Enviroment and Climate Regional Accession Network ECRAN

ENVIRONMENT AND CLIMATE REGIONAL ACCESSION NETWORK (ECRAN)

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

Introduction

Ike van der Putte

ECRAN coordinator WG ECENA; WG IED/Chemicals

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Enviroment and Climate Regional Accession Network ECRAN

Project summary

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

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From RENA towards ECRAN

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

Overall objective (same as in RENA):

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

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Results to be achieved

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Improved institutional set-up and technical working arrangements established;

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

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

Improved skills in relation to enforcement of the legislation;

Improved strategic planning and investments;

Experience-sharing and networking activities established;

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

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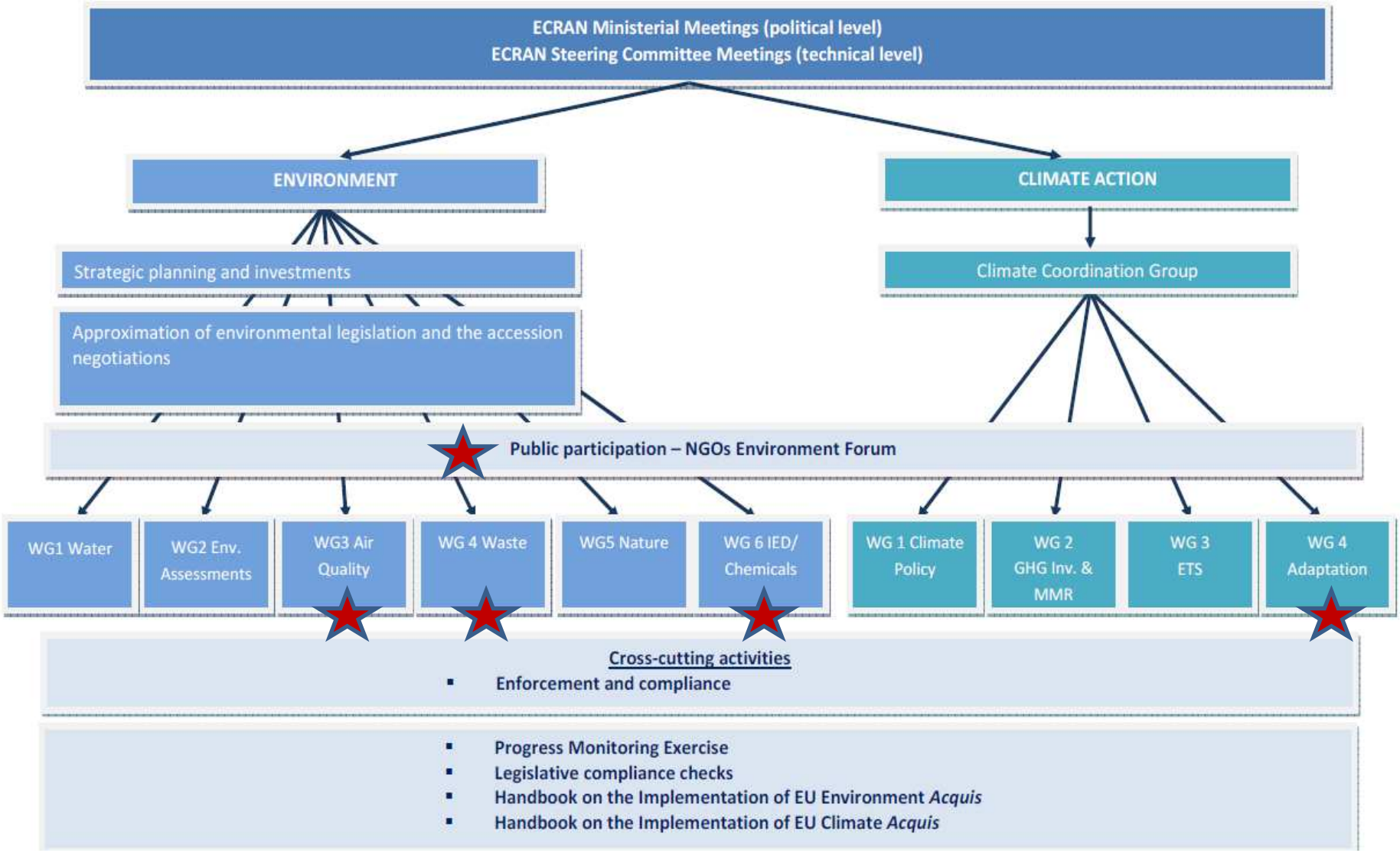
ECRAN Structure

Enviroment and Climate Regional Accession Network ECRAN



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Planned activities

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- EF Public Participation:

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

✓ Organisation of annual meetings with the EC;

✓ Design and delivery of tailor made training programme.

Enhanced public participation in environmental and climate planning and decisionmaking process

- Enforcement and Compliance (ECENA):

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

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

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

Improved skills in relation to enforcement of the legislation

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Planned activities

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- Progress Monitoring:

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

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

- Approximation of environmental legislation and the accession negotiations:

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

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

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

Improved institutional set-up and technical working arrangements established

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Planned activities

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- Strategic Planning and Investments Working Group:

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

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

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

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

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Planned activities

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- Water Management Working Group:

✓ Selection of pilot site (river basin);

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

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

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

- Environmental Assessments Working Group:

✓ Selection of pilot sites;

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

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

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

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

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Planned activities

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

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

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

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Planned activities

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- Climate component:

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

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

✓ Best practice document for a fully functioning MMR system;

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

✓ ETS Implementation and ETS strategy and roadmap development;

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

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

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

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

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Practical arrangements

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ECRAN

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

TAIEX

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

Important: continuous participation and timely nominations

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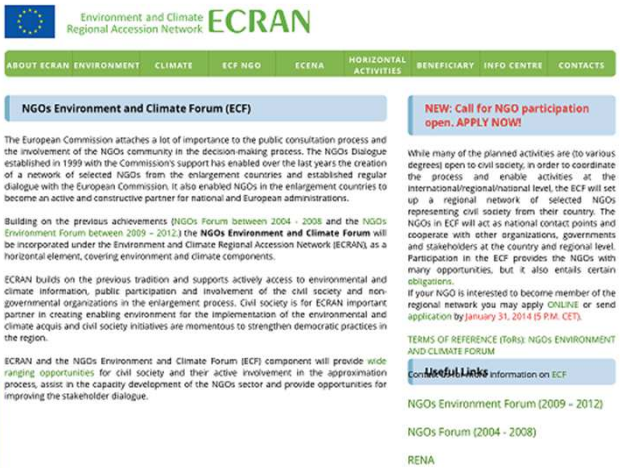
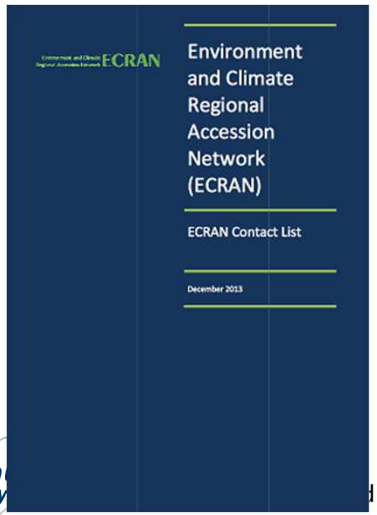
ECRAN visibility and info sharing

Enviroment and Climate Regional Accession Network ECRAN

- Website (www.ecranetwork.org)





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

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

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

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

Croatian accession to the European Union

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

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

Related links

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

See also

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

Key material in Croatian

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

Thank you for your attention

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General Introduction on REACH Regulation

Ike van der Putte

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Main elements of REACH

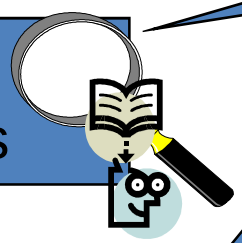
Registration of all substances > 1 t/yr

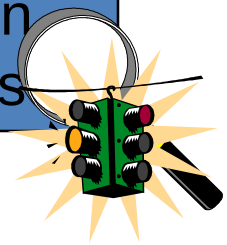
Evaluation by competent authorities

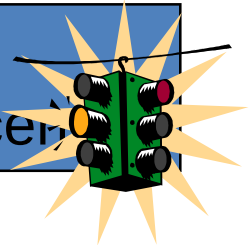
Authorisation of certain hazardous substances

Restrictions for substances of concern

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







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The registration process

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

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Registration: general

AIM:

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

Registration Dossier = Documentation

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

No formal acceptance - industry retains responsibility

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Who Has to Register?

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

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What Must Be Registered?

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

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Registration

Are substances in articles to be registered?

Only if:

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

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

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

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Registration

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And what if there is no intended release?

In that case there are no registration obligations

There is a notification obligation for substances in articles if:

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

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

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

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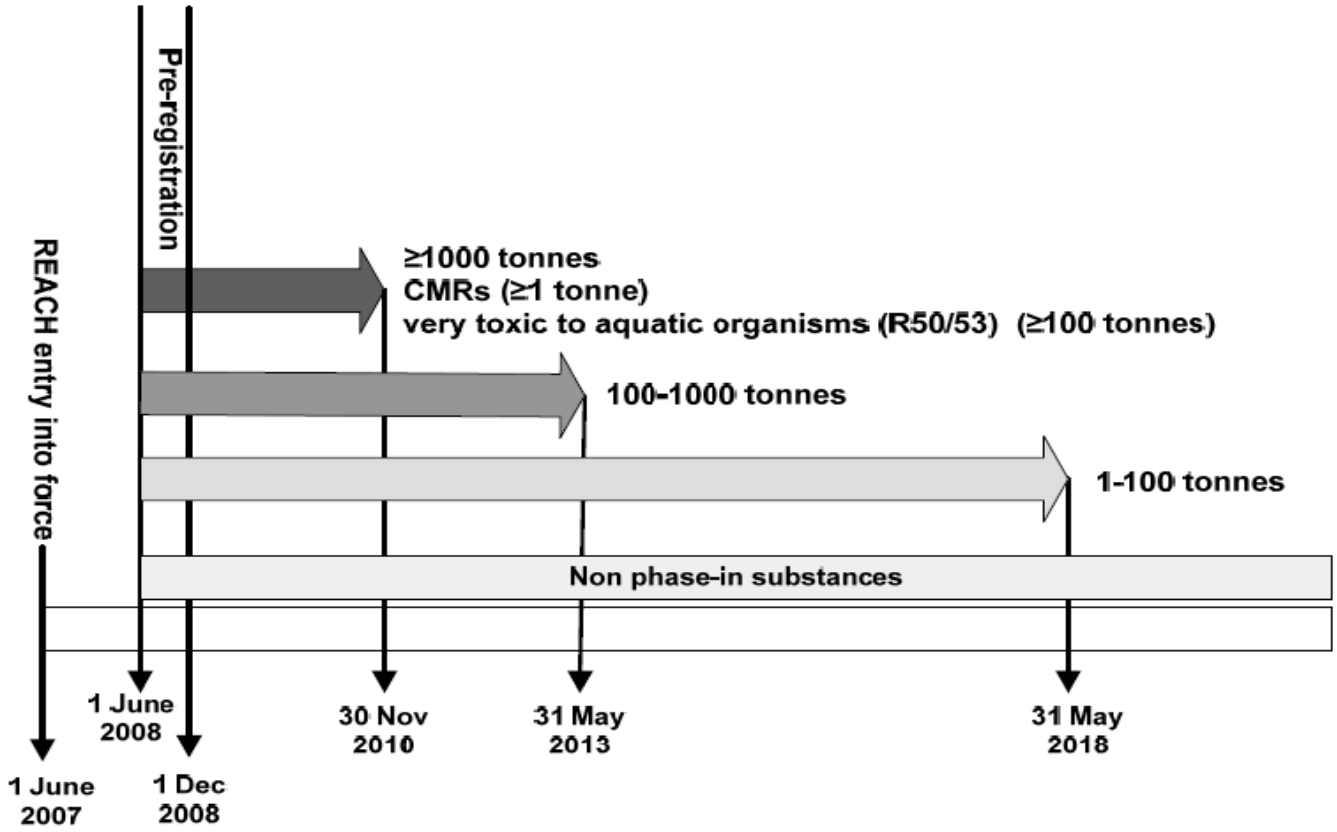
Registration – when?

1 June 2008

Deadlines for registration of phase in substances



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Registration & ECHA

Registration dossier:

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

Registration dossier & SIEFs

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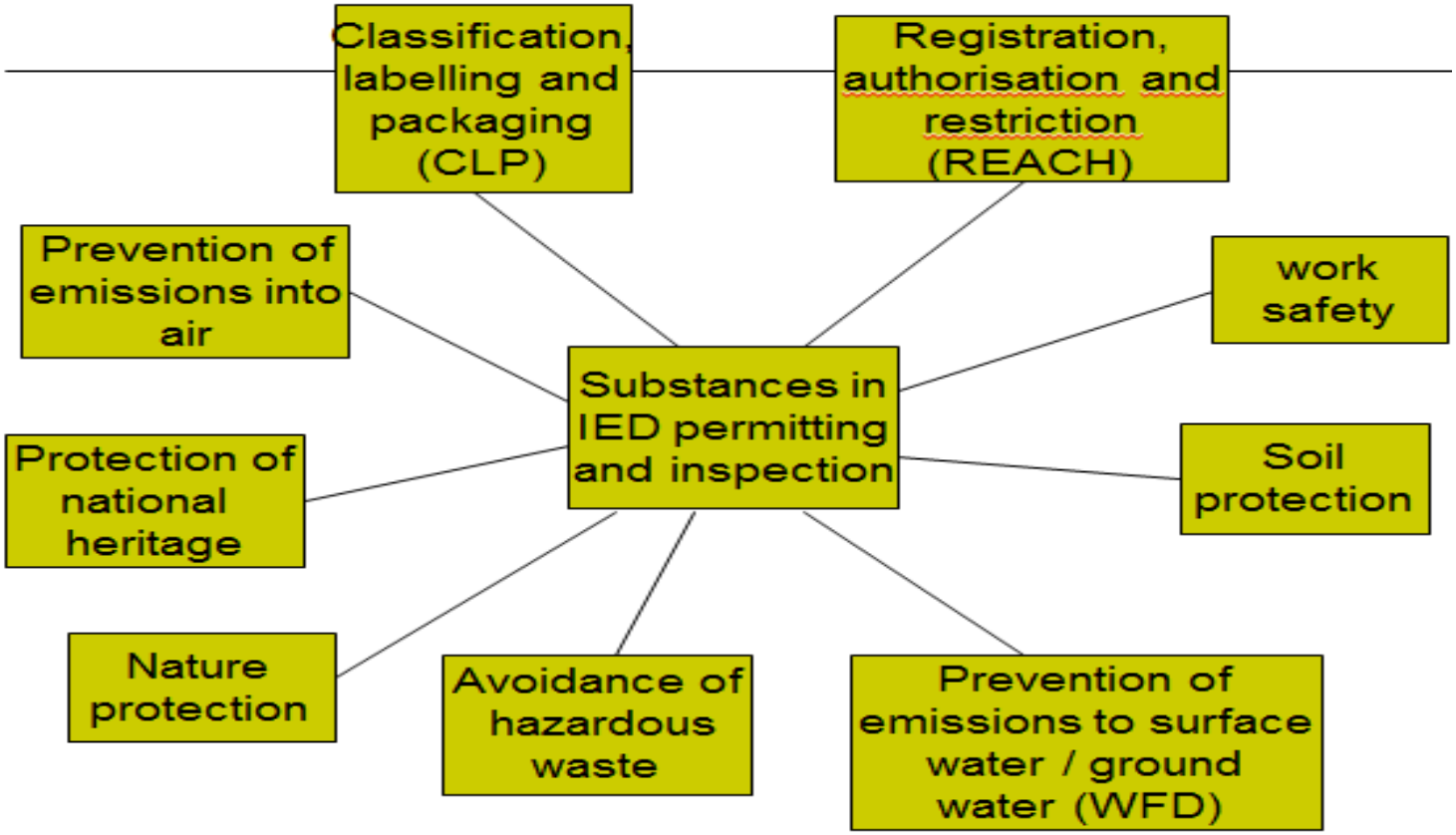
IED interaction



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REACH Specifics
Roles & Responsibility

Outline:

A: Short refreshment on REACH

B: Roles in REACH

C: Responsibility at each role

Arnold van der Wielen

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Basic principles of REACH

- **Sustainable development**
  - Industry is responsible for safe use of substances
  - Authority controls compliance of industry
  - NGO's must accept marketing of sustainable substances; no phasing-out across the board
- **Priority for data collection**
  - Manufacturing / marketing according to quantity
    - Three categories of priority: 1000 – 100 - 1 tonnes/year
  - Hazardous properties
    - CMR properties (high priority)
    - PBT/vPvB properties > 100 tonnes/year (high priority)
- **Risk management**
  - Communication (CLH and SDS)
  - Authorisation of uses with identified Very High Concern Substances
  - Restriction measures

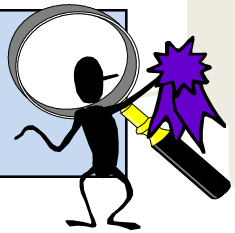
Scope of REACH

- **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

Main elements of REACH

Registration of all substances > 1 t/yr

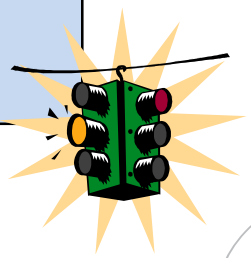
Evaluation by competent authorities



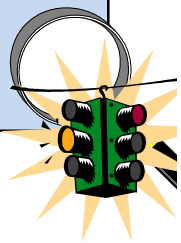
Scope:
- **evaluation required > 100 t/yr**
- **selective evaluation < 100 t/yr**
- **decisions for additional information**
- **proposal for authorisation**
- **Proposal for restriction measures**

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

Restriction measures for substances of concern



Authorization of certain hazardous substances



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)** of a substance or preparation (professional)
- **Distributor**, distributive trades
- **Producer** of an article

Attention: a company may perform several roles

Registration obligation

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

  (Totally dependent on implementation strategy in Accession States)

- **From [date] all non phase-in substances to submit registration before manufacturing, importing or placing on the market**

- **For phase-in substances transitional arrangements possible, depending on negotiation with European Commission**
  - Between starting date and deadline submitting preregistrations
  - Between starting dates and deadlines submitting registrations depending on volume 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);
- **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.

