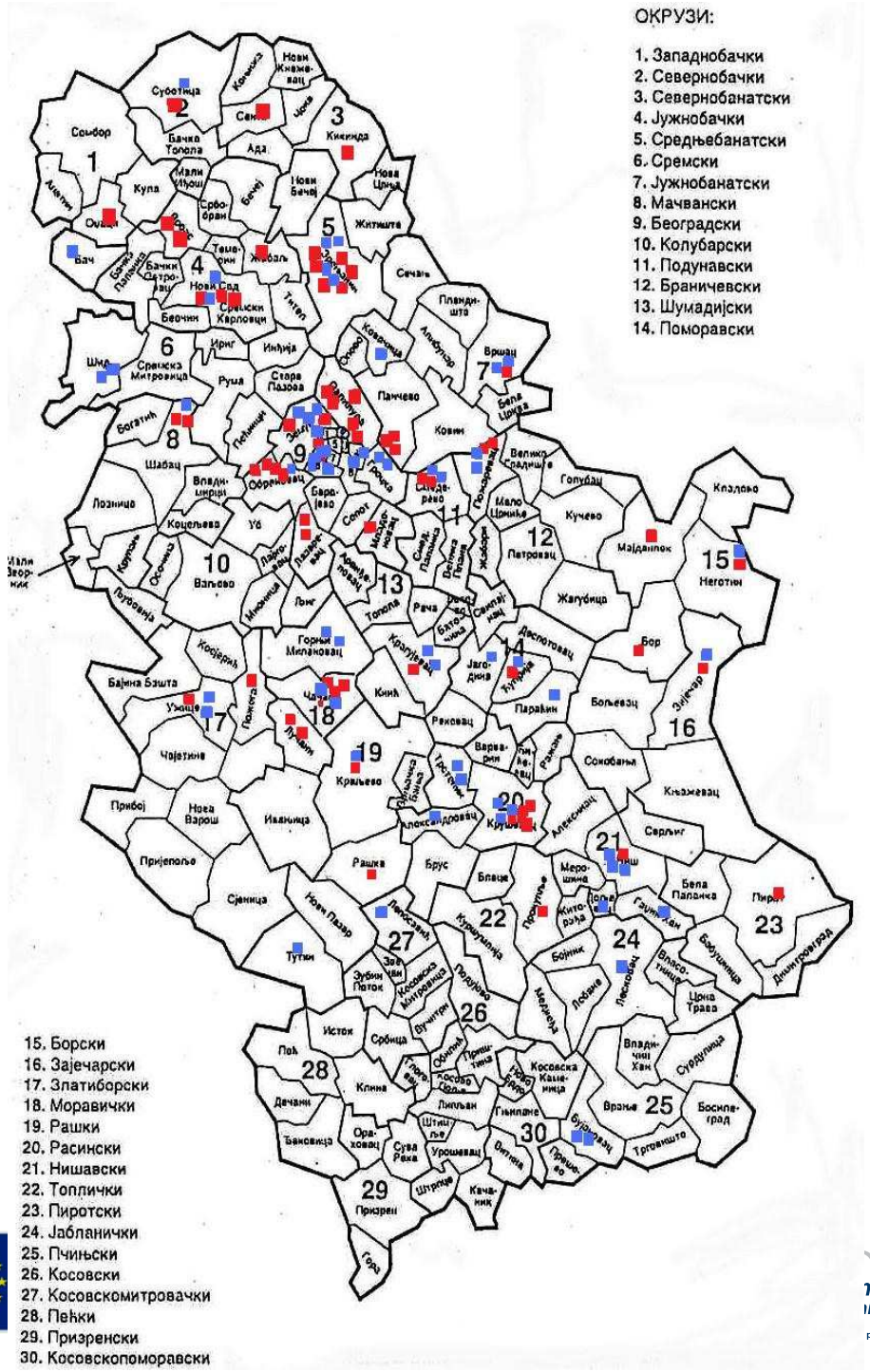
Project implemented by Human Dynamics Consortium