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 EU to fulfil the obligations of importers within the EEA
  - An OR might be an importer within the 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

Main tasks depending on role – 1/2

- **Manufacturer / importer / only representative:**
  - Preregister phase-in (=existing) substances
  - Register substances > 1 tpa within the legally defined deadlines according to volume and hazardous properties
  - Classify & label the substance
  - Draft and distribute (e)SDS in case of substances placed on the market
  - Communicate down the supply chain
- **Downstream user:**
  - Implement recommended risk reduction measures in (e)SDS, or draft a Chemical Safety Report for own use
  - Classify & label formulated mixtures
  - Draft and distribute (e)SDS of formulated mixtures
  - Communicate up the supply chain

Main tasks depending on role – 2/2

- **Producer of an article:**
  - Register a substance > 1 tpa in an article if intended to be released during normal or reasonable forseeable conditions of use, if not registered for that use
  - To submit notification of a substance > 1 tpa in an article being identified as SVHC (listed as candidate for authorisation)
- **Distributor:**
  - Distribute (e)SDSs
  - Communicate up- and down supply chain

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)

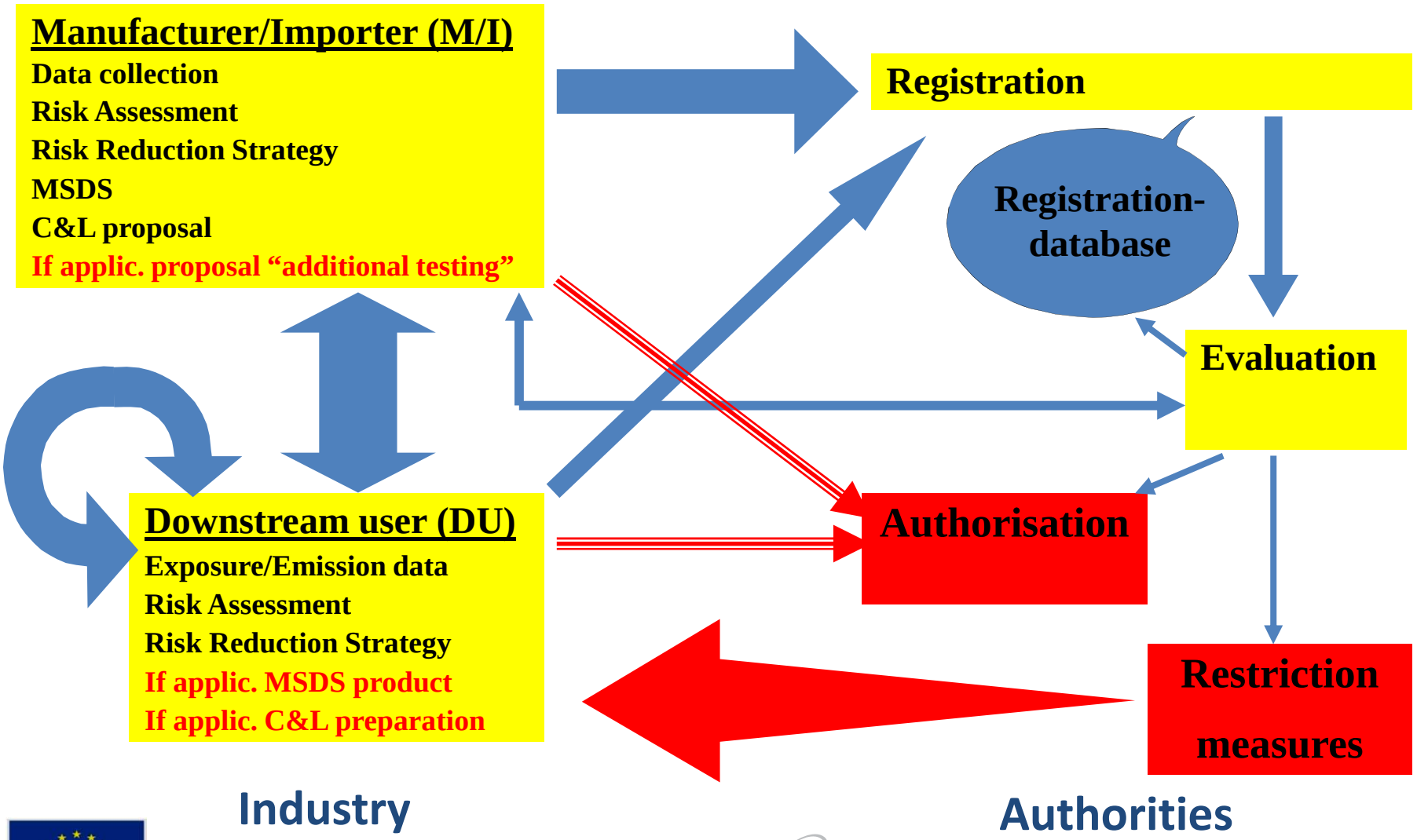
- **Chemical Safety Report needed ?**
  - Identified uses: actualising M/I CSA (exposure/emission)
  - Not-identified uses: completion of M/I CSA

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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Pre-registration and exchange of information
Task for M/I/OR (potential registrants)

Mandatory data sharing (reason is animal welfare)

- Non phase-in (=new) substances:
  - Agency involvement for contact between parties
  - If no agreement; Agency involvement as arbiter
    - Compensation; claims lawfully in all Member States
- Phase-in substances:
  - Pre-registration is required
  - SIEF (substances information exchange forum)
  - If no agreement; Agency involvement as arbiter
    - Compensation; claims lawfully in all Member States

Attention for downstream users:
- Check listing of your essential substances;
- If not, contact supplier
- If supplier not interested, prepare alternative routes for registration

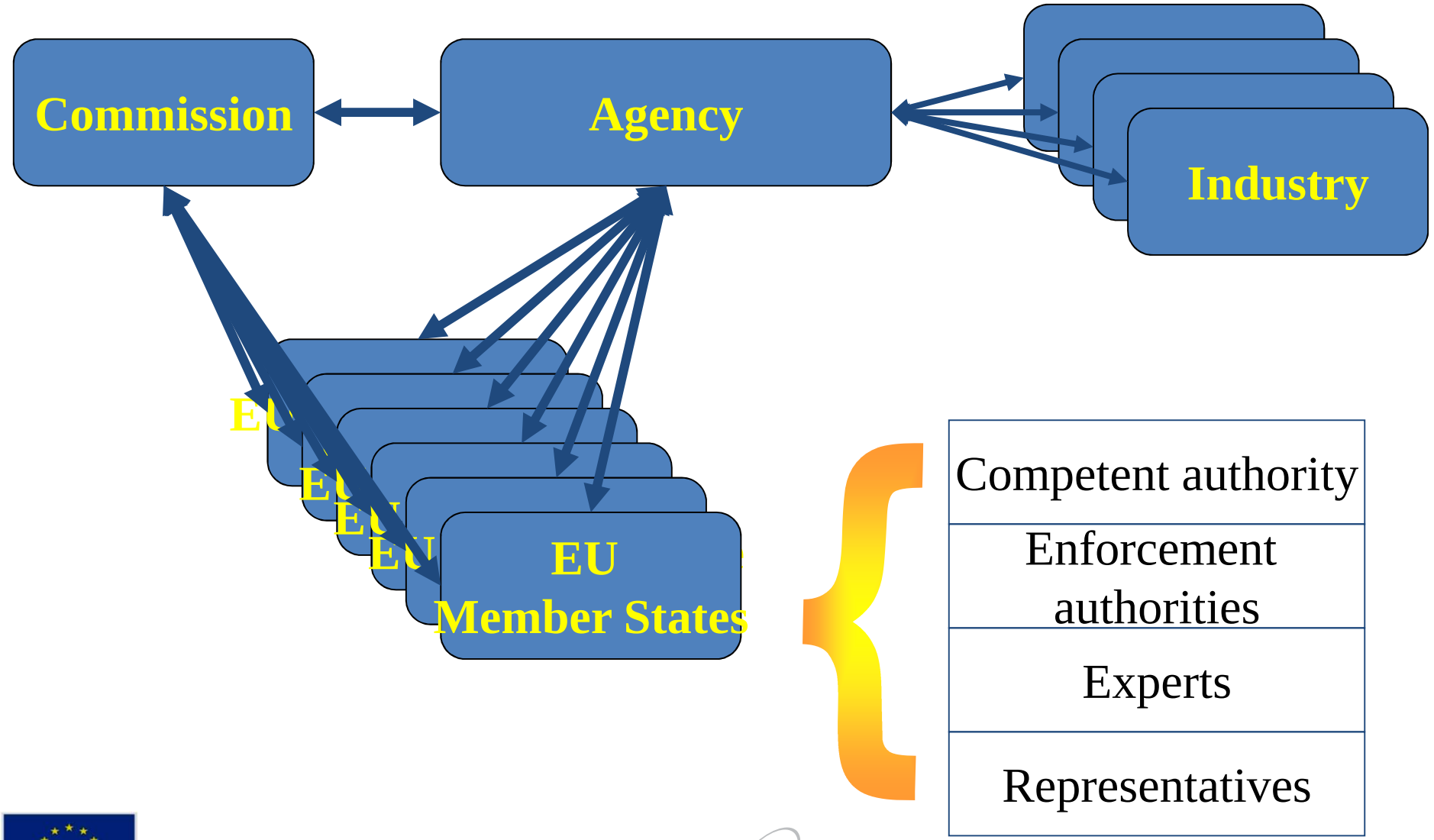
Evaluation by authorities

- **Evaluation based on submitted registrations**
  - Proposals for additional information (high tonnage requirement)
  - Completeness and compliance check of dossiers
  - Substance evaluation based on all information
- **Procedure:**
  - Test proposals: draft decisions by Agency, comments from registrant(s), final decision by MSC / Commission
  - Compliance check: the same procedure
  - Completeness check: decisions by Agency
  - Substance evaluation:
    - Selected by priorities, listed in Community Rolling Action Plan
    - MS rapporteur start evaluation, draft report / decisions, draft opinions from RAC and SEAC, external comments, final decision by MSC / Commission

Drafting decisions by authorities

- **Identify substances candidate for authorisation, criteria:**
  - CMR, categories 1 and 2
  - PBT and vPvB
  - Equivalent concern
- **Select substances for authorisation (Annex XIV)**
- **Granting requests for authorisation**
- **Draft Annex XV dossiers for substances of concern**
- **Draft proposals for restrictions in use**

Organization of REACH



What companies should do in advance

- Analyse consequences of REACH for your business
- Re-(structure) business organisation and decision-making process
  - Responsibility, centralised decisions, acceptance by hierarchy
- (Re-)organise internal records
  - Total view, including legal status, quick access
- Take stock of your portfolio
  - Manufacturing, importing, directly or via toll-manufacturing
  - Substances, composition of preparations, substances in articles
  - Quantities, uses, need
- Contact suppliers and clients
  - Intensify communication
  - Create awareness of REACH requirements up and down supply chain
  - Guarantee availability of essential products
  - Collect information on use/exposure/emission from own uses
  - Collect information on use/exposure/emission from clients

Recommendation to companies

- **Organise a network with other business members or trade associations**
- **Establish as business association a “helpdesk” for members**
  - Prepare, develop, use emission scenarios for standardised applications (uses)
- **Intensify communication up and down supply chain**
  - Arrangement for covering CBI issues

Environment and Climate Regional Accession Network ECRAN

REACH Specifics
Roles & Responsibility

Case studies
A: Clarifications
B: Case studies

Arnold van der Wielen

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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
- Manufacture for use by other “manufacturers”
  - Transported isolated intermediates

Requirements

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

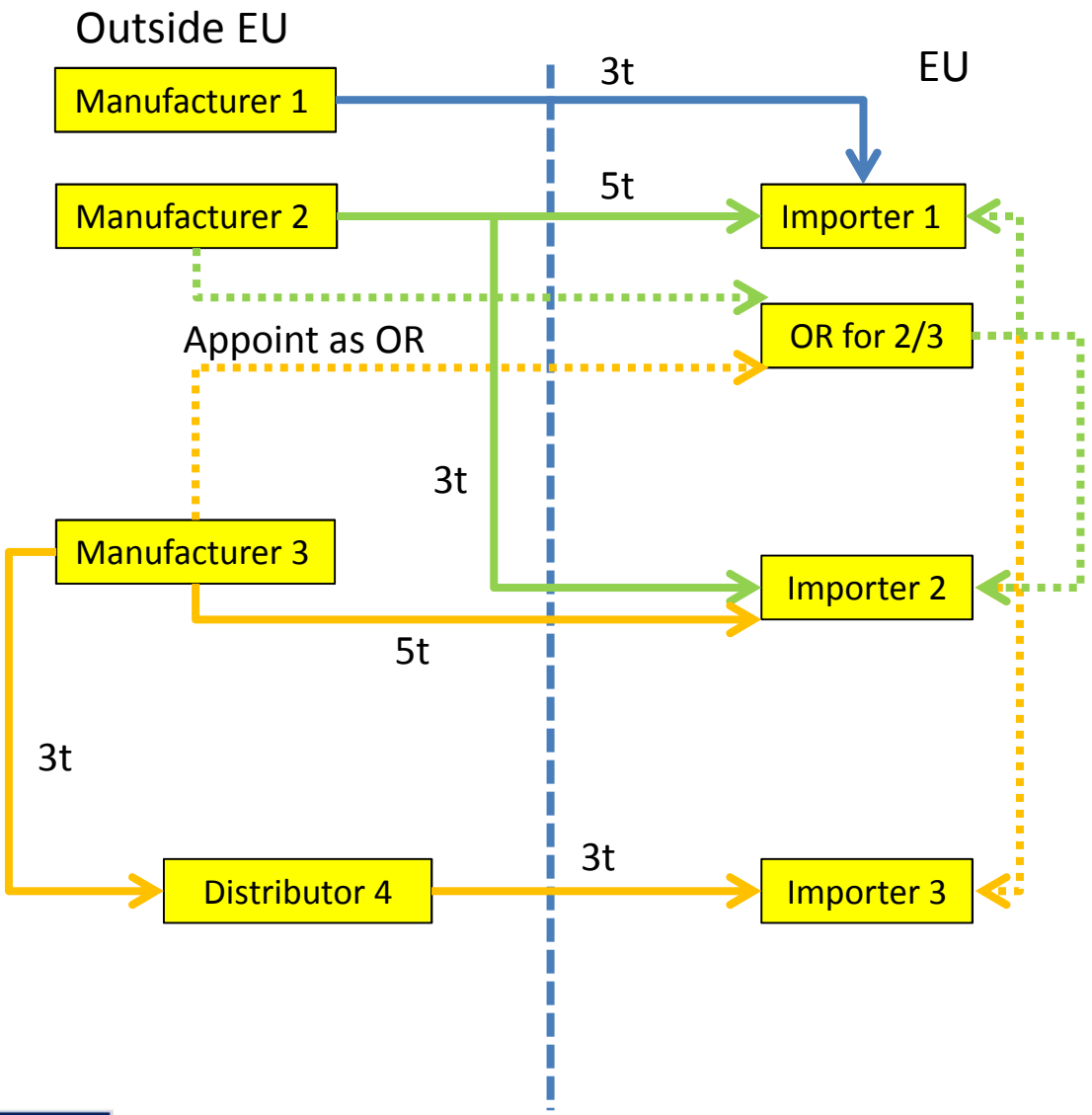
Import

- **Import means physical introduction into the customs territory of the EEA**
  - Trading within EEA is no importation
  - Basic principle if REACH is a.o. free trading within EU (EEA)
- **Example:**
  - "Import" from Bulgaria to Croatia is not an import as defined under REACH. So, a registered substance by a BU company (M/I/OR) does not require further registration
  - "Import" from Switzerland to Croatia requires registration by a HR I/OR

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:**
  - See next slide

Exercise 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"

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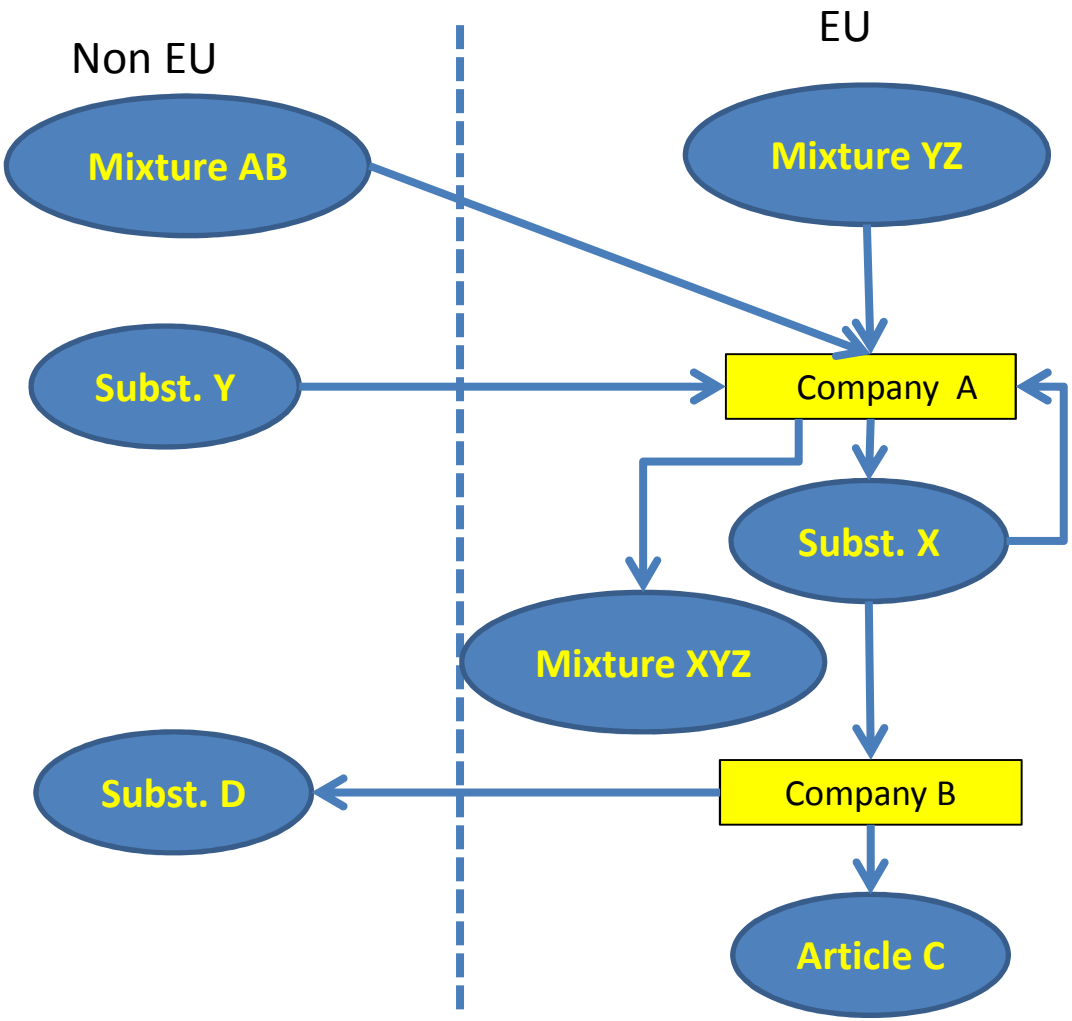
Company may have different roles

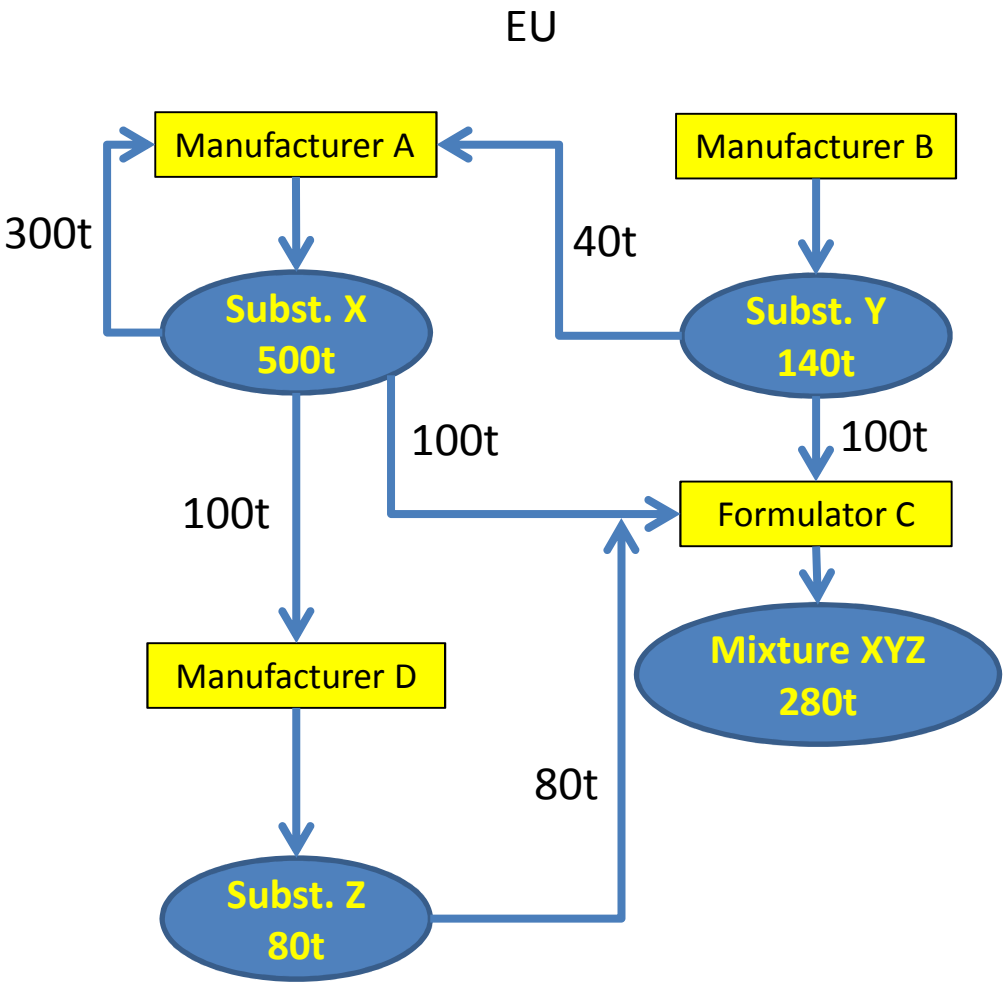


Roles

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

Examples of manufacture



Registration obligations

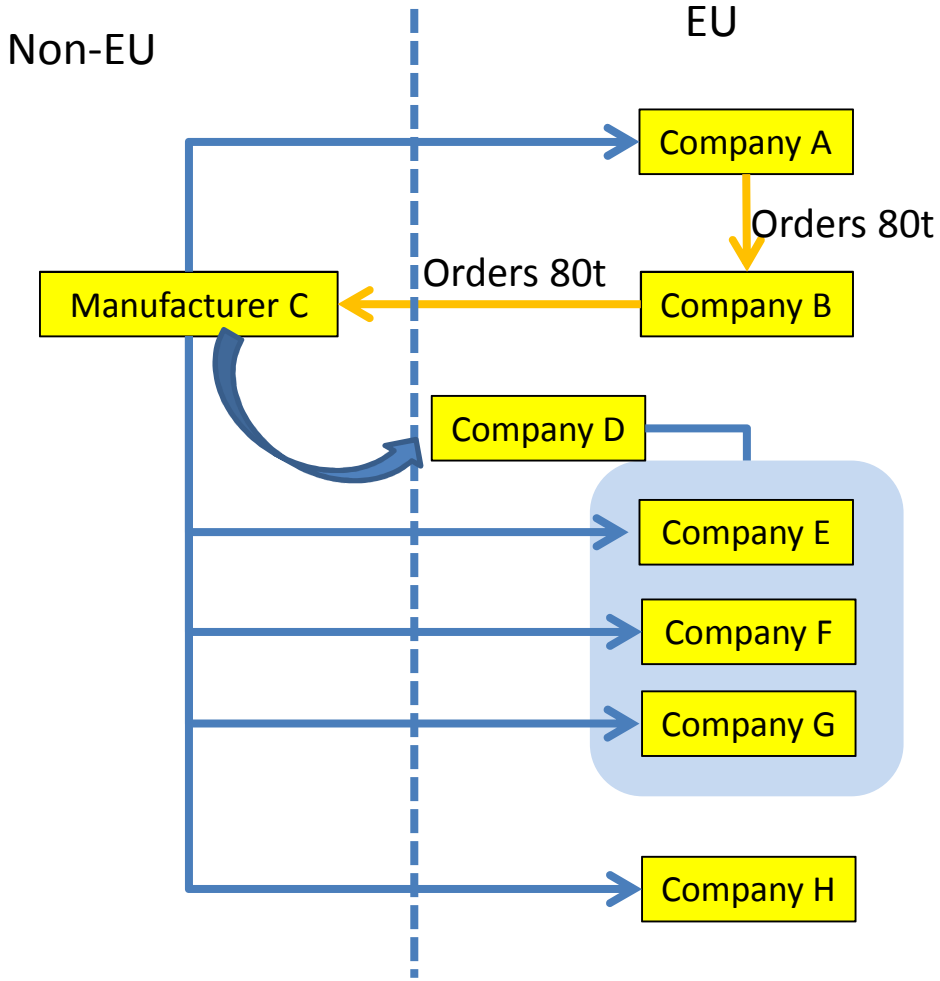
Manufacturer A registers
+ 300t X (isolated inter.)
+ 100t X (transp. Isolat. interm.)
+ 100t X (full registration)

Manufacturer B registers
+ 40t Y (transp. Isolat. Interm.)
+ 100t Y (full registration)

Formulator C no registration requirement

Manufacturer D registers
+ 80t Z (full registration)

Examples of import



Roles of companies

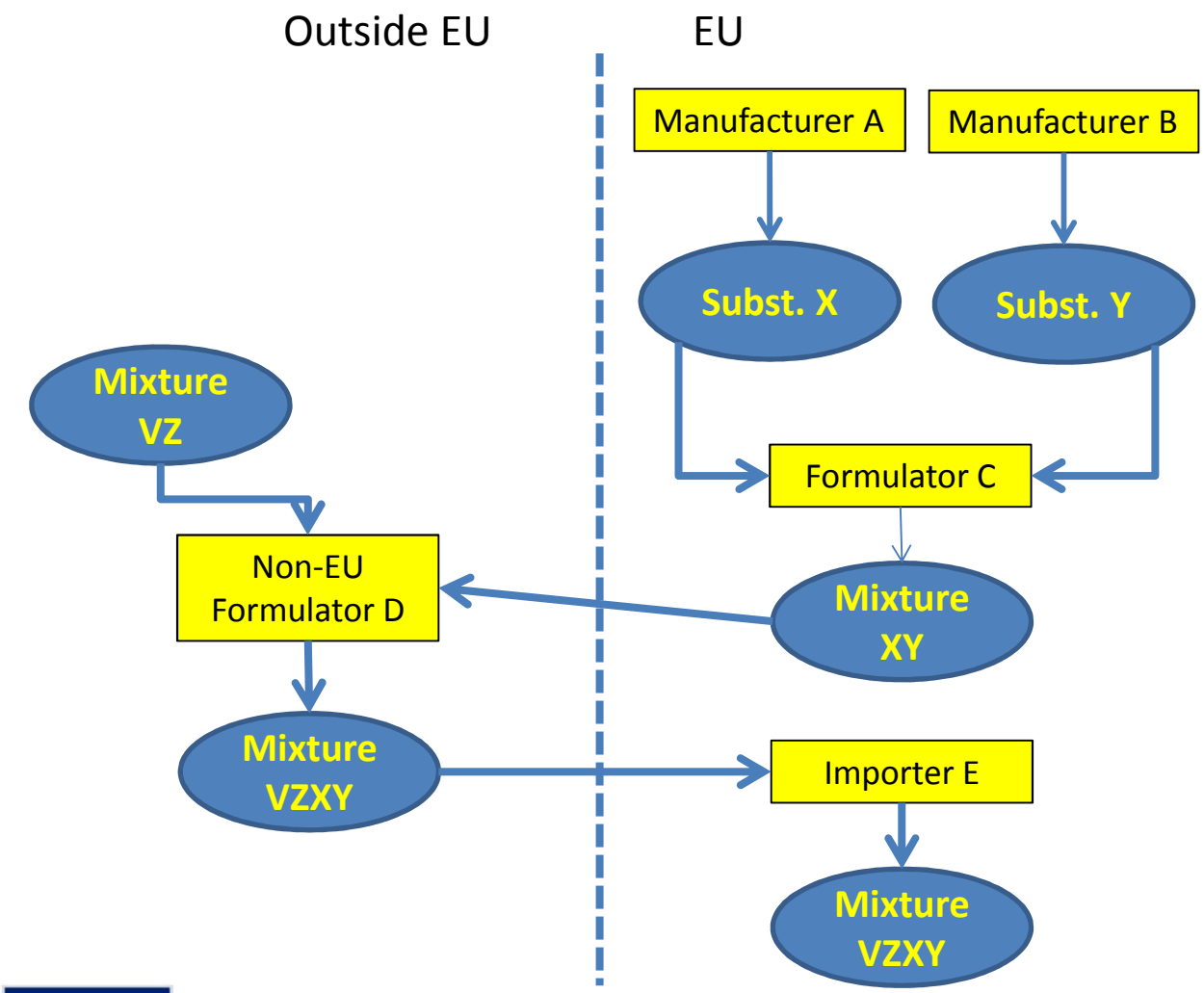
Standard:
Company A is importer (Reg.)
Company B is sales agency
Company C is non-EU manufacturer

But, also possible:
Company A is DU
Company B is importer (≈OR) (Reg.)

Example OR:
Company D = OR for E, F, G (Reg.), should be appointed by C
Companies E, F, G become DUs according to REACH
Company H is importer (Reg.)

Note: Only non-EU M/F/P-article may appoint an OR

Example of re-import



Registration obligations

Manufacturer A register X
Manufacturer B register Y

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

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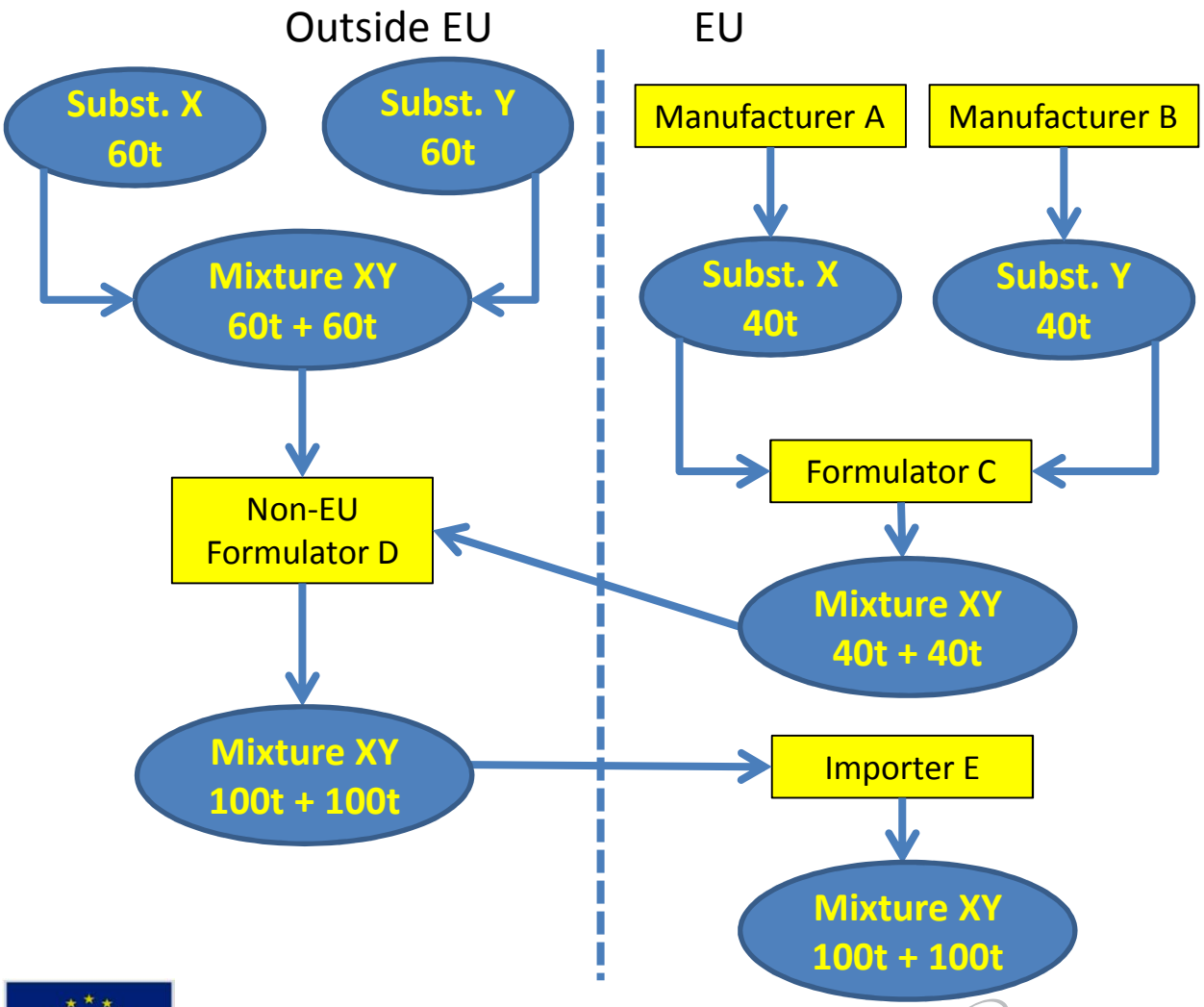
Exercise



Registration obligations

Manufacturer A registers 40t X
Manufacturer B registers 40t Y

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

Producer of an article

Is a DU with specific additional requirements

- Registration requirement for a component in an article intended to be released during normal or reasonable foreseeable use
- Notification requirement for non-releasing Candidate List substance(s) in an article if ….
  - > 1 tpa per producer/importer of an article
  - Present in article > 0.1% (w/w)
- Information down the supply chain, certainly if article contains candidate list substance(s)

Note: Most "articles" with intended release during normal use are considered to be containers of substances/mixtures and not articles according to REACH

Environment and Climate Regional Accession Network ECRAN

National helpdesks

REACH Specifics – Helpdesk

Awareness and info dissemination

Shufan Keetlaer-Qi

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Overview

Helpdesks under REACH and CLP

- Obligation of Member States
- ECHA Helpdesk
- Network of Member State Helpdesks
- The Dutch helpdesks

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Why National Helpdesks?

Article 124 REACH and article 44 CLP

The Member states shall establish **National Helpdesks** to provide advice on their respective responsibilities and obligations to:

- ***Manufacturers***
- ***Importers***
- ***Distributors***
- ***Downstream users or***
- ***Any other interested parties***

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REACH National Helpdesk (NHD)

- The countries of the European Union, Norway, Iceland and Liechtenstein
- NHD give support on questions related to BPR (Biocidal Products Regulation), CLP (Classification, Labelling and Packaging) and REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) obligations
- In many cases, NHD are located in national competent authorities.
- NHD is the first point of contact for companies based in those countries.

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REACH helpdesk & CLP helpdesk

Expectations from ECHA

- To be first point of contact for companies located in their countries
- Provide high quality answers in their own language
- Disseminate information on REACH and CLP to all relevant parties
- Closely follow up updates of the ECHA website and relevant publications

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REACH helpdesk & CLP helpdesk

Pragmatic approach

- start small with existing organizations
- information through website/FAQ as first filter
- monitoring of what market needs & developments
- flexible organization (quickly adjustable)

Identity

- Independant (free of commercial influences)
- Reliable
- Accesible

Scope

- no company specific advice
- ”WHAT” not ”HOW”
- no consultancy

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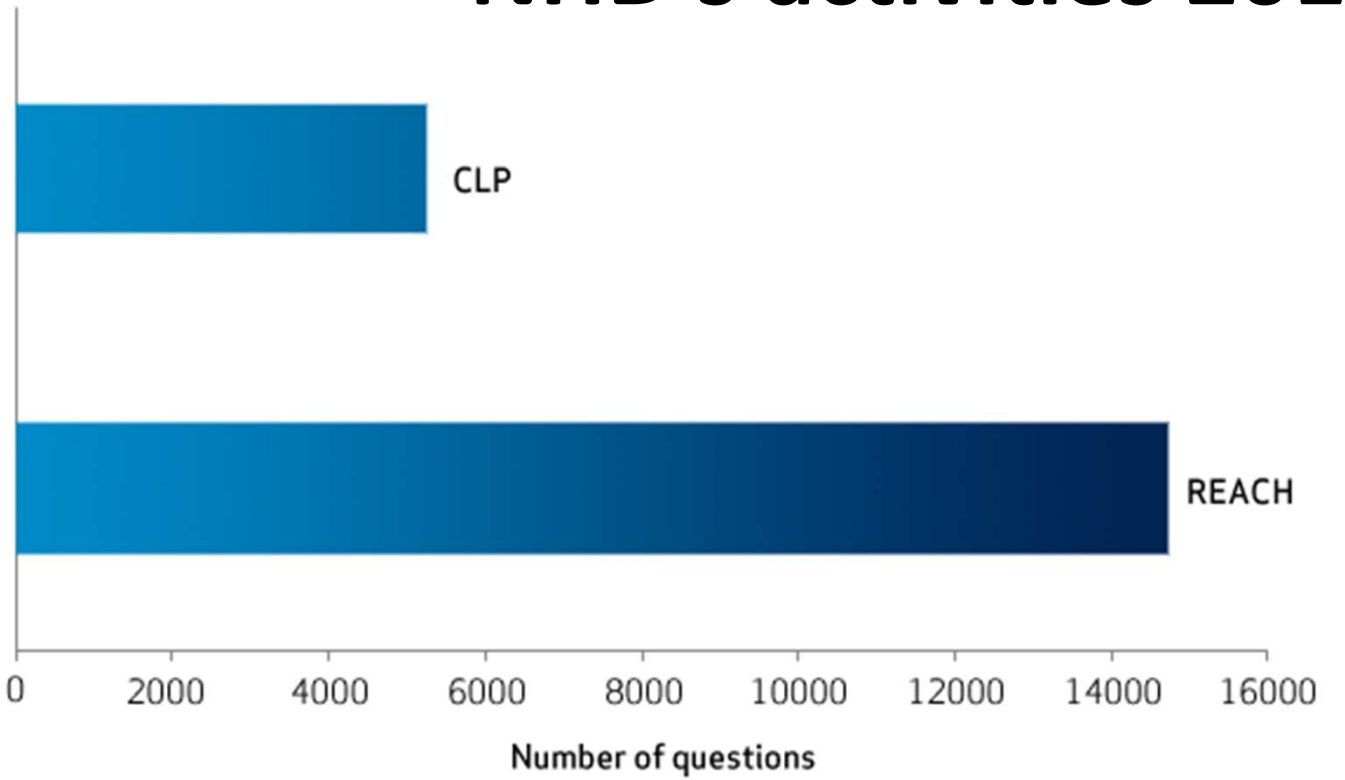
Annual statistics of CLP and REACH NHD's activities 2013



Received by national helpdesks (28 MSs, Iceland, Liechtenstein, Norway, Serbia and Turkey)

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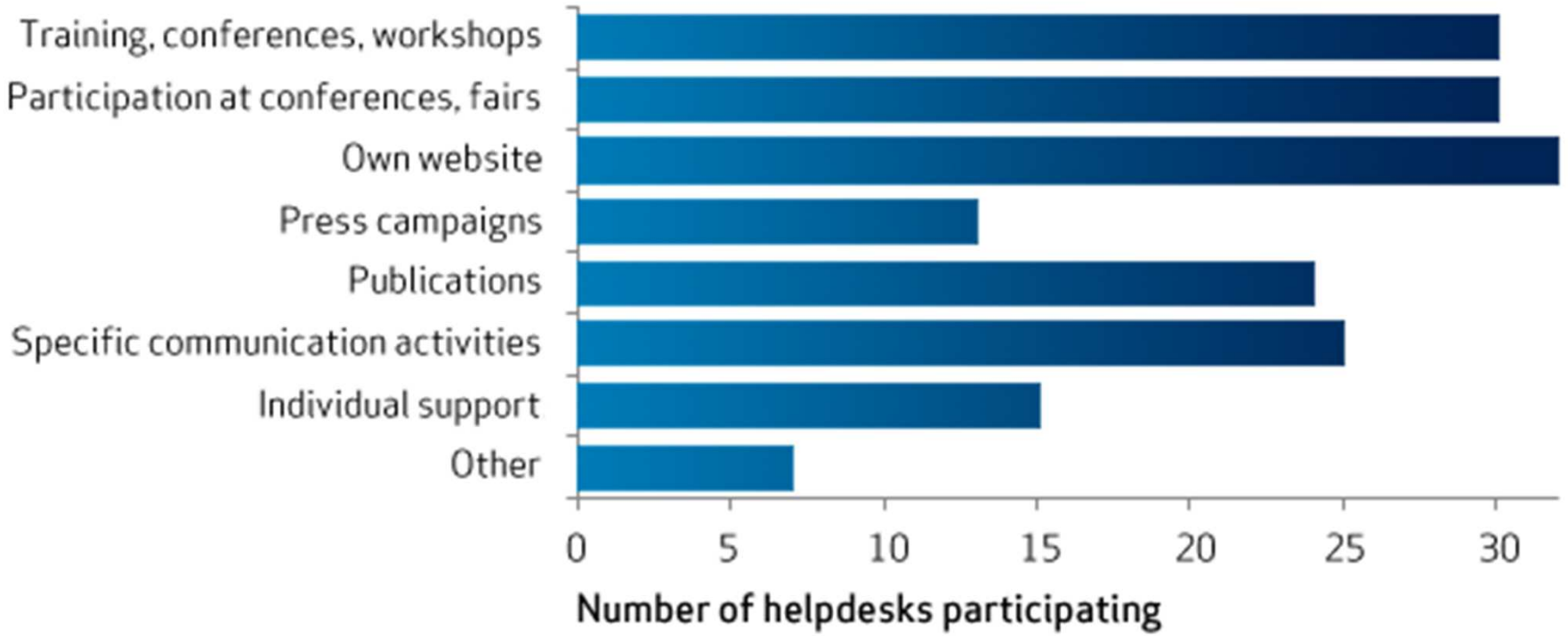