Seveso plants in Republic of Serbia

- Upper tier installations
- Lower tier installations

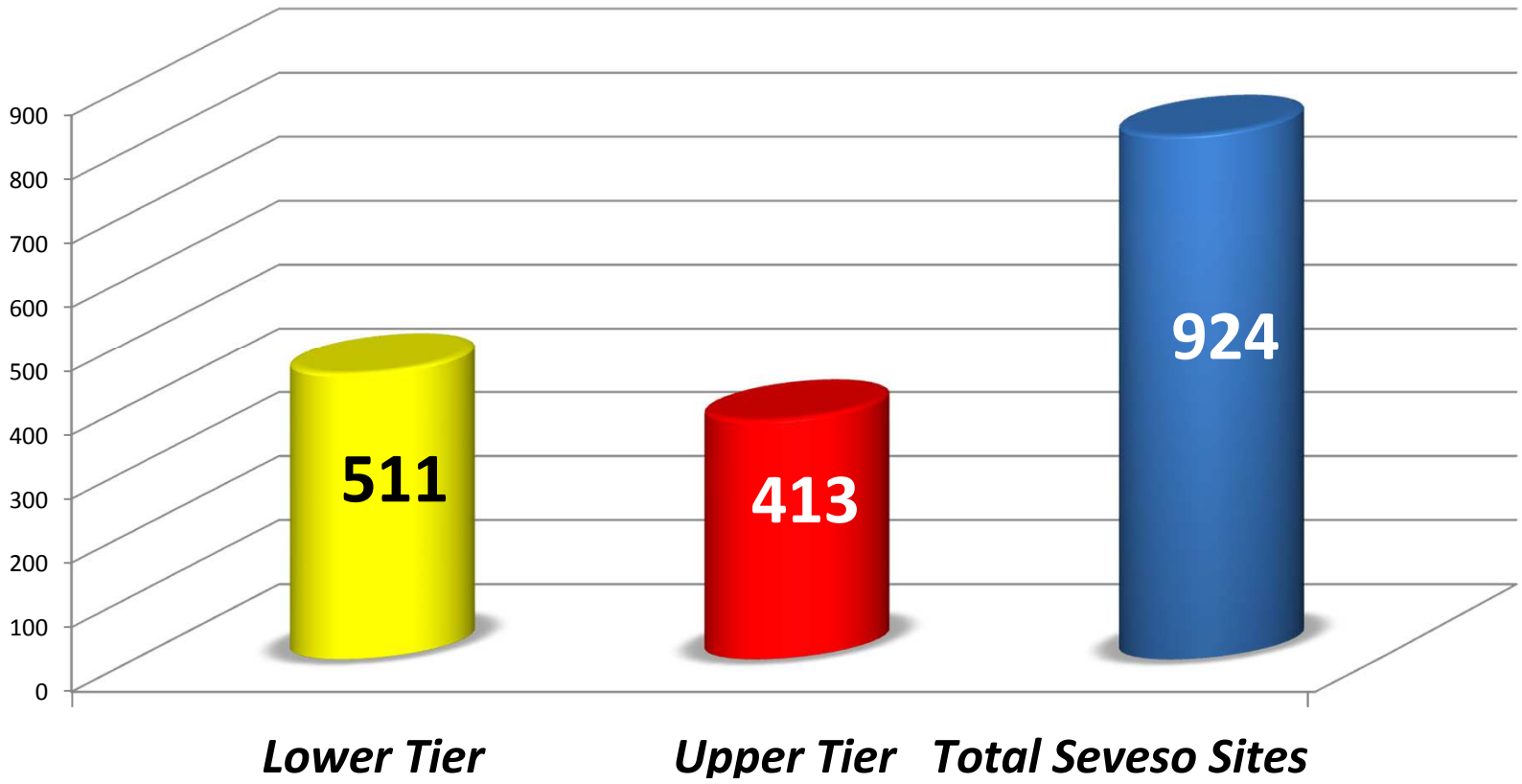
T.C.
ÇEVRE VE ŞEHİRCİLİK
BAKANLIĞI

GEOGRAPHICAL DISTRIBUTION OF SEVESO ESTABLISHMENTS

Ref.ÖNDER GÜRPINAR

T.C.
ÇEVRE VE ŞEHİRCİLİK
BAKANLIĞI

SEVESO ESTABLISHMENTS IN TURKEY



Ref. ÖNDER GÜRPINAR

Two Tier Approach

- Consequences for Establishment:
- Quantities below lower tier have no obligations
- Quantities above lower tier must be reported to Local Authorities
- Quantities above upper tier have full obligations

(What Are Full Obligations?)

- Establishment has to prepare:
- Safety Management System
- Safety report for the Establishment
- Internal Emergency Plan
- Local authorities update external emergency plan
- Involving the public

Threshold Quantities

Enviroment and Climate Regional Accession Network ECRAN

- Given in SEVESO III Annex 1 for two categories of dangerous substances:
  - Generally Classified Substances (part 1)
  - Named Substances (part 2)

Generic Category of Substances (Part 1):

SEVESO II
Toxic
Very Toxic
Oxidising
Explosive
Flammable
Highly Flammable
Extremely Flammable
Dangerous for the Environment
Other

SEVESO III

Health Hazards H 1, 2, 3

Physical Hazards, P

- Explosives 1a, 1b
- Flammable gases, 2 cat 1 and 2
- Flammable aerosols, 3a, 3b
- Oxidising gases, 4
- Flammable liquids, 5b, 5c
- Selfreactive & mixt & peroxides, 6a, 6b
- Pyrophoric liquids, 7, cat
- Oxidising liquids and solids

Environmental Hazards E, E1, E2

Other

List of “Named” Substances (Part 2), e.g.

Bromine
Chlorine
Hydrogen
Methanol
Automotive Petrol and Other Petroleum
Spirits

Named Substances

- Examples from Annex 1, Part 2:

Dangerous Substances [CAS Number]	Lower Tier (t)	Upper Tier (t)
Ammonium Nitrate [6484-52-2]	350	2500
Chlorine [7782-50-5]	10	25
Hydrogen [1333-74-0]	5	50
Liquefied High Flammable Gases (Incl. LPG) and Methane	50	200
Polychlorodibenzofurans and Polychlorodibenzodioxins		0.001

Generic Classification is based on:

In SEVESO II

•Classification, Packaging and Labelling of Dangerous Substances and Preparations (67/548/EEC)

•Use LD_{50} or LC_{50} values if available, e.g. very toxic if LD_{50} orally in rats is <25 mg/kg

•Use 'R' phrases if available, e.g. risk phrase R11 indicates a highly flammable liquid

In December 2008 the European Parliament and the Council adopted a new Regulation on classification, labeling and packaging of substances and mixtures (CLP - Regulation (EC) No 1272/2008) to align existing EU legislation with the GHS.

In SEVESO III (2015) adaptations were required in classifications (Annex I)

Generally Classified Substances

- Examples from SEVESO III Annex 1, Part 1:

Group of Dangerous Substances		Lower Tier (t)	Upper Tier (t)
1.	VERY TOXIC (SEVESO III – H1)	5	20
2.	TOXIC (SEVESO III – H2, H3)	50	200
3.	OXIDIZING (SEVESO III – P8)	50	200

Rule On Addition

- Formula:

$$\sum_i \frac{q_i}{Q} > 1$$

Triggering criteria regarding

Lower or Upper Tier

q_i - the quantity of dangerous substances *i*

Q - the relevant threshold quantity to be applied for all dangerous substances

Rules In Annex 1

- Mixtures and Preparations → as Pure Substances (Properties)
- Ignore $q_i/Q < 0.02$
- Add separately q_i/Q for Toxic (H= health hazards), Flammable/Explosive/Oxidising (P = Physical Hazards) and Environmental Hazardous Substances (E = Environmental Hazards)
- In the case of dangerous substances with properties giving rise to more than one classification, the lowest qualifying quantities shall apply.

Example 1

•Name	•Amount •(q)	•Low •Tier (Q)		•Upper Tier •(Q)	
	•tons	•tons	•q/Q	•tons	•q/Q
• Hydrogen	•10	•5		•50	
• Propane	•20	•50		•200	
• Methanol	•50	•500		•5000	
• Sum:	•80	•-	> 1?	•-	•> 1?

Lower Tier !

Upper Tier !

This Project is funded by the European Union

EXAMPLE 2

Chemical		Classification	Quantity On Site (tonne)	Thresholds (tonne) Lower Tier	Thresholds (tonne) Upper Tier
A	Ethylene Oxide	Named substance, Toxic and Extremely Flammable	3	5	50
B	Methanol	Named substance, Toxic and Highly Flammable	400	500	5000
C	Misc. Flammable Liquids	Flammable	3500	5000	50000
D	LPG	Named Substance, Extremely Flammable	10	50	200
E	Misc. Substances	Extremely Flammable	1	10	50
F	Misc. Toxic Substance	Toxic	5	50	200
G	Aqueous Waste Stream	R50, Dangerous for the Environment (E2)	15	200	500
H	Di-tert-butyl peroxide	Highly Flammable and Oxidising	20	5000 and 50	50000 and 200

EXAMPLE 3

Chemical		Classification	Quantity On Site (tonne)	Thresholds (tonne) Lower Tier	Thresholds (tonne) Upper Tier
A	Ethylene Oxide	Named substance, Toxic and Extremely Flammable	3	5	50
B	Methanol	Named substance, Toxic and Highly Flammable	400	500	5000
C	Misc. Flammable Liquids	Flammable	3500	5000	50000
D	LPG	Named Substance, Extremely Flammable	10	50	200
E	Misc. Substances	Extremely Flammable	1	10	50
F	Misc. Toxic Substance	Toxic	5	50	200
G	Aqueous Waste Stream	R50, Dangerous for the Environment (E2)	15	200	500
H	Di-tert-butyl peroxide	Highly Flammable and Oxidising	20	5000 and 50	50000 and 200
I	Calcium Carbide Casno:75-20-7	??	600	??	??

Typical Oil Terminal

Storage capacity:

- Kerosine 2000 tonnes (flammable)
- Petrol 3500 tonnes (named substance)
- Diesel 1600 tonnes (not classified)
- Heavy Fuel Oil - 5000 tonnes (not classified)

This is a Seveso lower tier site

Typical Pharmaceutical/ Chemical Company

Storage Capacity

- Flammable chemicals - 20000 tonne
- Benzene - 100 tonnes (toxic)
- Acetonitrile - 150 tonnes (toxic and flammable)
- Hydrochloric acid - 100 tonnes (not classified)
- Sodium hydroxide - 150 tonnes (not classified)

This is a Seveso top tier site

EXAMPLE 4 – WHAT ARE THE REQUIRED PROTECTION MEASURES FOR RESIDENTS IN CASE OF AN INCIDENT (RELEASE OF LPG)

Vertical LPG Storage Vessels (250m³)

Railway Car unloading Station

View of Site from Top of Vertical Storage Vessels

Cylinder Filling Station

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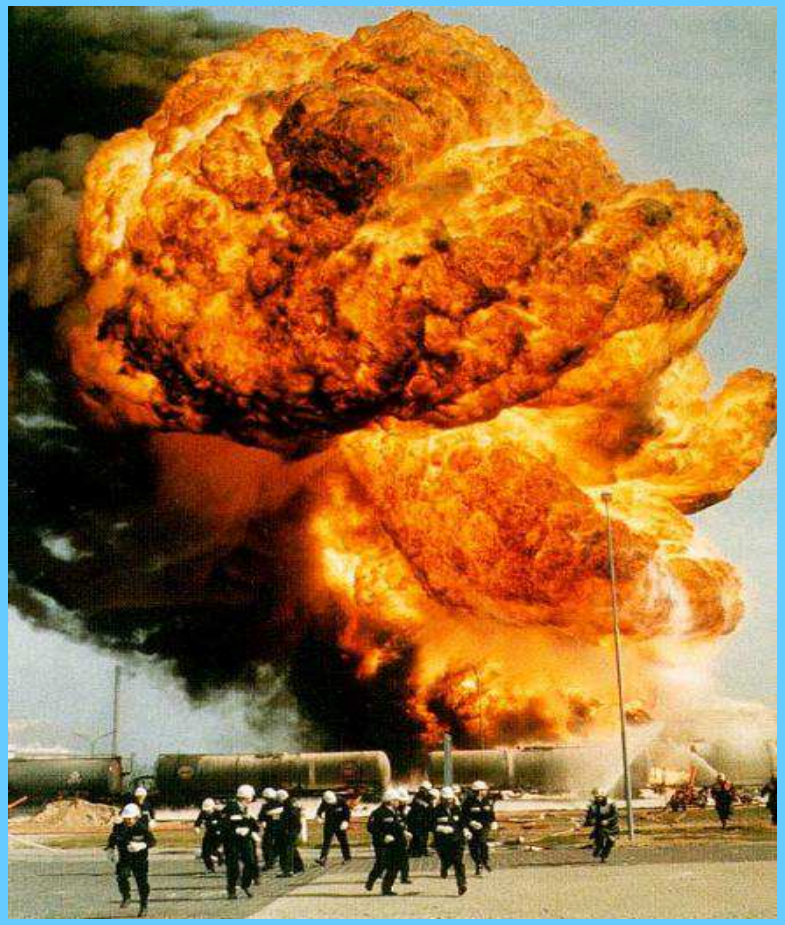
BLEVE (Boiling Liquid Expanding Vapour Explosion)



Vapor cloud explosion

Photos taken from article of
Universiti Teknologi Malaysia
Dr. Arshad Ahmad

Interlinkage REACH and IED
recent developments

Gisela Holzgraefe

ECRAN – 61197, Workshop Istanbul
Date: 8 – 10 Dezember 2015

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Content

Interactions of REACH / CLP and IED …

- 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

- IED directly refers to REACH and CLP

Interactions REACH / CLP and IED

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- IMPEL projects on the item assessed relevant REACH processes and their relevance for the interactions between IED and REACH

- Link between IED and REACH = substances and their properties / characteristics
- examples for explanation of relevance of interactions between REACH / CLP and IED

- Example 1: baseline report and waste
- Example 2: new classification of formaldehyde and consequences
- Example 3: use of trace element mixtures for biogas plants

Example 1 baseline report – waste

- The baseline report on soil and groundwater contamination is a new instrument - there was a need for guidance on its content and for criteria concerning “the relevant hazardous substances” and “the relevant amounts”. Guidance was published by COM in 2014.