Activities of national helpdesk besides replying to questions

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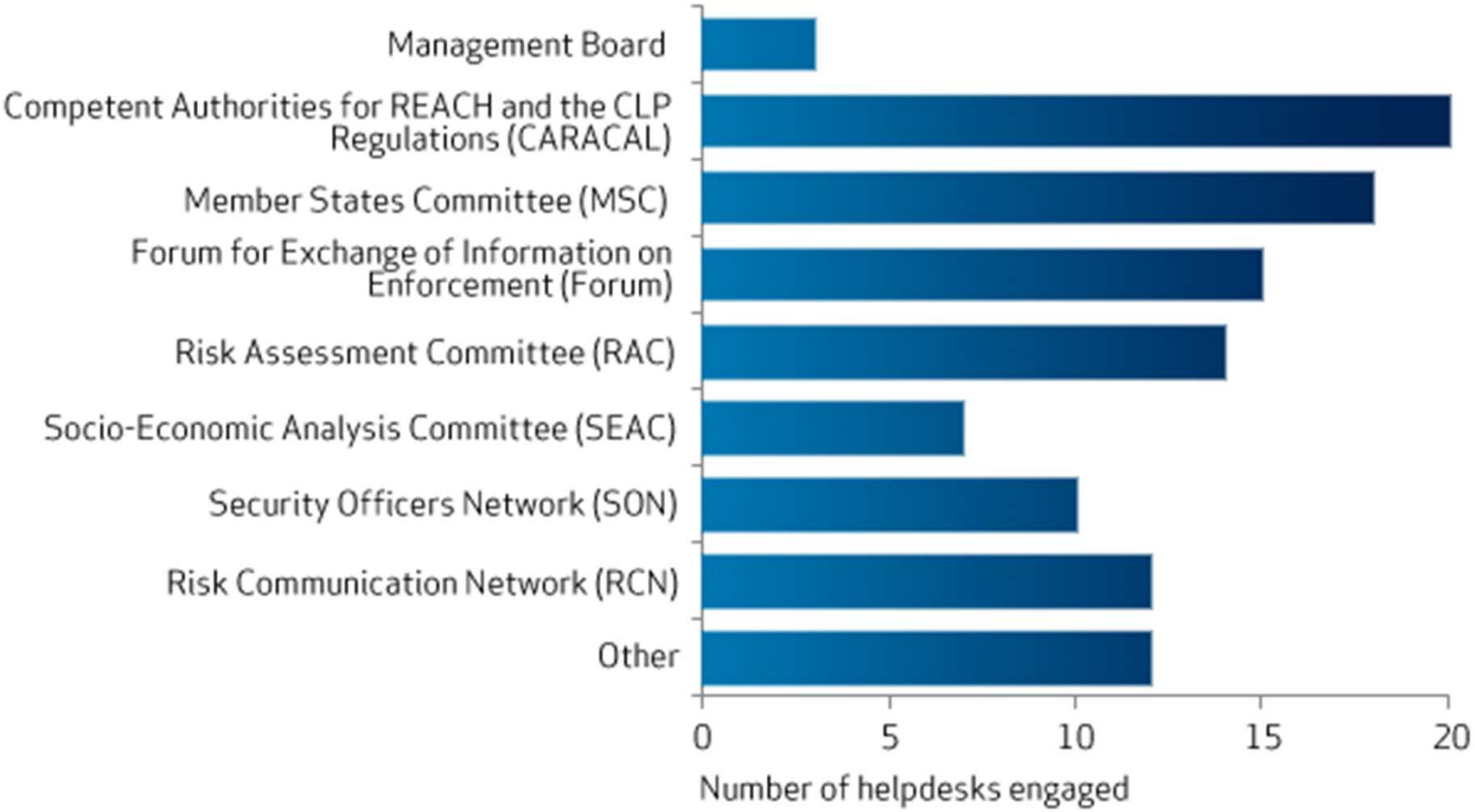

Involvement of national helpdesk staff in activities and network of ECHA and the EC

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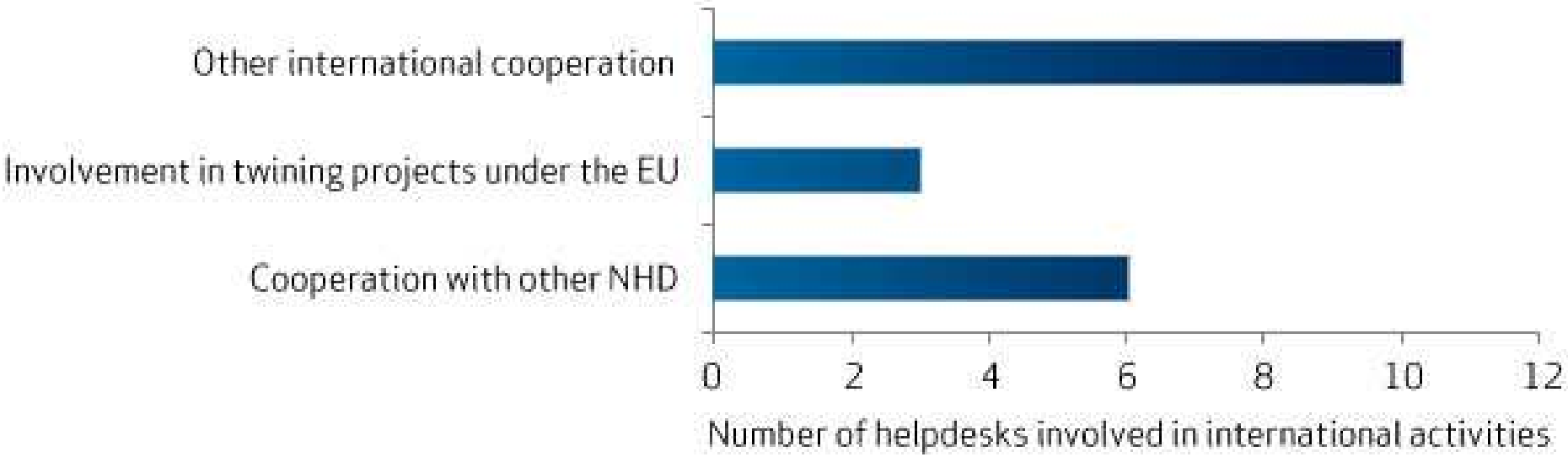

Involvement of national helpdesk staff in international activities in 2013

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ECHA Helpdesk

- Gives advice on obligations under the BPR, CLP, PIC* and REACH regulations
- Offers support on ECHA's IT tools, such as IUCLID 5, REACH-IT, R4BP 3 # and Chesar.
- Free of charge.
- Within 15 working days

*** PIC**: Prior Informed Consent Regulation
 # R4BP 3: Register for Biocidal Products

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ECHA Helpdesks

4 domain solutions:

IUCLID 5 support for registered IUCLID users
REACH support for registrants
REACH IT support (mainly for MS CA and ECHA staff)
ECHA-ICT support for ECHA staff

Helpdesks enable efficient exchange of information:

Knowledge database to inquire answers
Answer questions
Solving Problems (e.g. resolve root cause of IT related incidents or update of guidance)

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Network of NHD - Helpnet

- Participants: MS BPR, CLP and REACH helpdesks + ECHA
- Scope:
  - •Information exchange on the implementation of the BPR, CLP and REACH regulations.
  - •Common understanding on the legal requirements under these regulations.
  - •Consistent and harmonized advice to stakeholders
  - •Capacity building of NHD.
  - •Communication and awareness raising activities with a particular emphasis on SMEs.
  - •Training for NHD.

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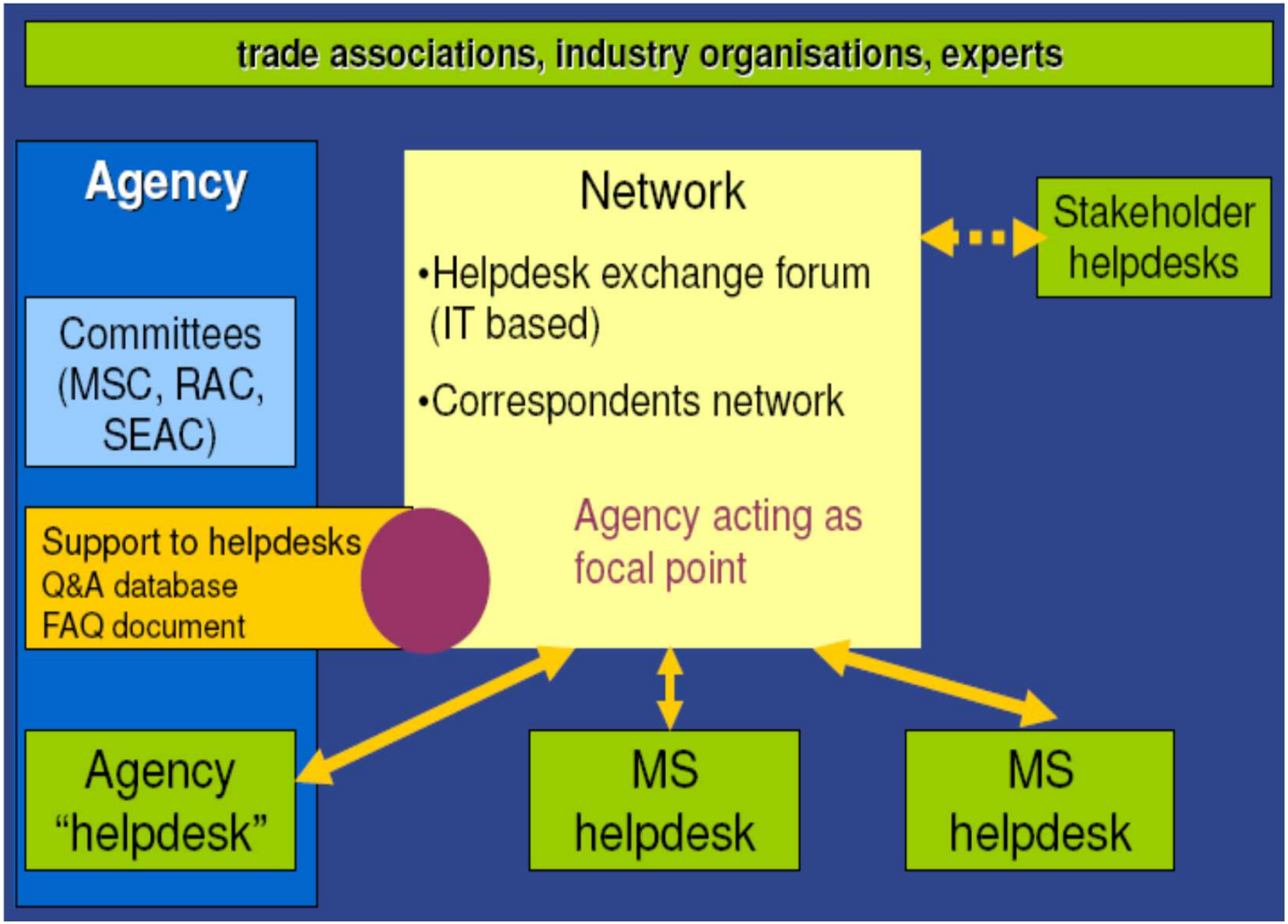
Operation of HelpNet

- The HelpNet Steering Group is the governing body of the HelpNet.
- Steering Group: MS NHD + ECHA + EC + observers from candidate countries and/or stakeholder
- Meets at least once a year at the premises of ECHA and its work is coordinated by the HelpNet Secretariat.

Network of Member States Helpdesks



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Tools for the network of MS helpdesks

Internal Q&A database

contains all questions posted in the exchange forum and final answers given by originating helpdesks

in addition, questions and answers from national helpdesks may be added

will not be “filtered” (i.e. may contain confidential information, no quality control on the answers given etc.)

only for internal use of network

FAQ document/database

will contain questions in a standard formulation and answers agreed among the helpdesks

publicly available

will serve as a reference for future questions

+ About Us
+ Regulations
+ Addressing Chemicals of Concern
+ Information on Chemicals
+ Chemicals in our Life
+ Support
Publications
+ REACH 2018

National helpdesks contact details

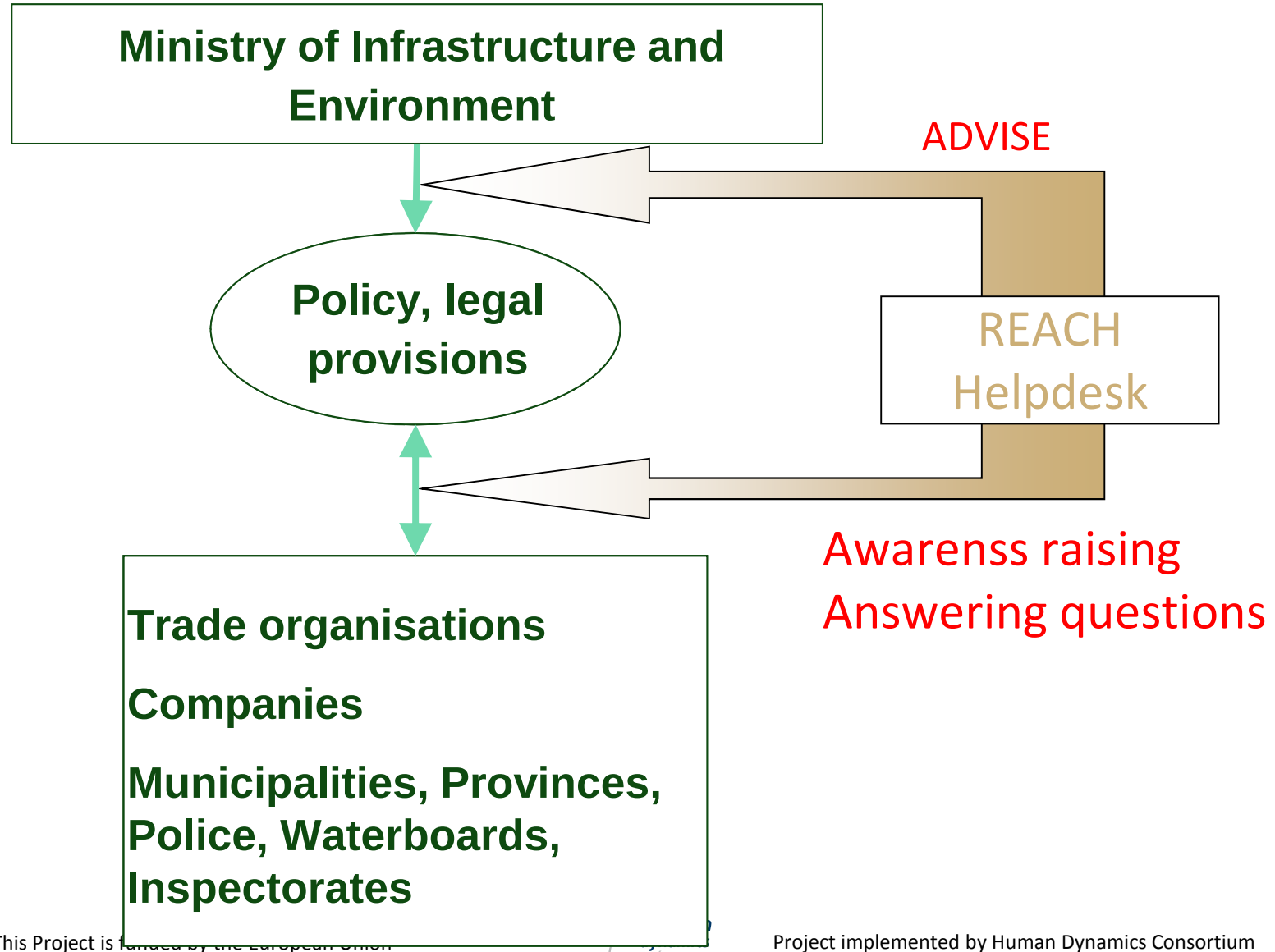
- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany

- Lithuania
- Luxembourg
- Malta
- **Netherlands**

BPR helpdesk	CtGB - College voor de toelating van gewasbeschermingsmiddelen en biociden Stadsbrink 5, 6707 AA Wageningen Telephone: +31 0 317 47 18 10 Email: helpdesk (at) ctgb.nl BPR website
CLP helpdesk	Ministry of Health, Welfare and Sport (VWS) PO Box 20350 2500 EZ Den Haag CLP website
REACH helpdesk	Ministerie voor Infrastructuur en Milieu Postbus 20951 2500 EZ Den Haag REACH website
Safety Data Sheet	national emergency telephone number - to be included in section 1.4 of SDS

- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain

Position of Dutch REACH Helpdesk



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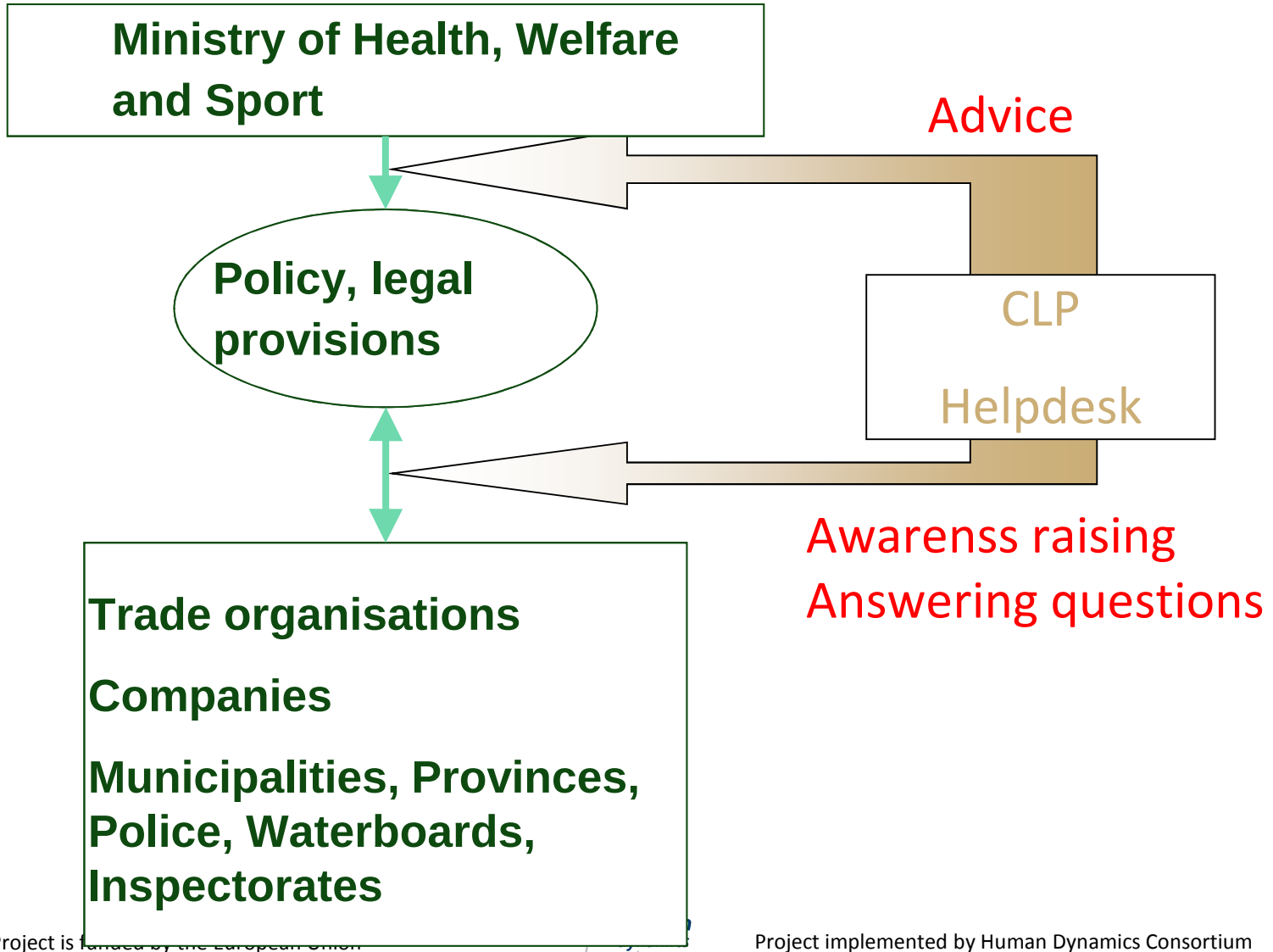
Position of Dutch CLP Helpdesk



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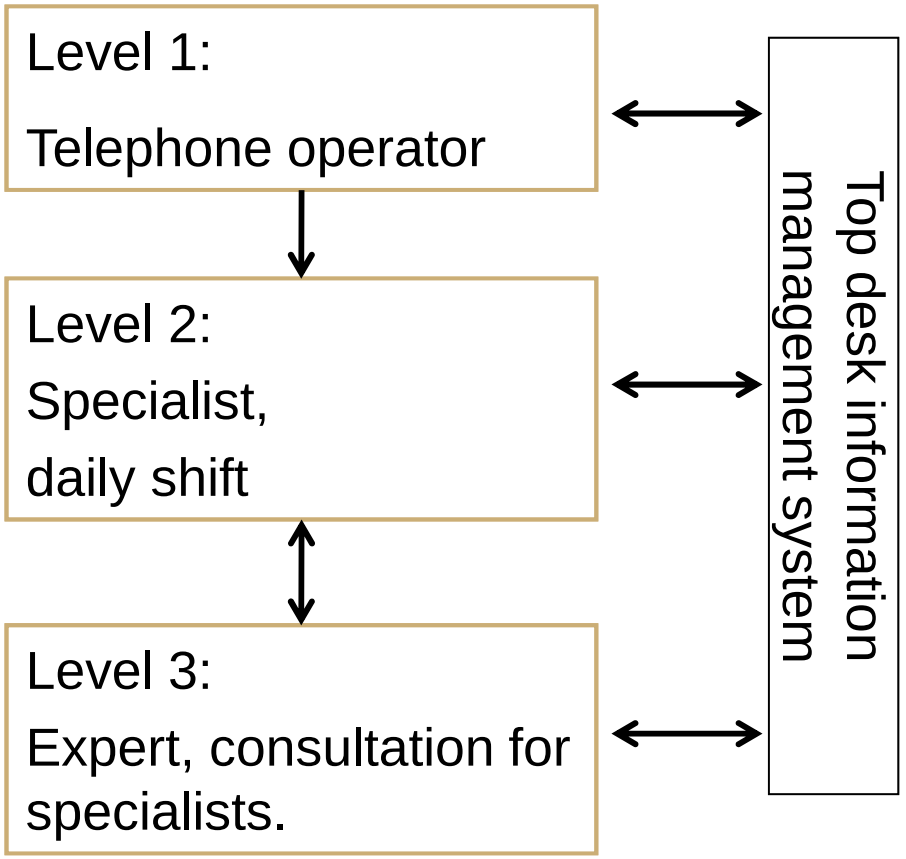
Organisation