- 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 Seveso Directive)

Example 1 baseline report - waste

Guidance concerning baseline reports under Art. 22(2) IED

Definition „hazardous substance“ - reference to CLP Regulation (EC) No. 1272/2008

Reference to: 4.3 Landfill Directive: point 3 Annex requirements concerning the protection of soil and groundwater

Main **stages** (8) of preparing the baseline report:

- Stage 1: identifying hazardous substances used, produced or released at the installation -

  produce a list of all hazardous substances dealt with inside the installation boundary (raw materials, products, intermediates, by-products, emissions or **waste**)

Example 1 baseline report - waste

- Stage 2: identifying the relevant hazardous substances – determine the potential pollution risk of each hazardous substance
- Stage 3: assessment of site-specific pollution possibility – quantity, single emission or accumulation from multiple emissions
- Stage 4: site history – i.a. What changes or improvements were made to the process, chemicals handled, storage locations, disposal methods and why? E.g to reduce waste.
- Stage 5: environmental setting: 1 – 4 past and future emissions identified. Now determination of the fate of any such emissions.
- Stage 6: site characterisation
- Stage 7: site investigation
- Stage 8: Production of baseline report

Example 2: new classification of formaldehyde and consequences

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- Example 2: 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
2015	Regulation (EU) 2015/491: new classification enters into force 1 January 2016

Example 2: new classification of formaldehyde and consequences

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	CLP	DSD
Current entry in AnnexVI 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**

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

Example 2: new classification of formaldehyde - consequences

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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

Example 2: new classification of formaldehyde – consequences in DE

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- **national level**, e.g. consequences in Germany for industrial installations:
- approach of TA Luft:
  - ❖ now general emission limit value (ELV) for organic substances class I in exhaust air: 20 mg/m³ or 0,1 kg/h plus specific ELVs for different types of installations
  - ❖ with new classification: change to carceogenic substance class III
    - → general ELV would be 1 mg/m³ or 2,5 g/h
- expert discussions showed that it is difficult to find technologies that could comply with that
- July 2014: start of a project to determine new emission limit values (general ELV and sector specific ELVs – based on criteria for determining BAT)

Example 2: new classification of formaldehyde - consequences

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Results: (proposal for a guidance – not yet adopted by Conference of Ministers for the Environment)

- General ELV: 5 mg/m³ or 12,5 g/h (not Class III because of threshold)

Sector / installation	Current ELV	proposal
Combustion engines (gas and oil)	60 mg/m³	20 mg/m²
Manufacture of glass	20 mg/m³ *	10 mg/m³
Melting of mineral substances	20 mg/m³	10 mg/m³
Production of synthetic resins (with formaldehyde)	20 mg/m³	10 mg/m³ or 25 g/h
Production of paper and card board (depending of type of dryer)	20 mg/m³	5 (indirect, IR), 15 Flotation dryer

Example 2: new classification of formaldehyde - consequences

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Activity	Current ELV	Proposal
Installations for coating, waterproofing, laminating, painting or impregnation of glass and mineral fibres – impregnating and drying	30 mg/m³	5 – 10 mg/m³
Production of chip boards, wood fibre or wood fibre mats: depending on drying technology	TOC → cannot be compared	10 – 20 mg/m³
Production of synthetic rubbers	20 mg/m³	10 mg/m³
Smoke installations for meat and fish products	20 mg/m³	10 mg/m³
Coffee roasting	20 mg/m³	15 mg/m³
Textile industry: depending on process step	TOC and other criteria → not comparable	5 – 20 mg/m³

Example 2: new classification of formaldehyde - consequences

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2. work safety requirements have to be adjusted

Discussion about the measures in Germany started

→ occupational exposure limit value (OEL), identification of alternatives

Example 3: use of trace element mixtures for biogas plants

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Case of an occupational disease with nickel intoxication and high concentration of other heavy metals

Background:	work at a biogas plant,
Task inter alia:	regular (daily) addition of a trace element mixture (in powder form) to the substrate in the fermenter
Characteristics:	no protective measures → without respiratory protection, mesures for avoidance of skin contact (protective gloves)
Findings:	Operators optimise the fermentation biology through addition of trace element mixtures. (biomass biogas plants without use of manure)
Germany:	ca. 30 companies offering such mixtures

Example 3: Components *of trace element mixtures* (metal salts of):

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cobalt	carciogenic, mutagenic, reproduction toxic, toxic, sensitising, dangerous for the environment
copper	harmful to human health and to the environment
iron	harmful to human health
manganese	harmful to human health and to the envir onment
molybdenum	harmful to human health
nickel	carciogenic, mutagenic, reproduction toxic, toxic, sensitising, specific organ toxicity, dangerous for the environemnt
selenium	toxic, specific organ toxicity, sensitising, dangerous for the environment
tungsten	harmful to human health
zinc	Hazardous to the environment

Example 3: use of trace element mixtures for biogas plants - consequences

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Inspections manufacturers / distributers

- Check of labelling: low concentrations of Co and NI compounds (e.g. 0,1 %) may lead to a labelling as carciogenic resp. toxic
- Check of safety data sheets (in several cases poor quality)
- control of compliance with provisions on storage and provisions on sales
- control of compliance with occupational safety regulations
- Communication in the supply chain

Recent developments:

- Change to liquid trace element mixtures
- change to solid trace element mixtures in biodegradeable packages

Example 3: use of trace element mixtures for biogas plants - questions

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Permit application(s):

Why no information about the mixtures ?

Why no notification to the authrity(ies) about the use of additives ?

Permit should contain obligations on

- Regular analysis of the substrate
- Regular analysis of the fermentation residues
- Requirements concerning work safety

interactions REACH / CLP and IED

Conclusions

- Clear statements needed in guidance documents (example baseline report – guidance document has no clear position)
- Developments in legislation on chemical substances influence the work of permit authorities to a good deal (example formaldehyde)
- Up to now in many MS permit authorities and operators are not aware of the role of requirements concerning chemicals (example biogas plants)

- **Exchange between IED and REACH regulating bodies needed on national and on European level (including procedures for the development of BREF documents)**

Development of BREF documents

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Step 1: European IPPC Bureau sets up a **Technical Working Group (TWG)** (40 – 100 experts)

EIPPCB as neutral and technically competent body – organises the process and writes the BREF document

Representatves of MS from authorities (air, water, soil waste, and energy / climate), industry and NGOs plus COM

(REACH / CLP experts not involved)

Step 2: **Data collection**

- quantitative data (emission concentrations, consumption quantities, plant operating parameters)
- qualitative data (techniques, process routes, material types, output…)

Development of BREF documents

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Step 3: Data validation by IPPCB and **data analysis**

Step 4: TWG consultation and IPPCB drafts **first draft**

Step 5: Consultation concerning first draft

Step 6: Development of **second draft**

Step 7: Final discussion in TWG

Step 8: Adoption through comitology procedure

- BAT conclusions are binding for MS

Recommendations IMPEL project 2014

- Proposals for integration of REACH aspects into the procedure for the development of BREF documents
- Cooperation between IPPC Bureau and ECHA in the development of BREF documents
- General chapter on chemicals should be in the BREF documents and in the BAT conclusions, to the extent that is relevant.
- „The use of substance x for process y is not BAT“ could be an acceptable approach for making operators substitute substance x.
- In BREF documents appropriate alternatives for substances regulated by the REACH candidate list, Annex XIV and XVII should be mentioned.
- BREF documents should take into account phasing out obligations under the Water Framework Directive and offer alternatives.

Recommendations IMPEL project 2014

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- For a separate guidance document on REACH and IED a stepwise approach might be successful: To begin with, a webpage (IMPEL?) with links and best practice examples. Guidance from different countries could provide valuable information. Translations are necessary.
- REACH national competent authorities together with ECHA should raise awareness of the Chemical Safety Reports (CSR) and their value to IED authorities.


Thank you for your attention!
Any questions?

Guidance for REACH inspection

Gisela Holzgraefe

ECRAN – 61197, Workshop Istanbul
Date: 8 – 10 Dezember 2015

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Content

Sources for information on inspections

REACH and CLP Regulation

- Article 125 REACH and Article 46 CLP: Member States have to maintain a system of official controls and other activities as appropriate to the circumstances
- Article 126 REACH and Article 46 CLP: MS have to lay down provisions on effective penalties
- Article 117 (1) and 127 REACH: reporting of results of inspections, monitoring, penalties and other measures to the European Commission every five years (first time 2010)

- No detailed information about requirements concerning inspections and frequencies in Regulations
- The Forum for Exchange of Information on Enforcement provide some information

Forum – role and responsibilities

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The **Forum for Exchange of Information on Enforcement** (Forum), according to Regulation (EC) 1907/2006, coordinates a network of Member State authorities responsible for enforcement.

The Forum is **composed of**:

- Members appointed by the Member States (one member per MS – EU MS plus EEA-EFTA States Iceland, Liechtenstein and Norway).
- Up to five co-opted members chosen on the basis of their specific competence.
- Stakeholders may be invited to attend meetings as observers.

Forum – tasks

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- **Spread good practice** and highlight problems at Community level
- **Propose, coordinate and evaluate harmonised enforcement projects** and joint inspections
- Identify **enforcement strategies**, as well as best practice in enforcement
- Develop **working methods and tools** of use to local inspectors
- Liaise with industry,
- Examine proposals for restrictions with a view to advising on enforceability (Art.77(4))

Guidance on REACH / CLP inspections

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❖**Strategies for Enforcement of REACH and CLP (March 2011)**

❖**Minimum Criteria for REACH and CLP Inspections (March 2011)**

- REACH and CLP inspection activities should be carried out in Member States **following minimum criteria** to be applied in the effective organisation, planning, implementation, carrying out and review of such tasks
- Comprehensive **risk analysis** should be used to ensure that enforcing authorities concentrate their resources on the areas that need them the most.

Enforcement Strategy

- For a structured and transparent approach to REACH and CLP enforcement, an appropriate enforcement strategy or strategies should be developed.

Minimum Criteria for REACH / CLP Inspections

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- **Organisation:**
- Appropriate provisions should be made to **ensure that enforcing authorities cooperate and exchange information.**
- **Planning**:
- MS should have at all times **an inspection plan** or plans, collectively taking into account all the territory of the MS and of the known target groups
- **Carrying out REACH and/or CLP inspections**

  criteria in respect of all REACH and/or CLP inspection:

  a) that the role of the dutyholder is correctly identified

  b) that an appropriate check is made of compliance with the REACH and/or CLP requirements

Minimum Criteria for REACH / CLP Inspections

- c) that if **site visits** are to be carried out **by more than one enforcing authority**, and as far as possible they **exchange information** on each others' activities and coordinate site visits and other REACH and/or CLP inspection work;

- d) that the **findings of the inspections** are contained **in reports**

- i) that **serious accidents or incidents are investigated** without undue delay after these come to the notice of the relevant enforcing authorities,

- k) that, **if hazards are identified** related to any product, the enforcing authorities shall take **measures** to alert users by using the appropriate procedures as required by Article 19(2) of the AMS Regulation;

Minimum Criteria for REACH / CLP Inspections

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- **Action following REACH and / or CLP inspections**
- Enforcing authorities should ensure that after every inspection **reports** are produced and stored. **Content:**
- basic data on the inspection
- the significant findings of the REACH and/or CLP inspection
- …. steps of evaluation
- …
- the **measures taken** pursuant to the REACH and/or CLP inspection, by the enforcing authority and/or by the dutyholder.

Minimum Criteria for REACH / CLP Inspections

- The **reports should be communicated to dutyholders** promptly with clear explanations of what action they are required to take.

- The enforcing authorities should **ascertain that the required action has been taken**, and as soon as possible after the expiry of any deadline given to the dutyholder.