Daily: telephone 9:00 – 12:00
e-mail and website 24 hours



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Dutch REACH and CLP helpdesk

- Launch REACH helpdesk:
  January 1, 2007

- March 14, 2007
  Official opening by the Minister of Economic Affairs, Maria van Hoeven

- Start of the CLP Helpdesk and Website: March 2008

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Dutch REACH & CLP helpdesk

Executive body:

- Cooperation between NL Agency & RIVM

Commissioning Authority :

- REACH: Ministry of I&E
- CLP: Ministry of Health, Welfare and Sport

Supervising committee

- ministries, branch organisations, SME's

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Dutch REACH and CLP helpdesk

Main achievements:

- Website with up-to-date information on the Regulations including:
  - FAQs
  - Links to other information sources (e.g. downstream legislation), enforcement and ECHA
- Informing stakeholders: via separate education campaign (meetings, workshops, flyers etc..)
- Repeated training sessions of national enforcement staff
- Providing answers to stakeholders

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Dutch REACH Helpdesk

Products

- Guidance
- Role Identification Tool
- Specification of responsibilities for each role
- Links to other organisations and tools
- FAQ
- Newsletter
- General information

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Dutch REACH Helpdesk

75% of the questions concern:

- Substances in articles
- Registration
- Information-exchange, SIEFs and consortia
- Import
- Safety data sheets
- Globally Harmonised System (GHS)

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Dutch CLP helpdesk

75% of the questions concern:

- Labelling
- Classification in general (translation)
- Information campaign

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Preparation of the Dutch Ministerie on REACH and CLP

- **Ministry in cooperation with:**
  - Trade organizations
  - Other departments

- **Main roles:**
  - Trade organizations: answer on ‘how’- question
  - Government/helpdesk: answer on ‘what’- question

- International frameworks also determine the playground

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Important Elements for the Preparation

- **Support the trade and industry**
  - Inform and monitoring effectiveness
  - Helpdesks

- **Implementation governmental tasks**
  - Design acting organisation
  - Design enforcement (Inspections)
  - Support permit providers
  - Implementation in the legal regulations

- **Design plan for monitoring the effects of information**

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The information course

- Aimed at branches
  - Reach: Roll-out programme
  - Specify folders and information sheets

- Role Identification Tool:
  - Insight in actor (producer/importer/user)
  - and accompanying tasks

- Branches stay primary responsible to inform the members with adjusted information

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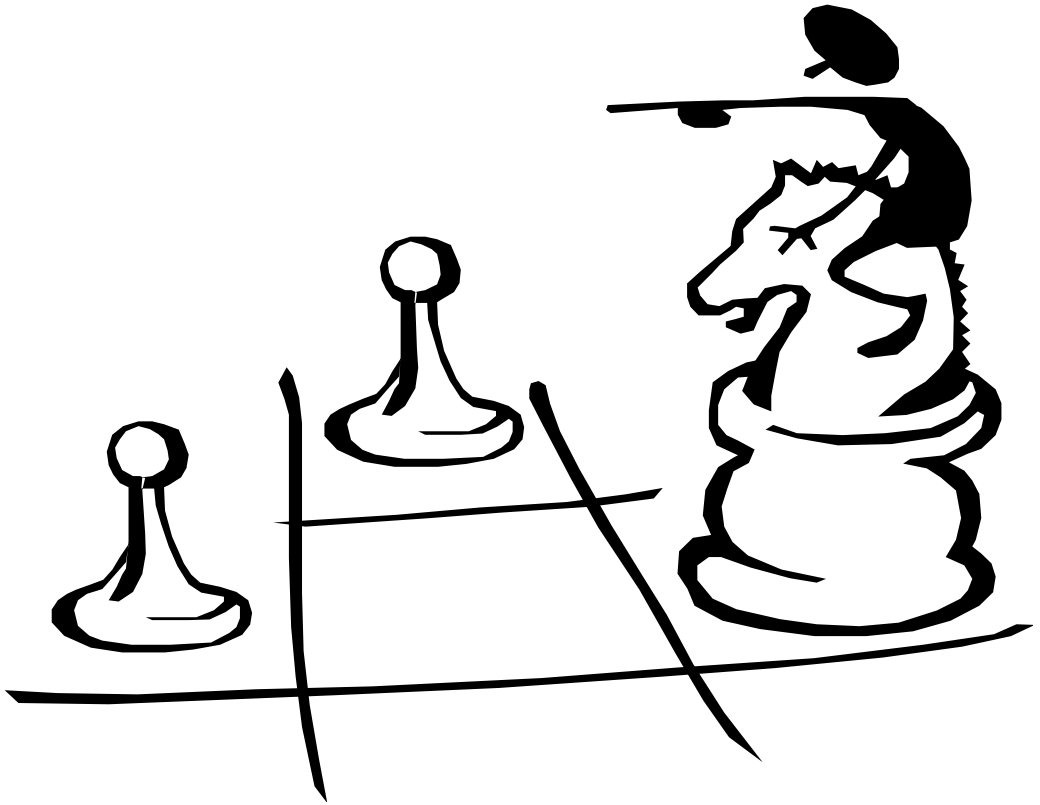
Discussion



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- What will be the role and tasks of the REACH and CLP helpdesks in your country?

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- Who are the customers of the REACH and CLP helpdesk in your country?

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- What are the products in your country which can be relevant for REACH?

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Enforcement of the REACH and CLP Regulations in EU Member States

Ike van der Putte

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PART 2 Practical Consequences REACH Enforcement

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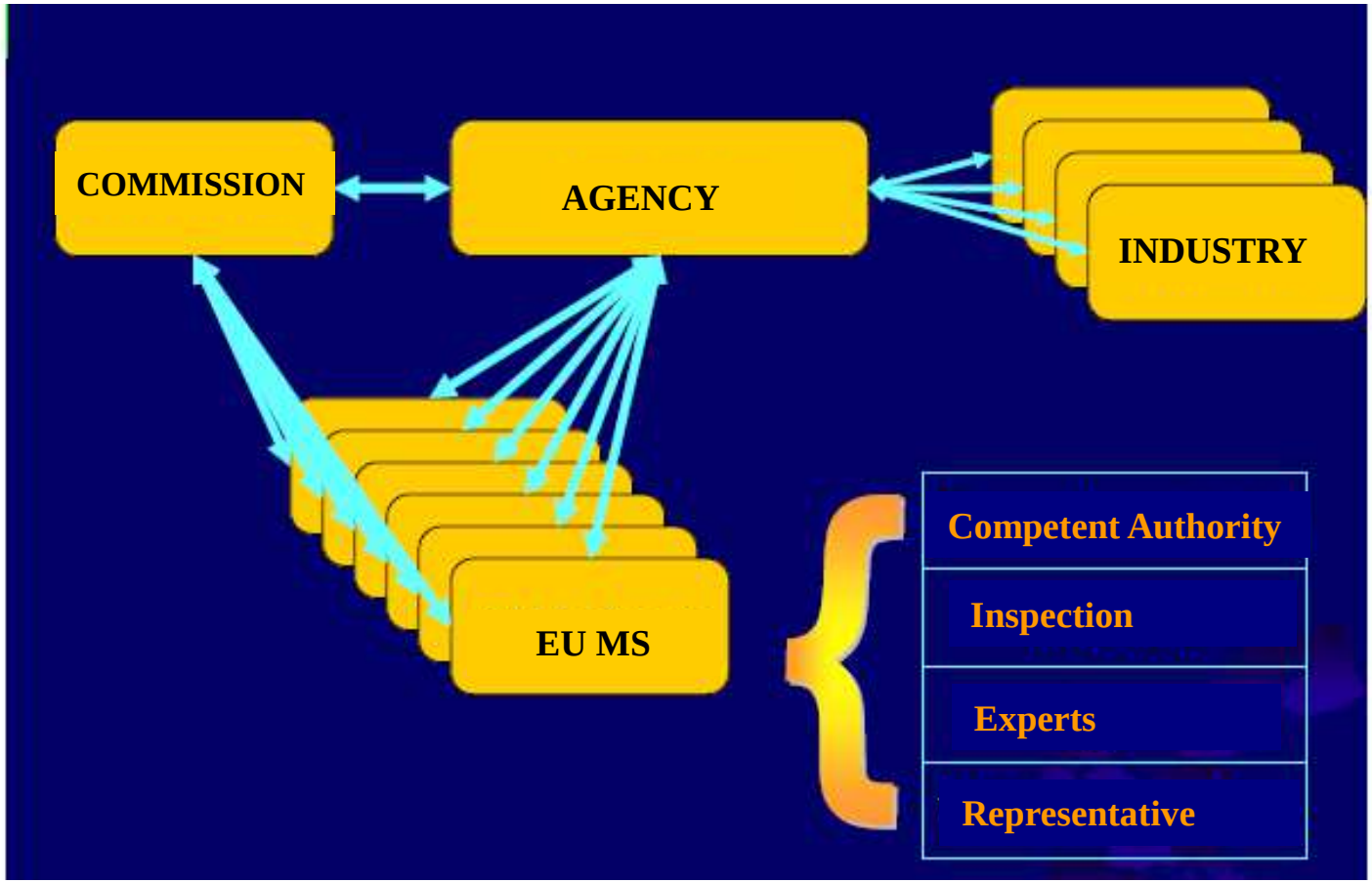
REACH Organisation



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Registration & Testing Costs

REACH Regulation (1907/2006)

Type of REACH obligation	Annual Quantity	Number of sustances	Registration Costs**	Estimated testing costs***
Evaluation (level 2)	≥ 1000 t (& SVHC)	15,000	€24,000-31,000	€ 200,000
Evaluation (level 1)	≥ 100 t	4,500	€ 8,600 - 11,000	€ 160,000
Registration (CSR)*	≥ 10 t	6,000	€ 3,000 - 4,000	€ 40,000
Registration (base set)	≥ 1 t	26,000	€ 1,200 - 1,600	€ 12,000
Out of REACH	≥ 100 kg & < 1 t	???	Not applicable	Not applicable
Out of REACH	≥ 10 kg & < 100 kg		Not applicable	Not applicable

* Excluding Chemical Safety Report

** Depending on size of the company and consortium Participation. Costs are per registrant!

*** Average costs

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Base Set (REACH ANNEX VII) > 1 tonne/year

- ✓chemical identity
- ✓production information
- ✓physical chemical properties information
- ✓skin & eye irritation studies
- ✓*in vitro* mutagenicity study
- ✓acute oral toxicity study
- ✓acute ecotoxicological (Daphnia) studies
- ✓degradation studies

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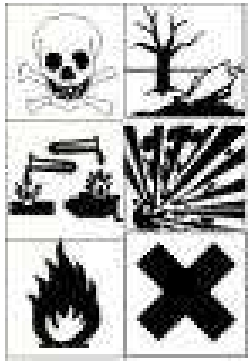
Need for Enforcement 2 – Safety of Man & Environment

Classification & Labelling



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Need for Enforcement 2 – Safety of Man & Environment

Safety Data Sheet (SDS)

The SDS and packaging of cements and cement preparations containing more than 0.0002 % soluble chromium (VI) of the total dry weight of the cement must bear the inscription:

"Contains chromium (VI). May produce an allergic reaction"

unless the preparation is already classified and labelled as a sensitiser with phrase R43. (H317)

Example: Construction Channel Tunnel

5000 workers - 50% skin problems

(50% sensitive to chromium)

Solution: reduce Cr(VI) by adding 0.35% ferrosulfate

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Need for Enforcement 2 – Safety of Man & Environment

SDS under REACH (Title IV) – info supply chain

- If substance is put on the EU market >10 tonne/year a Chemical Safety Assessment (CSA) will have to be made
  - ✓ Human health hazard assessment
  - ✓ Environmental hazard assessment
  - ✓ PBT and vPvB assessment
  - ✓ Exposure assessment
  - ✓ Risk Characterisation
- This information has to be reported in a Chemical Safety Report (CSR) including information regarding:
  - ✓ properties
  - ✓ manufacturing & use
  - ✓ classification & labelling
  - ✓ exposure scenario's
- SDS will be extended (ESDS) under REACH due to inclusion of exposure information.

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Conditions for Enforcement

- Effective implementation of environmental and chemicals legislation can be guaranteed only if its requirements (permits,notification, proper labelling…) are enforced in an
- appropriate and effective way.

- This is facilitated if the legislation is clear and the responsibilities of industry and government are specified.

- There are various European networks in which national authorities are working together to reach harmonized working methods in the enforcement of environmental and chemicals legislation.

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Environment and Climate Regional Accession Network ECRAN

European Enforcement Networks

Environmental Legislation: IMPEL

Implementation and Enforcement of Environmental Law network

Chemicals Legislation: CLEEN

Chemicals Legislation European Enforcement Network

ECHA FORUM

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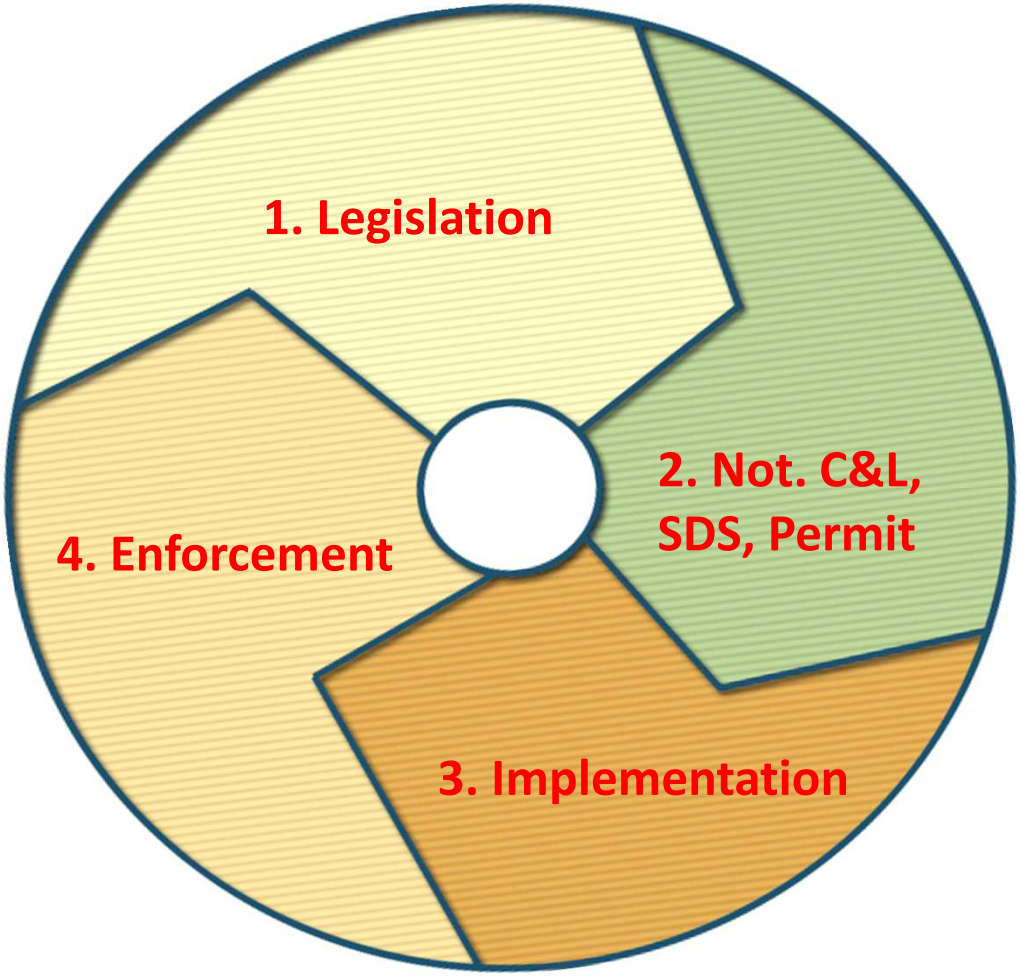
Enforcement: Regulatory Cycle



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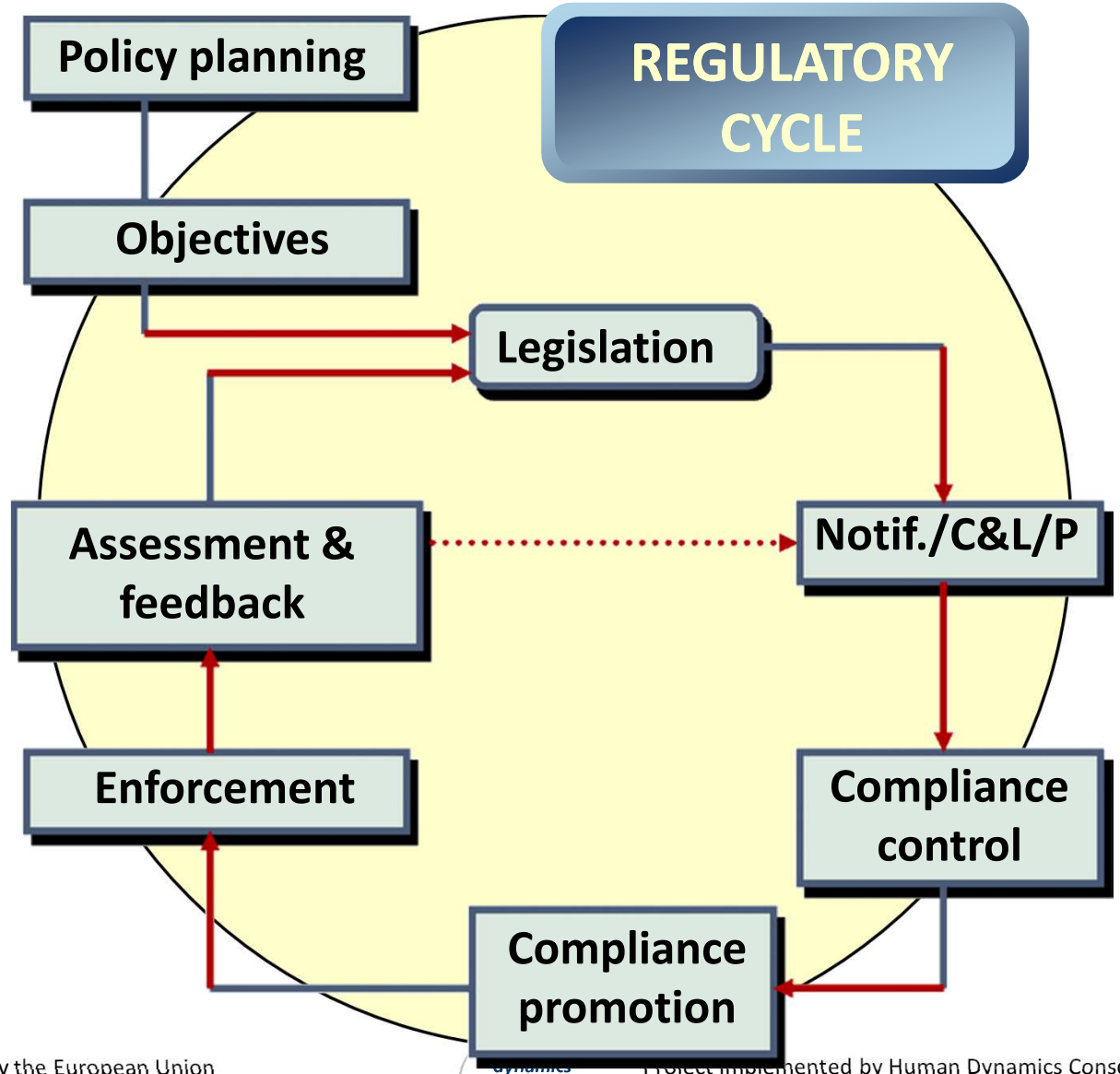

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Lessons learned
Past initiative Chemicals Legislation - CLEEN

NONS *(Notification of New Substances), 1995 – 1996*

- Scope: Notification of New Substances Dir. 67/548/EEC and 92/32/EEC
- Focus: Dyestuffs

SENSE *(Solid Enforcement of Substances in Europe), 1996 - 1997*

- Scope: Notification of New Substances, C&L and MSDS of Substances Dir. 67/548/EEC and 92/32/EEC
  Focus: Photochemicals, paints, intermediates, dyestuffs, paper industry chemicals

EUREX *(European Enforcement Project on Existing Chemicals),1997 – 1999*

- Scope: Existing Substances Regulation Reg. (EEC) 793/93
- Focus: Art. 3 and 4 (data submission)

ECLIPS *(European Classification and Labelling Inspections of Preparations, including Safety Data Sheets), 2002-2003*

- Scope: European legislation on classification and labelling of chemical products and on Safety Data Sheets.

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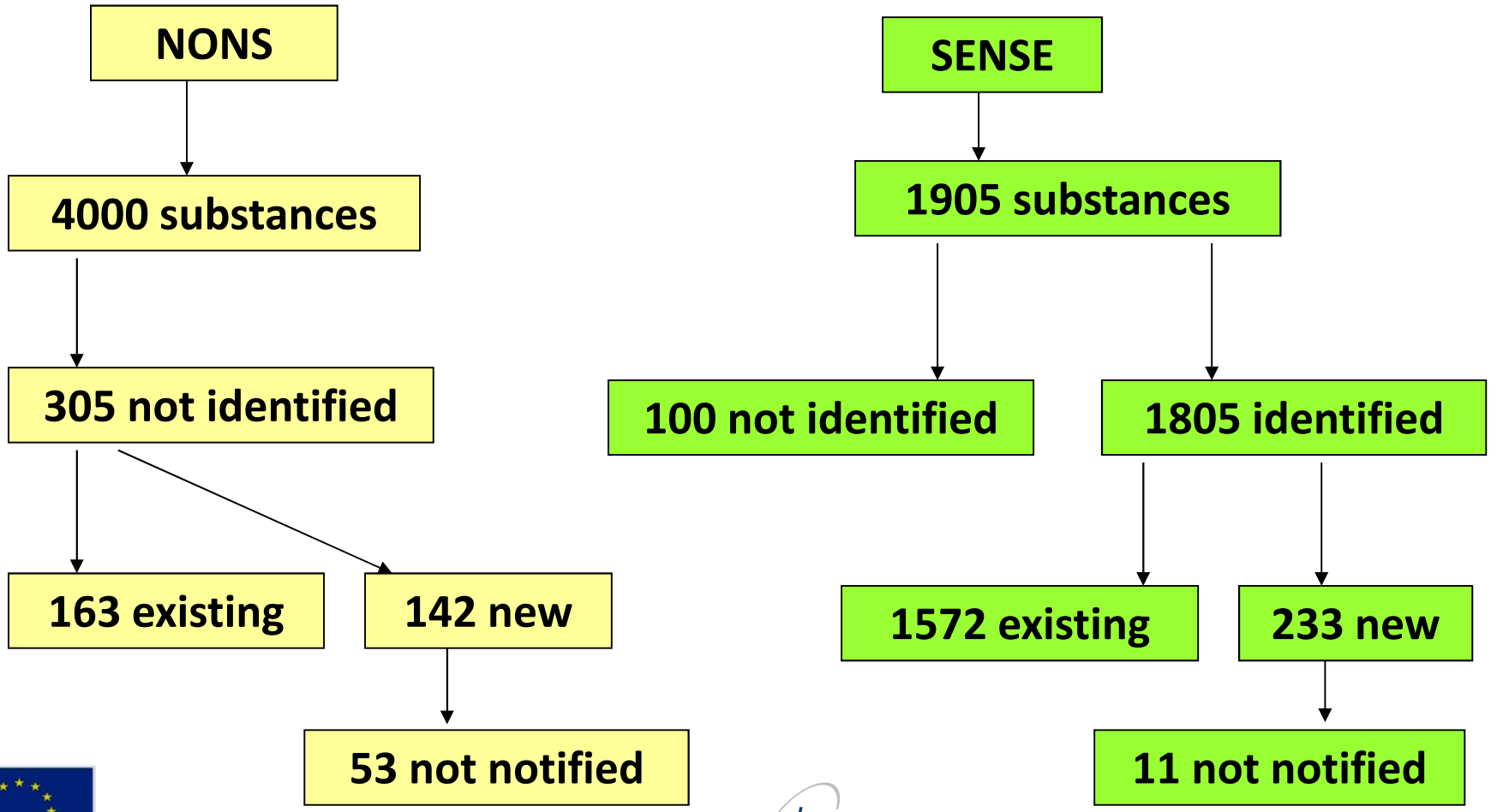
Lessons learned
Past initiative Chemicals Legislation - Notification



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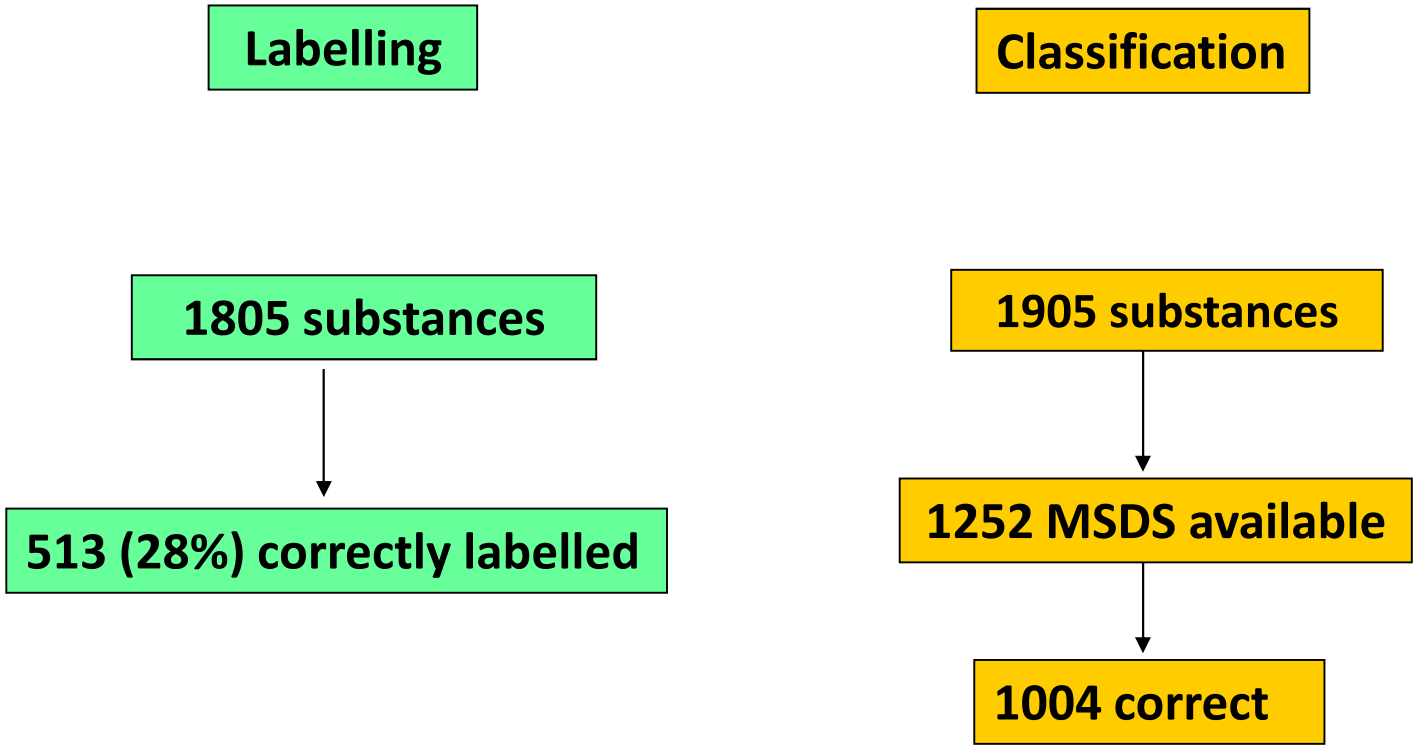
Lessons learned
Past initiative Chemicals Legislation – C&L and MSDS

SENSE Project



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What should we expect from REACH?

REACH Enforcement Network (Title X)

- Enforcement of REACH will have to be harmonized. This process will be covered by the establishment of the Forum (art.86).
  - ✓ This Forum is established by the Agency (Finland)
  - ✓ Each Member State shall appoint one member to the Forum
- This Forum will be responsible for exchanging experience on enforcement to reach a harmonization in the European enforcement of the REACH regulation

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What should we expect from REACH?

Enforcement (Title XIII & XIV)

- Competent Authorities of Member States are responsible for REACH enforcement (art. 121 and 125) :
  - ✓ Different inspections (labour, environment, health) will have to work together to avoid duplication
  - ✓ Penalties for non-compliance will have to be notified to the Commission before December 2008
- Member States have to report their enforcement activities to the European Commission (art. 127):
  - ✓ every 5 years this report will have to be submitted to the Commission (art.117)
  - ✓ first report to be submitted by June 2010

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What should we expect from REACH?

Dutch Example (1)

- Various inspectorates are now trained in REACH.
- Env. Insp. is co-ordinating enforcement
- Water, Goods, Health & Labour Insp. will have to share expertise to avoid duplication of inspections
- Penalties are published in Dutch Parliament
- Infringements will be punished according to Law for Economic Offences
- Penalties will be “light” or “heavy” depending on the infringement

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What should we expect with REACH?

Dutch Example (2) - Quiz

Infringements and the related penalties in The Netherlands:

- Art. 5: "No data no market" HEAVY

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

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

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

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Inspection – An impression of the field work

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CHECKLIST FOR THE INSPECTIONS 1

Former Chemicals legislation

Preparation of the inspection

a. selection of involved authorities and training of involved inspectors
b. involve other relevant organisations
c. selection of companies to be visited
d. ask notification unit for detailed information about the selected companies
e. announcement of visit

↓

Inspection of the company

↓

Follow up of the inspection

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CHECKLIST FOR THE INSPECTIONS 2

Former Chemicals legislation

Preparation of the inspection

Inspection of the company

a. collecting information about organization and documentation (system)
b. selection of substances (selection criteria)
c. selection of substances which are placed on the EU market
d. determine chemical identity of each of the selected substances
e. is the substance listed in EINECS
f. if not listed in EINECS: has the substance been notified by the firm?
g. if notified: check the allowed quantities for notified substances (compliance?)

h, i, j, k, l, m, n, o will follow next sheet

Follow up of the inspection

This Project is funded by the Eu[illegible] Implemented by Human Dynamics Consortium

CHECKLIST FOR THE INSPECTIONS 3

Former Chemicals legislation

Preparation of the inspection

Inspection of the company

a,b,c,d,e,f,g in previous sheet

h. if not listed in EINECS and not notified: check market quantities for new substances which were marketed in the EEA

i. are any exemptions applicable, eg. R&D

j. check if exempted substance is toxic, carcinogenic or mutagenic

k. are “Annex 1”substances traded

l. is the labelling of Annex 1 substances correct

m. check Material Safety Data Sheets (MSDS)

n. sampling of substances

o. finishing of the visit

Follow up of the inspection

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CHECKLIST FOR THE INSPECTIONS 4

Former Chemicals legislation

Preparation of the inspection

↓

Inspection of the company

↓

Follow up of the inspection

a. ask the company for additional information
b. check additional information
c. check analysis, does it comply with the given chemical structure
d. evt: take sanctions/actions
e. report the conclusion

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Time needed per company inspection 1

Selection of company and preparation of inspection: 4 days
Inspection: 1 day
Follow-up actions: 4 days

Differences due to:
- ✓in-depth or fast check
- ✓administered time
- ✓facilities (eg. EINECS on CD Rom)
- ✓quality of company records

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Time needed per company inspection 2

Country	Time needed per inspection
Belgium, Denmark, Finland, Netherlands, Sweden	Less than 3 days
Germany, Greece, Italy, Norway, United Kingdom	3 - 9 days
Austria, France, Ireland, Portugal, Spain	More than 9 days

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Competent authorities (CA) and enforcement authorities (EA) chemicals legislation

Country	CA	EA
Austria	MoE	Nine Fed. States
Denmark	MoE	Chemicals Inspectorate
Sweden	MoE Nat.Ch. Insp	Nat. Chem. Insp
Spain	MoH	Health. Dep. 17 comm
Italy	MoH	MoH
Netherlands	MoE/MoS/MoH	Env./Lab/ Cons. Goods Insp
United Kingdom	HSE	HSE Insp

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CHECKLIST FOR THE INSPECTIONS – REACH (1)

Preparation of the inspection

a. selection of involved authorities and training of involved inspectors
b. involve other relevant organisations
c. selection of companies to be visited
d. exchange information from various inspectorates
e. ask Agency for detailed information (including chemical safety reports; CSR) of the selected companies
f. announcement of visit

↓

Inspection of the company

↓

Follow up of the inspection

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CHECKLIST FOR THE INSPECTIONS – REACH (3)

Preparation of the inspection

Inspection of the company:

a. collect information about organisation and documentation (system)
b. selection of substances (selection criteria)
c. selection of substances which are placed on the EU market
d. selection of tonnage band of each sustance (>1t/y, >100 t/y, etc.)
e. determine chemical identity of each of the selected substances
f. is the substance registered (ECHA, Helsinki, Finland)?
~~g. is the substance listed in EINECS?~~
~~h. if not listed in EINECS: has the substance been notified by the firm?~~
~~i. if notified: check the allowed quantities for notified substances (compliance?)~~

h, i, j, k, l, m, n, o will follow next sheet

Follow up of the inspection

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CHECKLIST FOR THE INSPECTIONS – REACH (4)

Preparation of the inspection

Inspection of the company (a,b,c,d,e,f,g in previous sheet)

~~h. if not listed in EINECS and substance and/or use are not registered:~~
check if there are any exemptions applicable, eg. R&D

i. check if there is Authorisation for use if substance is toxic, carcinogenic or mutagenic, PBT, vPvB or of equivalent concern

j. (producers/importers only) is the Chemical Safety Report (CSR) available?

k. is the labelling according the information in the CSR?

l. compare information Extended Safety Data Sheets (ESDS) on intended use, risk reduction measurements to CSR information

m. sampling of substances

n. finishing of the visit

Follow up of the inspection

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CHECKLIST FOR THE INSPECTIONS – REACH (5)

Preparation of the inspection

↓

Inspection of the company

↓

Follow up of the inspection

a. ask the company for additional information
b. check additional information
c. check analysis, does it comply with the given chemical structure
d. evt: take sanctions/actions
e. report the conclusion

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Differences between inspection under current/former chemicals legislation and inspection under REACH

Emphasis on registration information:

✓EINECS / ELINCS information will fade out

✓registration of substance and intended uses

✓Authorisation necessary if Substances of Very High Concern (SVHC) are used

Differences between MS will have to fade out over time due to information exchange in Forum between enforcement experts of various MS

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Further Developments and Examples

What does REACH require as regards enforcement?

REACH (Titles XIII and XIV) requires each Member State to appoint a Competent Authority (CA) and maintain an appropriate control system with respect to enforcement. Member States are required to have an enforcement regime in place by 1 December 2008, which provides for 'effective, proportionate and dissuasive' penalties for non-compliance. Results of inspections, monitoring and penalties are to be reported to the European Commission by 1 June 2010, and after that every five years.

REACH also recognises the need for high levels of co-operation, co-ordination and exchange of information betweenthe Member States, ECHA and the European Commission regarding enforcement. It establishes a "Forum for Exchange of Information on Enforcement", which will coordinate harmonised enforcement projects and joint inspections, as well as develop working methods and tools for inspectors, identify enforcement strategies and develop an electronic information exchange procedure.

RIPE = **R**EACH **I**nformation **P**ortal for **E**nforcement; October 2011 vs 1.1 released

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REACH Enforcement in UK

Enforcement of use-related duties	Environmental protection	Health and safety
England & Wales	Environment Agency	HSE & Local Authorities
Scotland	SEPA	HSE & Local Authorities
Northern Ireland	NIEA	hseni & District Councils
Offshore	Department of Energy and Climate Change	HSE

Co-operation and co-ordination within the UK

Close co-operation and co-ordination between enforcing authorities will be crucial to the effective enforcement of REACH in the UK. The REACH Enforcement Regulations 2008 require enforcing authorities to co-operate and share information with each other to facilitate compliance with, and the effective enforcement of, REACH (Memorandum of Understanding – MOU is developed)

UK EXAMPLE REACH Enforcement (1)

To further strengthen co-operation and co-ordination, the MoU establishes a UK REACH
Enforcement Liaison Group. This will bring together representatives from all UK of enforcers of REACH at periodic intervals, and its functions include:

✓*carrying out the functions of the MoU, such as sharing information, arranging joint visits, notifying matters of concern, supporting enforcement action etc;*

✓*discussing emerging enforcement issues, grey areas, the interpretation of REACH and so on;*

✓*proposing amendments to guidance, based on practical experience;*

✓*determining priority substances and/or issues, and proposing and co-ordinating enforcement activity on these where possible.*

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UK EXAMPLE REACH Enforcement (2)

What are the penalties for non-compliance?

The REACH Enforcement Regulations 2008 provide that it is an offence for a person to

contravene a 'listed REACH provision' (=list of REACH articles)

Maximum penalties:

up to £5,000 fine and/or up to three months imprisonment following summary conviction; and

an unlimited fine and/or up to two years imprisonment following conviction on indictment.

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REACH Enforcement, the Netherlands

AIMED at target groups

Labour Inspectorate: Professional users of substances and preparations

Food and products safety authority: Producers, importers and distributors of consumer goods and articles

Environmental inspectorate: Producers, importers and distributors of
substances, preparations and articles for professional use

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Co-operation and co-ordination across the EU

The Forum for Exchange of Information on Enforcement ('the Forum')
is the principle mechanism for ensuring co-operation and co-ordination
across the European Union

Specific tasks of FORUM:

✓ spreading good practice and highlighting problems at Community level;
✓ proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;
✓ co-ordinating exchange of inspectors;
✓ identifying enforcement strategies, as well as best practice in enforcement;
✓ developing working methods and tools of use to local inspectors;
✓ developing an electronic information exchange procedure;
✓ liaising with industry and other stakeholders, including relevant international organisations; and
✓ examining proposals for restrictions with a view to advising on enforceability.

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Results of the Forum coordinated REACH enforcement project on registration, pre-registraion and safety data sheets (REACH –ENFORCE -1 project) - 2010

Factual background

✓25 Member States of the EEA participated
✓The participating inspectors inspected almost 1,600 companies.
✓The inspected companies in the Member States, which were manufacturers,importers, downstream users and only representatives, were selected on the basis of different criteria and selection methods.

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(REACH –ENFORCE -1 project) - 2010

Results

✓Non compliance regarding the (pre-)registration obligations was found in 8% of the inspected companies.

✓11 % of the required SDSs was non compliant with obligation to have a SDS and 20% did not comply with the obligation for the right language and the necessary headings in the SDS.

✓Only representatives were not always in compliance with Article 8* of REACH.

Note:*The results on the required SDSs must be seen with caution, as the scope of the SDS checks in the project was quite limited. Previous surveys of the content of SDSs made by the Inspectorates under CLEEN (ECLIPS) projects were much more advanced and detailed. Since the REACH-EN-Force-1 project checked only the basic and formal requirements of the SDSs, its results cannot be considered as an improvement of compliance for the SDSs.*

**OR obligations: sufficient background and up to date information on quantities importea*

REACH-EN-FORCE 2 Project Report (2013)
Obligation of *downstream* users - *formulators* of mixtures

Background

The project was carried out by 29 Member States1 with the inspection phase lasting from May 2011 until March 2012. The survey addressed the conduct of companies with regard to the registration (REACH) and notification (CLP) of substances and concerning their duties of providing information down the supply chain and implementing risk reduction measures on site. Particular attention was paid to the quality and management of the downstream users' own safety data sheets (SDSs).

Inspections of 1 181 enterprises of four size categories were reported with checks on approximately 6 900 substances, 4 500 mixtures and the evaluation of 4 500 SDSs. Although the majority of the visited companies were downstream users, more than 50% were also active in additional roles, e.g. as manufacturers, importers, only representatives.

Results

Two thirds of the surveyed enterprises (67%) violated provisions of the chemicals legislation to various extents of concern. Non-compliance included registration and notification contraventions, failing to sufficiently provide information on hazardous chemicals downstream and deficient implementation of risk management measures.

Some findings of non-compliance have been:

- 269 enterprises acting as manufacturers, importers or only representatives were proven by inspectors to actually be required to (pre-)register substances, of which 8% failed to fulfil their legal obligations. More than 50% of this non-compliant group were non-SME companies (57%).
- 275 enterprises acting as manufacturers, importers or only representatives were proven by inspectors to actually be required to notify their substances to the classification and labelling inventory at ECHA, of which 15% failed to fulfil this legal obligation.
- 52% of the checked SDSs have shown defects in the information of various types and to various extents within the sections of the SDSs that have been investigated.

Some Improvements in Compliance

The required SDSs have been available on site in 97% of 1 118 inspected companies signaling a somewhat improved compliance compared to the previous REF-1 project (87%).
Such a slight improvement in compliance has also been observed for 86% of the companies with regard to the national language and formats used for the SDSs.