-

Guidance in the Member States

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– IMPEL project 2014 (in cooperation with Forum) showed:

- Most countries have general guidance for carrying out REACH inspections in place
  - ➢ several countries use the manual / checklists of the FORUM-Enforcement projects,
  - ➢ others have own checklists for REACH in inspections.

Forum task no. 2:

Propose, coordinate and evaluate harmonised enforcement projects and joint inspections

Forum Enforcement Projects

- **REACH-EN-FORCE 1**
- Project on pre-registration/registration of phase in substances and SDS
- **REACH-EN-FORCE 2**
- Enforcement of obligations of downstream users – formulators of mixtures
- **REACH-EN-FORCE 3**
- Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs
- **REACH-EN-FORCE 4** preparatory phase 2015, operational phase 2016
- Enforcement of classification and labelling of mixtures

- + pilot projects and projects on special items

Forum Enforcement Projects – objectives

- Building the instutional capacity of enforcement authorities
- Training of inspectors
- Improvement of institutional cooperation of national authorities in enforcement of chemical legislation
- ….
- Contribution to coordination and harmonisation of REACH enforcement in the MS‘s of the EU and EEA-EFTA states,
- Harmonisation of reporting carried out by the MS

REACH-EN-Force projects

- **Preparatory phase:**

- Based on a proposal the Forum decides on the project.
- A working group is established. In each MS a national coordinator is appointed. Tasks: elaboration of a **manual,** developing the reporting tools and regulating the tasks of writing a final report

- **Training phase**

- Forum carries out a training phase – train the trainers of the MS
- Trainers inform the colleagues in their countries in workshops and supervise the project

- **Operational phase**

- authorities carry out inspections and report the results

- **Project report**

Development of Guidance Document by Forum?

- Development of a guidance document on REACH and / or CLP inspections based on experience from Forum Enforcement projects ??

Solution in Schleswig-Holstein

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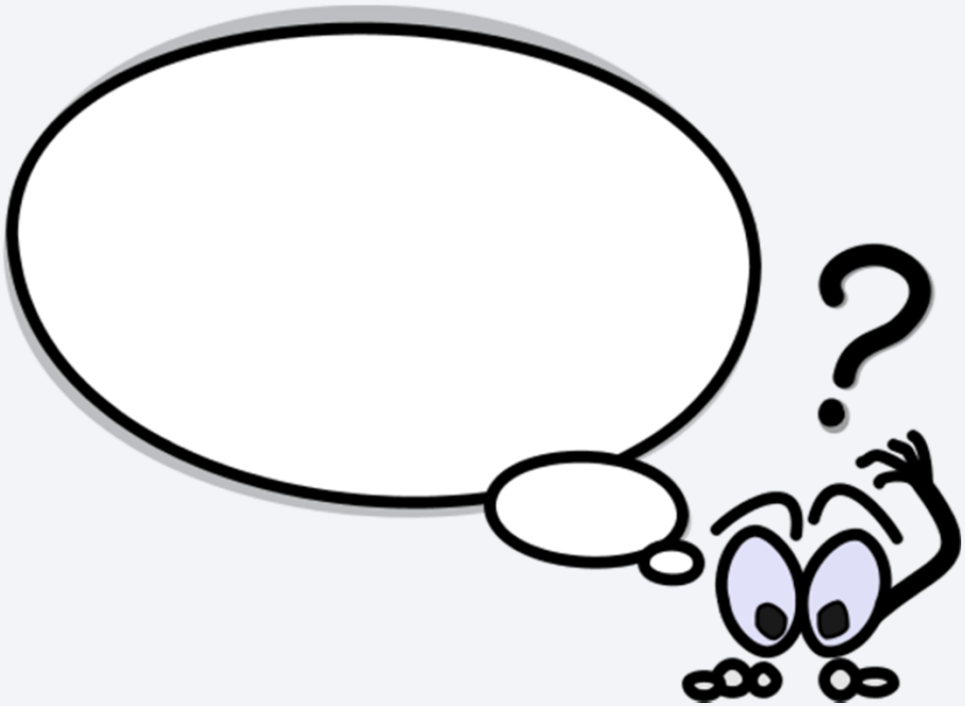
Establishment of an REACH/CLP expert group

Tasks:

- Advisory body for IED permitting and inspection activites
- Advisory body for authorities on community level (permitting a great deal of non-IED installations)
- Development of plan / programme and coordination of REACH inspections (competent authorities for manufacturers on state level, for distributers and importers community level)
- Preparation of reports



Environment and Climate Regional Accession Network ECRAN

REACH
Safety Data Sheet (SDS)