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REACH- ENFORCE- 3

Forum's third coordinated enforcement project (REF-3) focuses on checking the registration obligations of manufacturers, importers and only representatives in close cooperation **with customs authorities**.
The project is organised in two phases. The first phase finished in 2013 with the second phase just starting in February 2014. During this plenary meeting, the members discussed the draft report of the first phase, in which 28 countries participated.
Preliminary results show that inspectors checked 528 companies and 3 065 substances across European countries. 3% of the checked companies did not register any of the substances which they were supposed to register and 14% of companies were incompliant only with some registration duties. Non-compliance was found most frequently among only representatives and least frequently among manufacturers.
The final report of the first phase of REF-3 is expected to be published in mid-2014.

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Environment and Climate Regional Accession Network ECRAN

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

Inventory/register for chemicals

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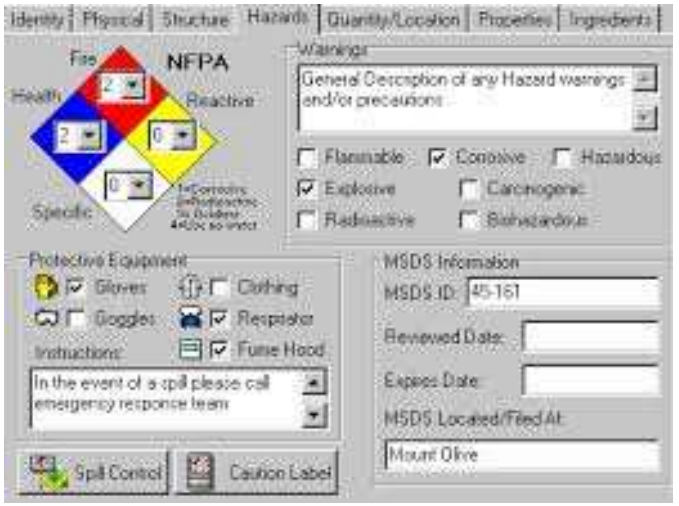
Chemicals Management Instruments

- Inventories of existing chemicals
- Pollutant Release and Transfer Registers
- Notification schemes for new chemicals
- Registration schemes
- Classification of chemicals
- Packaging and labeling schemes
- Product registers
- Integrated pest management

- Community/workers' right-to-know programmes
- Pollution prevention/cleaner production
- Life cycle assessment

Inventory of chemicals

- a listing of industrial chemicals manufactured in, or imported by, a country and is used primarily to distinguish between
  - **new and**
  - **existing chemicals**
- An inventory is a database created from information submitted to government authorities by manufacturers, processors, users, and/or importers.



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New vs Existing Substance

Existing Substances

100.195 chemicals which were present on the EC Market before 18th September 1981.

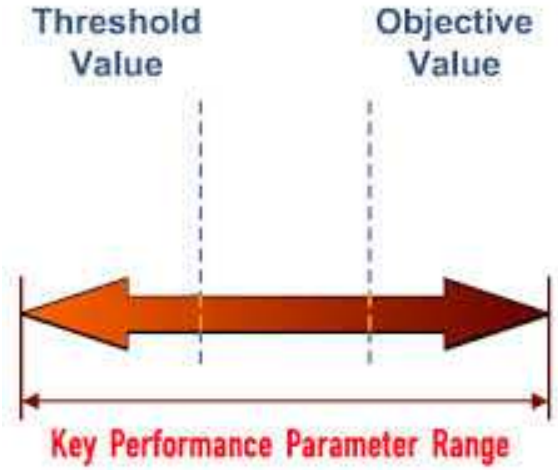
Existing Substances are listed in EINECS (European INventory of Existing Commercial chemical Substances)

New Substances

Are all substances placed on the EC Market after 18th September 1981 are New Substances and are listed in ELINCS (European List of Notified Chemical Substances)

Key parameters of chemicals inventory

- Inventory
  - Scope, purpose, legal basis
  - **"chemical"**
  - Person/company of duty
  - Time scope – one date or regular reporting?
  - Exclusion criteria – pesticides…
  - **Teritorry - country / region**
  - **Authority and legal instrument**



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Aims and Objectives

- To get information / basic knowledge about chemicals on the market:
  - –imported
  - –manufactured
  - –used
- **for legal purpose**

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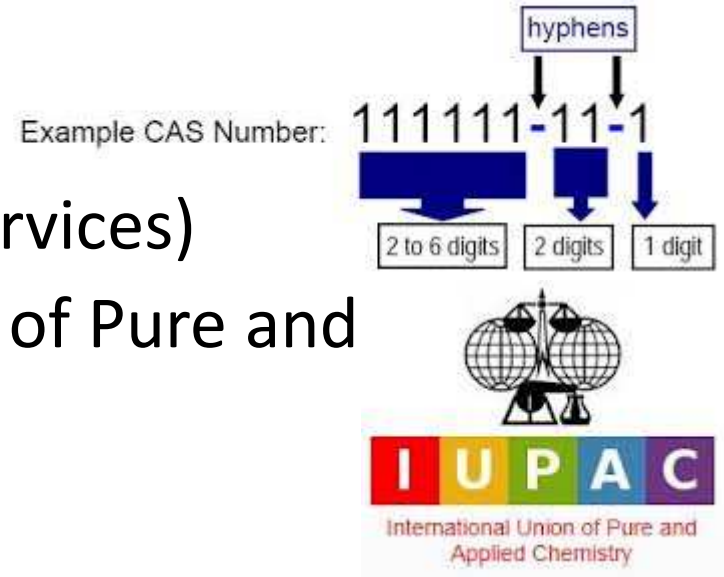
Chemical identity

- Name, synonyms
- Molecular formula
  - CAS (Chemical Abstracts Services)
  - IUPAC (International Union of Pure and Applied Chemistry)



- Chemical substances without a defined molecular formula – **UVCB** (Unknown or Variable composition, Complex reaction products and Biological materials)

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Chemicals inventory relevance

Environment and Climate Regional Accession Network ECRAN

- Inventories with no solid legal basis are bound to face problems with information gathering and compliance.
- The definitions and the scope of the inventory right from the beginning in order to avoid confusion by those required to report to the inventory.

CSA This Project is funded by the European Union

human dynamics public sector consulting Project implemented by Human Dynamics Consortium

Practical aspects

- **Importer Issues**
  - **Difficulties in communication with producer outside the territory**
- **Confidentiality**
  - Confidential business information (CBI)
- **Compliance Issues**
- verification of the existence of a chemical in commerce

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	Original Name	HPVC OECD	EU Prior	EHC	IRIS	CMR	PBT	Haz Environment	Endo Dis	WFD	PT
7-5	ethanol; ethyl alcohol	SIDS									
9-7	acetic acid ... %										
6-1	methanol										PRIORITY
42-5	styrene								ED1		
97-8	butane (containing ? 0.1 % butadiene (203-450-8));					C1					
05-4	vinyl acetate		P1								
88-3	toluene										
19-0	isobutyl acetate;										
02-7	Cetrimonium chloride										
04-9	adipic acid										
19-8	sodium carbonate	SIDS									PRIORITY
-13-2	zinc oxide										
-20-7	xylene										
-41-7	ammonia, anhydrous										
-93-9	sulphuric acid ... %	SIDS									
3-35-3	Boric acid								ED1		
2-82-1	Naphtha (petroleum), hydrodesulfurized heavy; Low boiling point hydrogen treated naphtha										
'2-43-1	Lubricating oils (petroleum), base oils, paraffinic; Baseoil - unspecified										
77-5	Pentaerythritol	SIDS									
-78-5	Tris										

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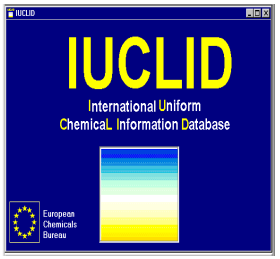
Tools to implement Regulation 793/93

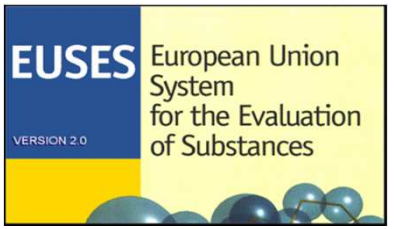
1. Data Collection Step **HEDSET, IUCLID**

2. Priority Setting Step **EURAM**

3. Risk Assessment Step **TGD - RA, EUSES**

4. Risk Reduction Step **TGD - RR**





2nd edition of the Technical Guidance Document (TGD) on Risk Assessment of Chemical Substances following European Regulations and Directives

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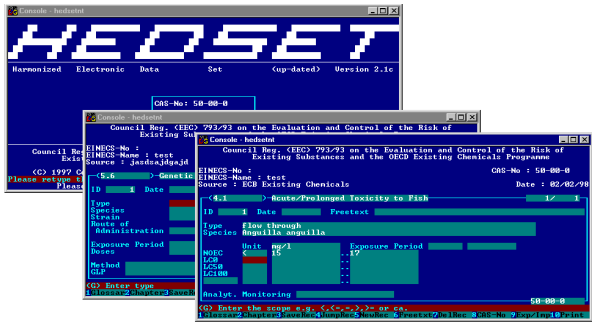
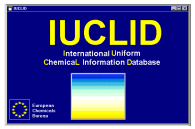
Implementation Tools of Regulation 793/93

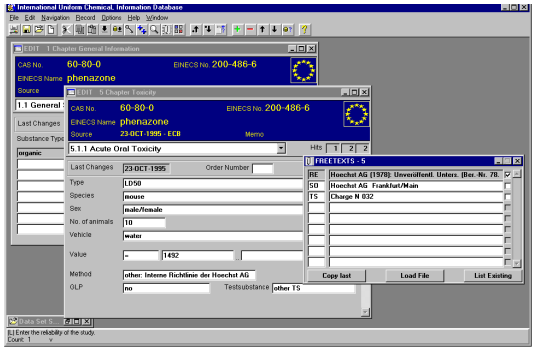
1. Data Collection

HEDSET



IUCLID





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Implementation Tools of Regulation 793/93

1. **Data Collection :** **HEDSET, IUCLID**

2. **Priority Setting** **EURAM**
EU Ranking Method

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EURAM using IUCLID data

EU Ranking Method for priority setting of Existing Substances

- **production in large volumes**
- **use in a dispersive manner**
- **persistence in the environment**
- **high toxicity to humans, animals or plants**
- **long term/chronic effects**
- **CMR: carcinogenic, mutagenic or toxic to reproduction**
- **little information about properties, use or effects**

Other factors to be taken into account:

Work carried out in other fora and other Community legislation and/or programmes relating to dangerous substances

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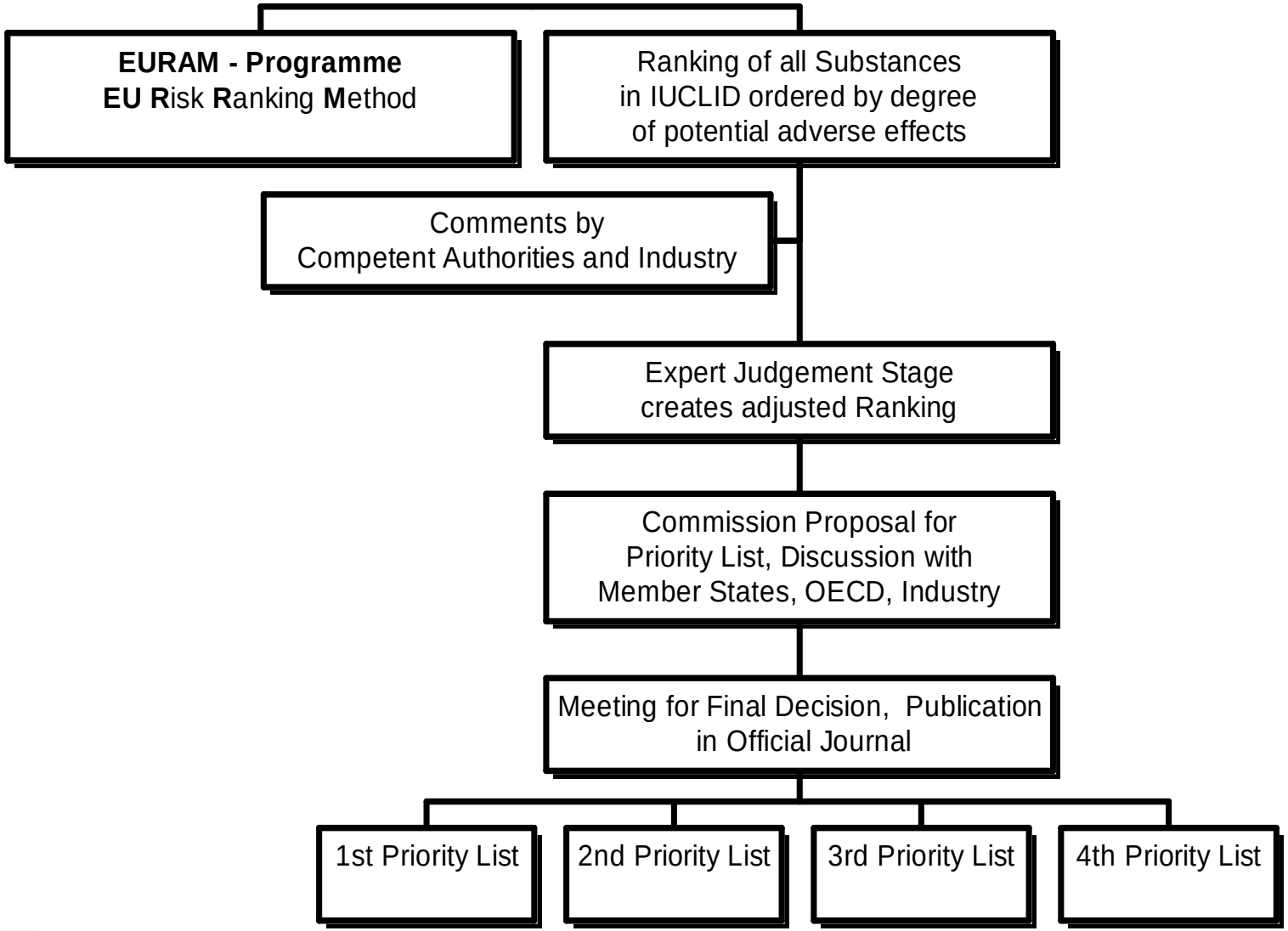
EURAM



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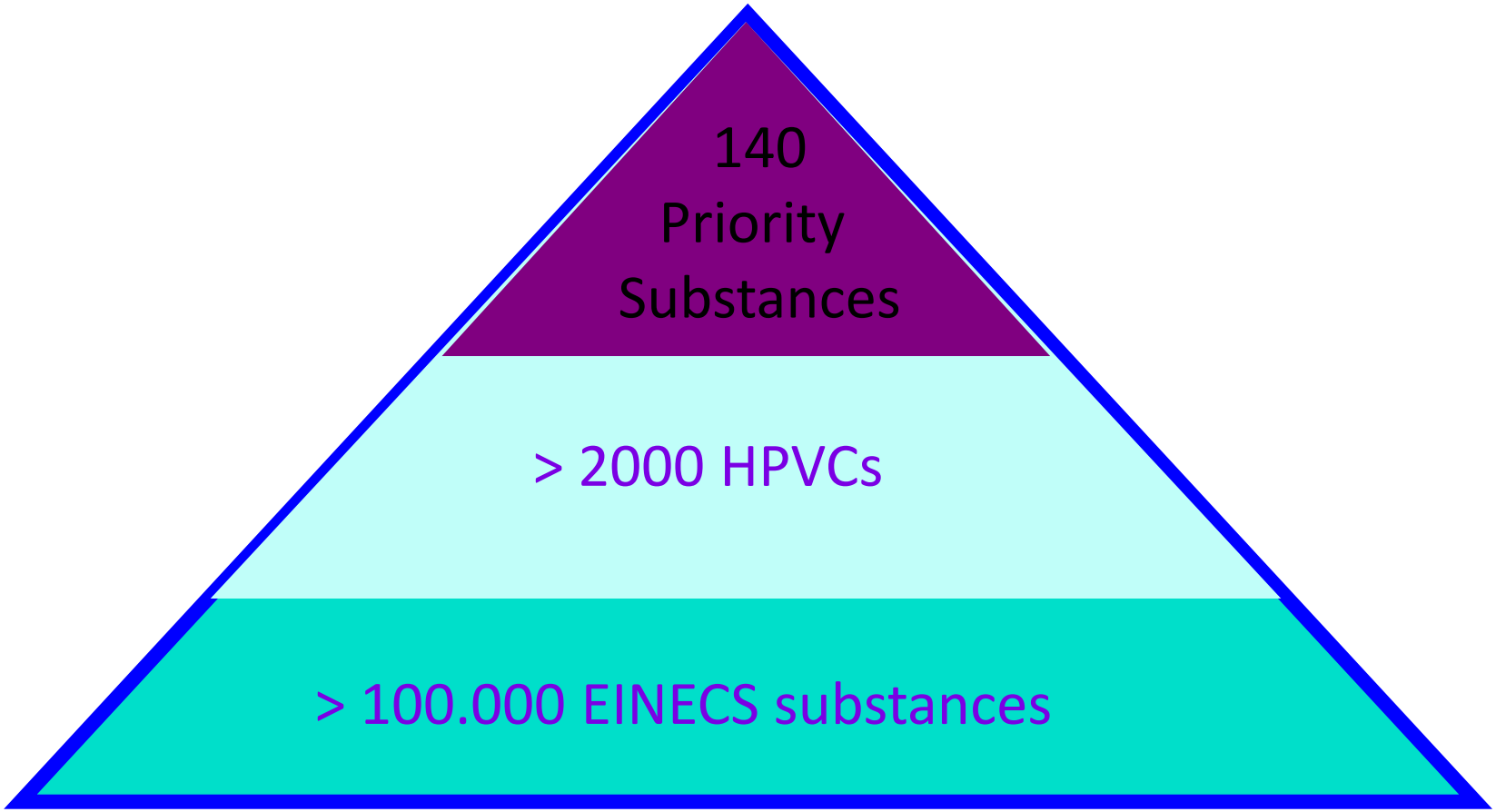
Priority Setting Existing Substances EU before REACH



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Environment and Climate Regional Accession Network ECRAN

Chemicals inventory for EU / OECD accession

- To know what is happening on a specific market
- To help industry to get official frame for the chemicals management of common market
- **Adoption to REACH / CLP / GHS**
- **“new” substances**
- Stay in – stay out status (but business is on-going = legal issues are taken through an import/export)

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Safety Data Sheets as communication instrument

General introduction on the SDS “new style Changes introduced by REACH

Arnold van der Wielen

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Note:

Contrary to the agenda, focus will be predominantly on legal background and on control, and not on the content of a SDS.

Why:

As employees from government and governmental institutes, you will not draft, but will control SDSs.