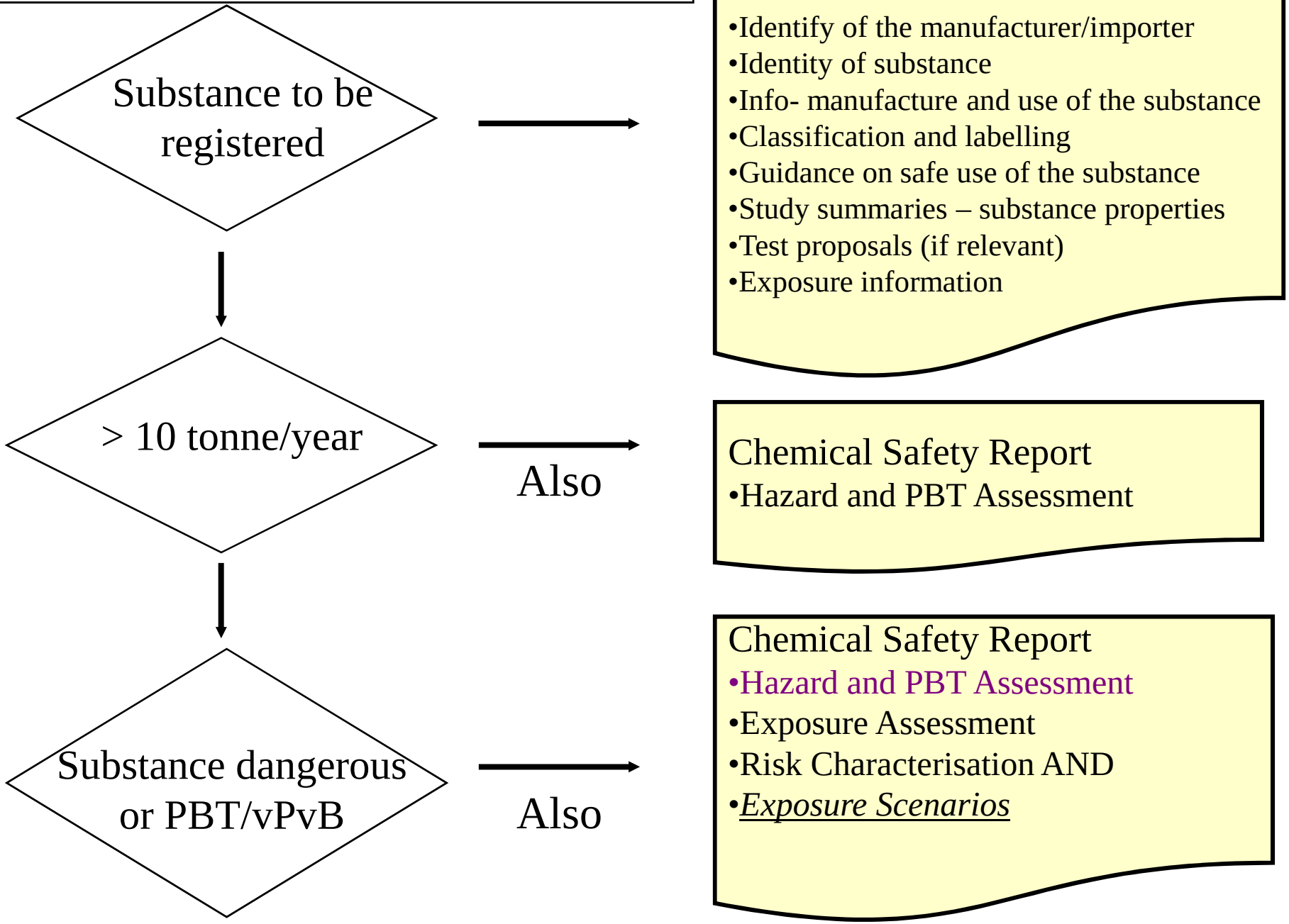
Istanbul, Turkey

8-10 December 2015

This Project is funded by the European Union

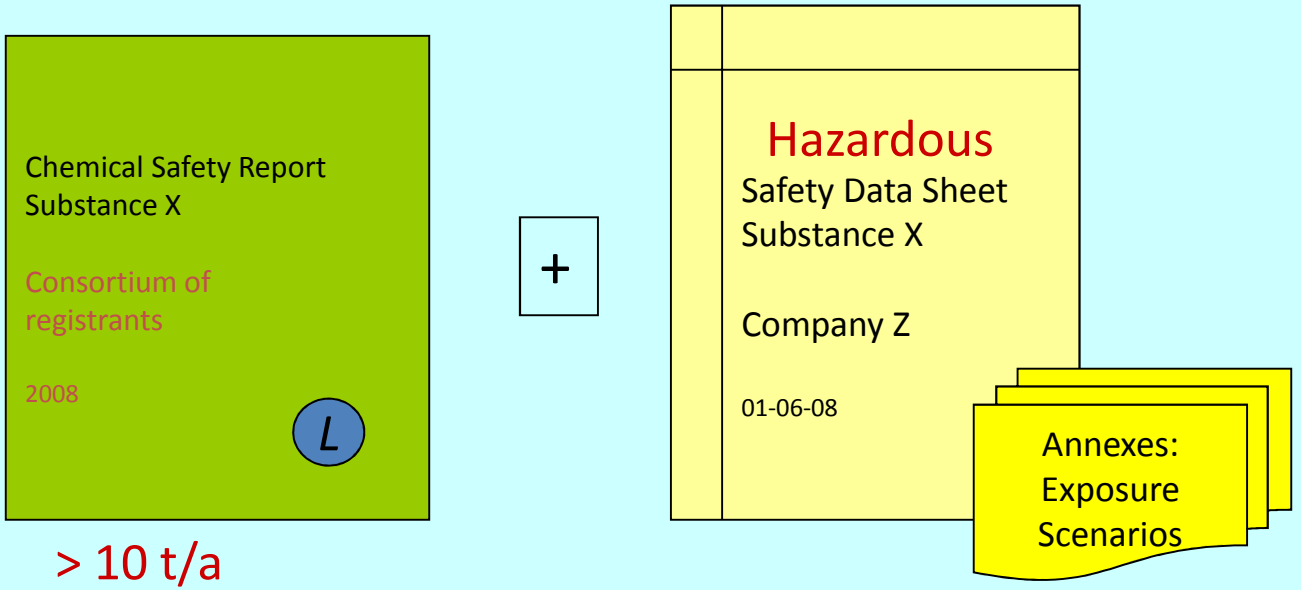
Project implemented by Human Dynamics Consortium

Registration dossier - content



Documentations under REACH

- Chemical Safety Report
- Safety Data Sheet
- Extended Safety Data Sheet



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Communication upstream and downstream

Who is a Downstream User?

Any industrial/ professional user of substances/ preparations who is not a manufacturer or importer:

- formulators of preparations of substances
- industrial use in production processes
- industrial manufacturing of articles
- professional user

Not regarded as DU:

- *distributors, retailers*
- *consumers*

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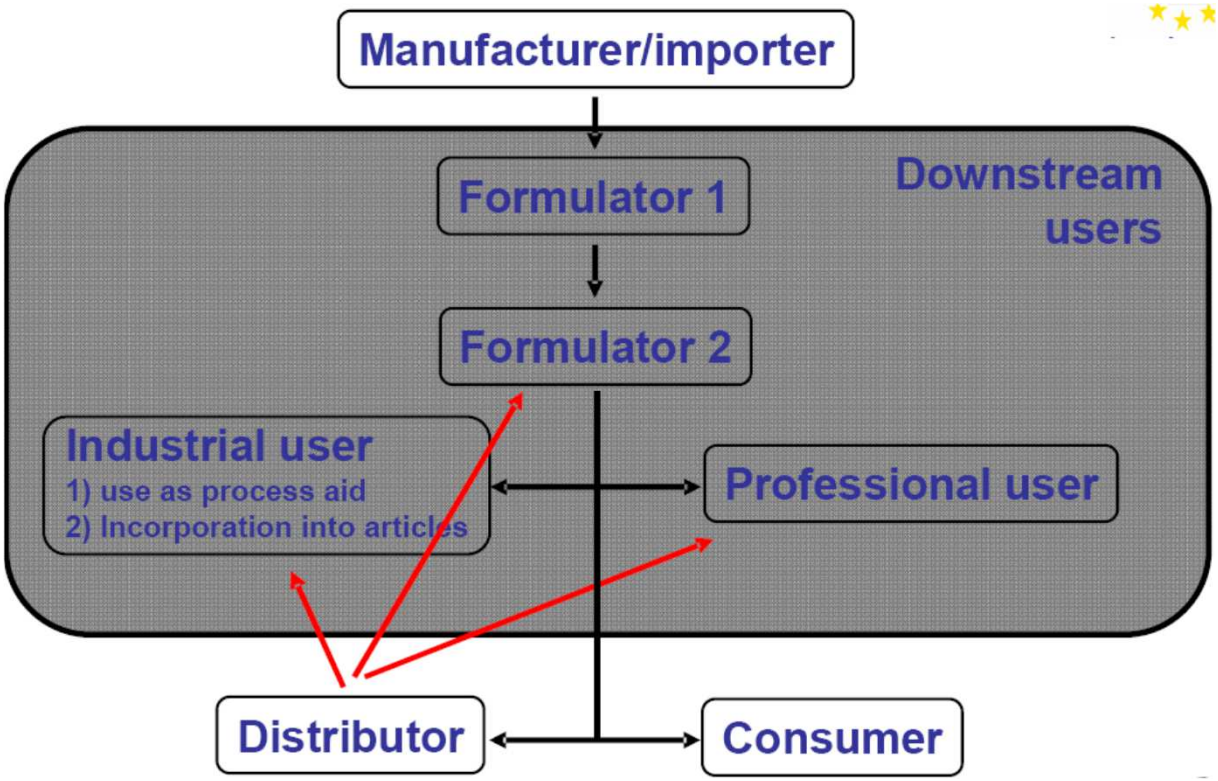

SDS with exposure scenario's and RMMs

Information on deviated use

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

Suppliers have to provide their customers with a SDS:

- 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 the language of the MS where placed on the marked
- Which in case of an CSR contains CSR info & ES

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Communication: If Safety Data Sheets is not required

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

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Hazard Communication: Safety Data Sheets

- Safety Data Sheets specified in Annex II REACH
- General format (order of sections) already reflects the CLP
- Annex II is amended for more detailed adaptation to CLP

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Links between REACH and CLP

- CLP article 57, 58 and 59 are amendments to REACH respectively from the entry into force of this Regulation, from 1 December 2010, and from 1 June 2015
- These articles concerns the SDS and changes in Article 31 of REACH.

Commission Regulation (EU) No 453/2010

Commission Regulation (EU) 2015/830

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Transition periods to include C&L

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General requirements: Safety Data Sheet

- 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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Headings:
Safety Data Sheets

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 and of the company/undertaking

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. Identification of the substance/mixture and of the company/undertaking

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. Hazards identification

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 e.g. formation of air contaminants during, hardening or processing, dustiness, explosive properties which do not fulfil the classification criteria

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.

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 such as inhalation, skin, eye and ingestion.

4. First aid measures

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

- Briefly summarized 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. Advice for fire-fighters

- Advice shall be provided on any protective actions to be taken during fire-fighting and on special protective equipment for firefighters

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. Precautions for safe 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. Conditions for safe storage, including any incompatibilities

- 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 end 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. Control parameters

- Describe the occupational exposure limit. This limit ensures that exposure to this chemical will not lead to health problems during a working life.
- National biological limit values
- 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. 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 (ies)
o. Partition coefficient:n-octanol/water
p. Auto-ignition temperature
q. Decomposition temprature
r. Viscosity
s. Explosive properties
t. Oxidising properties

9. Physical and chemical properties

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.

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

The relevant hazard classes, for which information shall be provided, are:

(a) acute toxicity;

(b) skin corrosion/irritation;

(c) serious eye damage/irritation;

(d) respiratory or skin sensitisation;

(e) germ cell mutagenicity;

(f) carcinogenicity;

(g) reproductive toxicity;

(h) STOT-single exposure;

(i) STOT-repeated exposure;

(j) aspiration hazard.

These hazards shall always be listed on the safety data sheet.

12. Ecological information

12.1. Toxicity

- 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. Persistence and degradability

- Description of the breakdown of the chemical in the environment

12.3. Bioaccumulative potential

- Description of the accumulation of the chemical in the food chain

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12. Ecological information

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB 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

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 proper shipping name,

14.3 UN transport hazard class(es),

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

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 whether a chemical safety assessment has been carried out for the substance or the mixture by the supplier.

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16. Other information

- In the case of a revised safety data sheet, a clear indication of where changes have been made to the previous version of the safety data sheet, unless such indication is given elsewhere in the safety data sheet, with an explanation of the changes, if appropriate;

- A key or legend to abbreviations and acronyms used in the safety data sheet;

- Key literature references and sources for data;

- In the case of mixtures, an indication of which of the methods of evaluating information was used for the purpose of classification;

- A list of relevant hazard statements and/or precautionary statements. Write out the full text of any statements which are not written out in full under Sections 2 to 15

- advice on any training appropriate for workers to ensure protection of human health and the environment.

Useful links

ECHA Safety Data Sheets eGuide

http://view.pagetiger.com/ECHAeGuide1-1/Issue1

Guidance on the compilation of safety data sheets

http://echa.europa.eu/documents/10162/13643/sds_en.pdf

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Evaluate Safety Data Sheets

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