Part 1

General Introduction

Requirements for the “new” SDS according to REACH

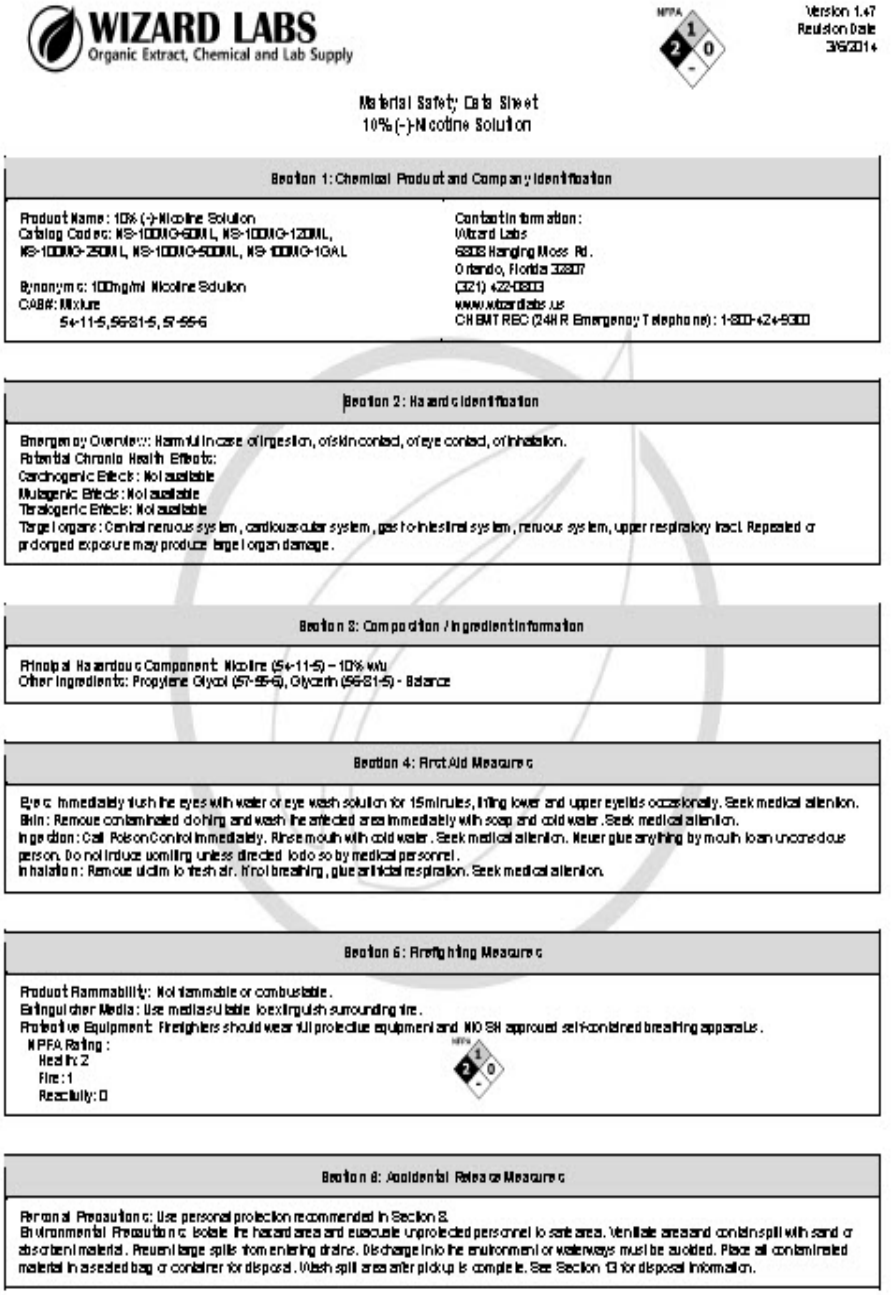
Function of the Safety Data Sheet

The SDS is the key instrument for the information flow down the supply chain, because:

- it informs the downstream user about the dangerous properties & potential hazards during normal handling and use
- it recommends necessary measures to manage the risk to health & environment (storage, use, disposal)
- it provides the basis for the assessment of hazards / risks

Fulfillment of all legal requirements of Article 31 REACH

addressed to suppliers & downstream users



WIZARD LABS
Organic Extract, Chemical and Lab Supply

Version 1.47
Revision Date
3/6/2014

Material Safety Data Sheet
10% (-)-Nicotine Solution

Section 1: Chemical Product and Company Identification

Product Name: 10% (-)-Nicotine Solution
Catalog Codes: NS-10MG-60ML, NS-10MG-120ML, NS-10MG-250ML, NS-10MG-500ML, NS-10MG-1GAL

Synonyms: 10mg/ml Nicotine Solution
CAS#: Mixture
54-11-5, 56-81-5, 57-55-6

Contact Information:
Wizard Labs
6808 Hanging Moss Rd.
Orlando, Florida 32807
(321) 422-0808
www.wizardlabs.us
CHEMTREC (24HR Emergency Telephone): 1-800-424-9300

Section 2: Hazards Identification

Emergency Overview: Harmful in case of ingestion, of skin contact, of eye contact, of inhalation.
Potential Chronic Health Effects:
Carcinogenic Effects: Not available
Mutagenic Effects: Not available
Teratogenic Effects: Not available
Target Organs: Central nervous system, cardiovascular system, gastrointestinal system, nervous system, upper respiratory tract. Repeated or prolonged exposure may produce target organ damage.

Section 3: Composition / Ingredient Information

Principal Hazardous Component: Nicotine (54-11-5) – 10% w/v
Other Ingredients: Propylene Glycol (57-55-6), Glycerin (56-81-5) - Balance

Section 4: First Aid Measures

Eyes: Immediately flush the eyes with water or eye wash solution for 15 minutes, lifting lower and upper eyelids occasionally. Seek medical attention.
Skin: Remove contaminated clothing and wash the affected area immediately with soap and cold water. Seek medical attention.
Ingestion: Call Poison Control immediately. Rinse mouth with cold water. Seek medical attention. Never give anything by mouth to an unconscious person. Do not induce vomiting unless directed to do so by medical personnel.
Inhalation: Remove victim to fresh air. If not breathing, give artificial respiration. Seek medical attention.

Section 5: Firefighting Measures

Product Flammability: Not flammable or combustible.
Extinguisher Media: Use media suitable to extinguish surrounding fire.
Protective Equipment: Firefighters should wear full protective equipment and NIOSH approved self-contained breathing apparatus.
NFPA Rating:
Health: 2
Fire: 1
Reactivity: 0

Section 6: Accidental Release Measures

Personal Precautions: Use personal protection recommended in Section 8.
Environmental Precautions: Isolate the hazard area and evacuate unprotected personnel to safe area. Ventilate area and contain spill with sand or absorbent material. Prevent large spills from entering drains. Discharge into the environment or waterways must be avoided. Place all contaminated material in a sealed bag or container for disposal. Wash spill area after pickup is complete. See Section 13 for disposal information.

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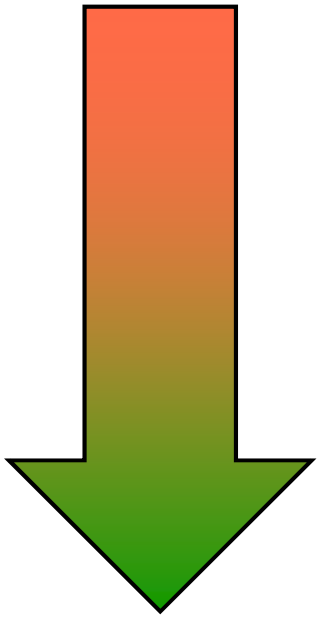
When should a Safety Data Sheet be provided?



System:

- unsolicitedly - Art. 31(1) REACH
- on request - Art. 31(3) REACH
- on a voluntary basis

"to be made available" → Means in this context, that it is not sufficient to simply offer the SDS via the Internet!

Customers must be informed about down-load options in written form!

SDS complete and in correct format in accordance with REACH Art. 31 and Annex II (Amended 453/2010)

When should a SDS be provided unsolicitedly? (REACH Art. 31.1)

Requirements for SDSs:

a) if a substance / mixture meets the criteria for classification as hazardous according to (EC) No 1272/2008 or 1999/45/EC

b) if a substance is PBT or vPvB 

c) if the substance was identified as an SVHC and was taken up in the candidate list, according to the criteria in Art. 57.f

Example: Endocrine Disrupting Chemicals

The SDS has to be provided at the latest at the time of first delivery

When should a SDS be provided upon request? (REACH Art. 31.3)

Requirements for SDSs

The consumer may request a SDS if a mixture is not classified by DPD (1999/45/EC) as dangerous, but contains:

a) a harmful or environmentally hazardous material in a concentration ≥ 1 weight percent for non-gaseous mixtures or ≥ 0.2 percents by volume for gaseous mixtures

b) PBT- or vPvB material in an individual concentration ≥ 0.1 weight percent for non-gaseous mixtures respectively > 0,2 volume percent for gaseous mixtures

c) a substance for which a Community workplace exposure limit has been established

the consumer may request a SDS.

When will it be useful to draft and provide a SDS on voluntary basis?

A SDS may be provided for mixtures which are not classified as dangerous, but:

- which - based on experience - often prompt questions
- which call for the communication of other dangers (suffocation frostbite, inclination for formation of dust … (see selection 2.3 “other hazards”)
- are descendants of other information duty, if not required by SDS
- as basis for its own assessment of dangers.

an SDS can be provided on voluntary basis
or
a free format sufficient for communicating essential information

Obliged to communicate information in case of no SDS requirement (REACH Art. 32)

If no SDS is required, in the following cases key information must be provided downstream:

- If substance is subject to authorisation, details of authorisation
- If substance is subject to restriction, details of restriction
- If available relevant information, essential for taking appropriate risk management measures
- …. Plus registration number, if available

NO STANDARD FORMAT PRESCRIBED

Other requirements for suppliers (REACH art. 33)

To professional downstream users, information about presence of SVHCs in articles, if >0,1%

- Free of charge, within 45 days after delivery
- As a minimum, name of the substance
- Essential details allowing safe use of the article

The same as above to consumers upon request

When to update an SDS ? (REACH Art. 31.9)

- **Suppliers have to modify an SDS (Annex 31(9)) if:**
  - new information is available, which may have effects on risk management measures!
  - an authorization for SVHC was given or denied!
  - a limitation for the substance was issued

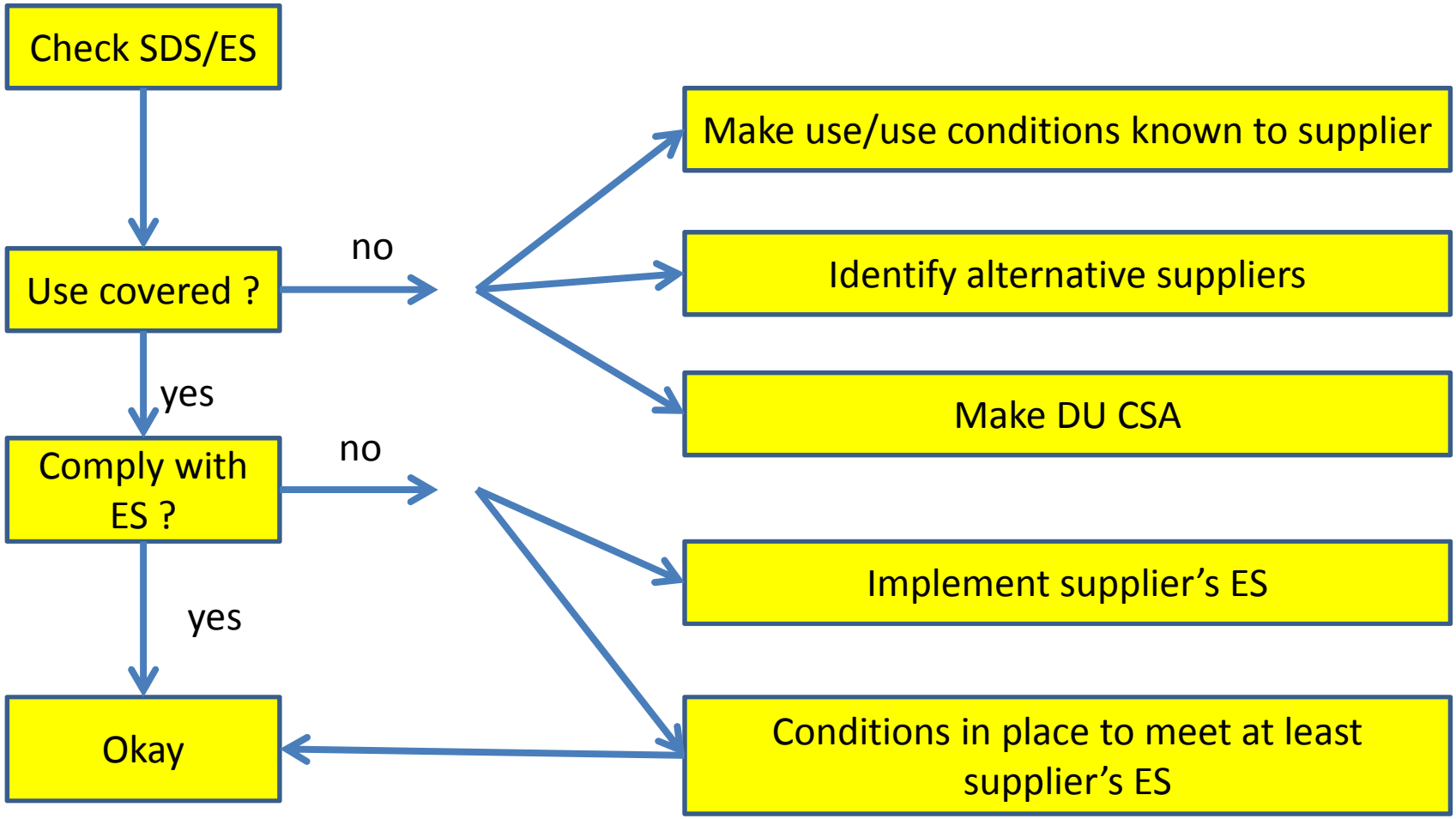
The correct version must be made available to all customers who were served within the last 12 months

- **But minor changes, like changed address of the Producer, do not trigger requirement to inform all customers**

Obligations to DUs

- **Obligation to implement the control measures communicated via**
  - Recommendations in section 8 (Exposure control and personal protection)
  - the Exposure Scenario in the SDS annex
- **Obligation to carry out CSA for his own use, if use not covered in the Exposure Scenario (non-identified uses)**
  - Develop exposure scenario for his own safety assessment
  - Notify ECHA (the Agency) for his non-identified use(s)
  - Communicate down the supply chain if he is the supplier
- **Use supplier information to carry out risk assessments on own products for next use down the supply chain**
- **Notify any new information up the supply chain, as new information on hazardous properties**

Workflow for a DU to check SDS



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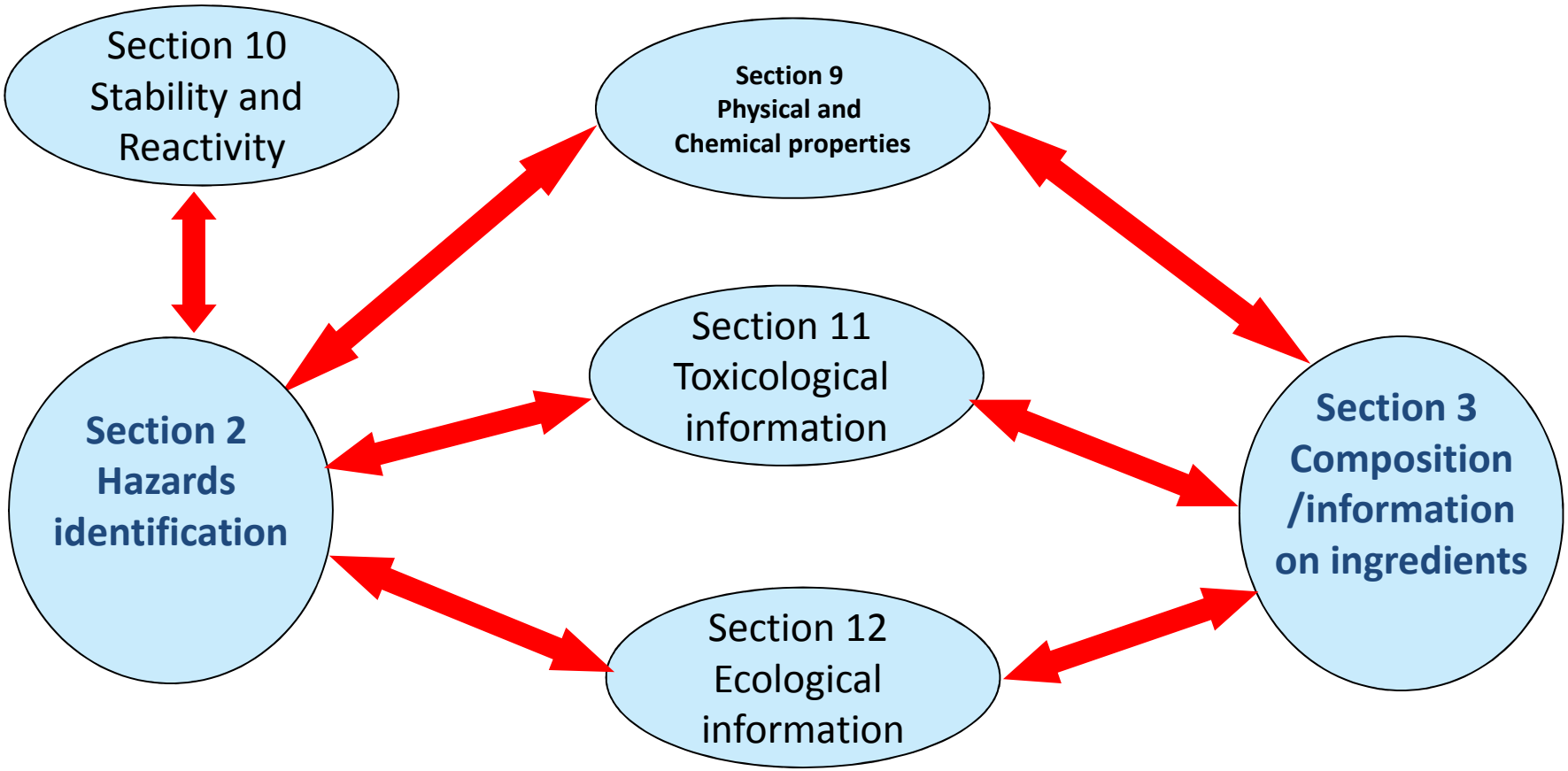
Part 2

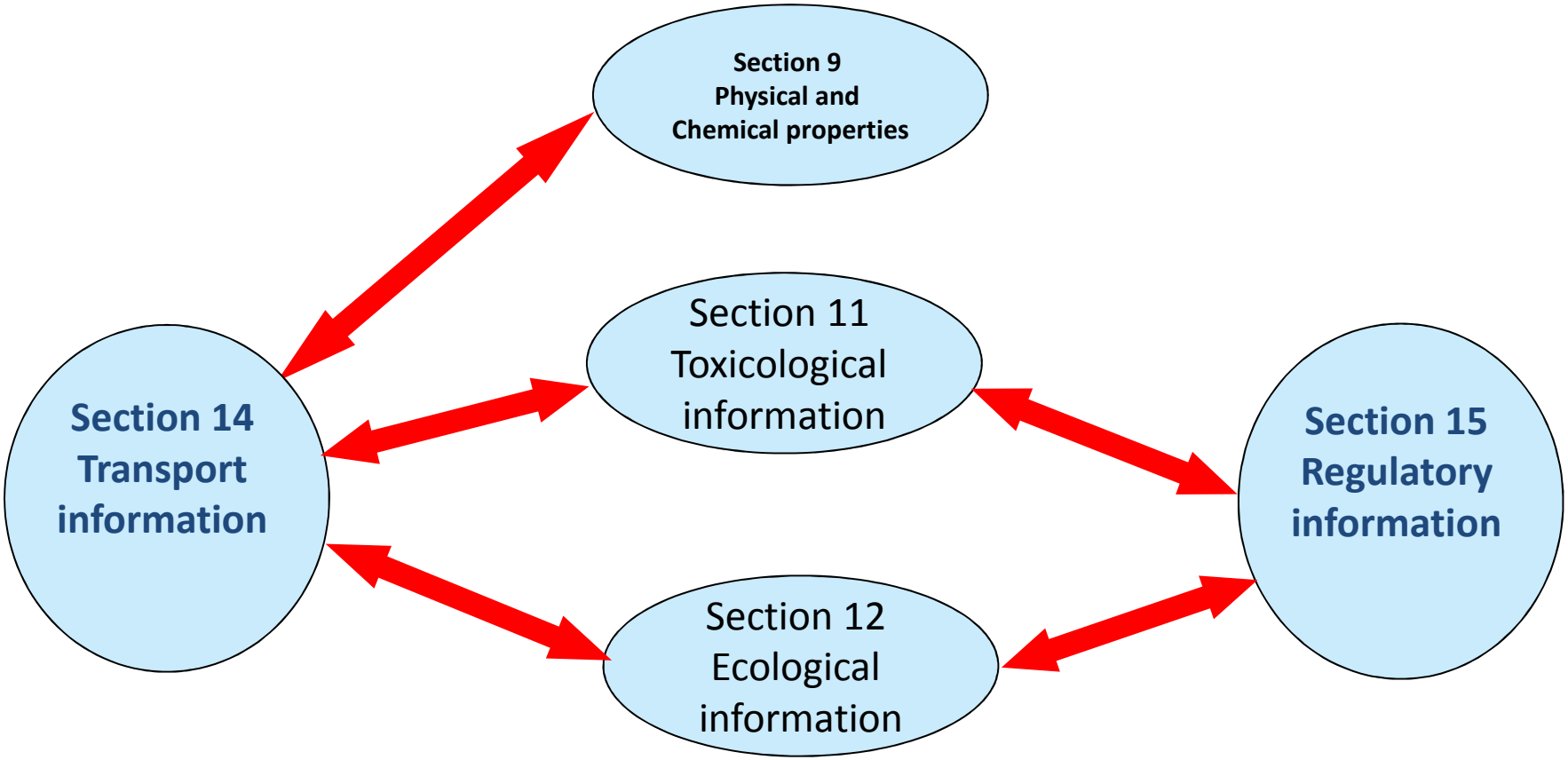
SDS Control Steps

Consistency check of the information in the different sections of SDS (two examples)

SDS sections 2 & 3 needs to be checked for consistency with the following sections:



SDS sections 14 & 15 needs to be checked for consistency with the following sections:



THANKS FOR YOUR ATTENTION

QUESTIONS?

Environment and Climate Regional Accession Network ECRAN

Controlling SDS Experience in practise

NL project in 2013 in supply chain working with organic solvents

Arnold van der Wielen

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General goal of enforcement

- **Promote circulation of good/excellent safety data sheets in the supply chain**
- **Check compliance with REACH and CLP**
  - Focus in project on 3 business sectors selected by way of integrated business control
- **Determine compliance of certain key rules from Biocides Products Regulation in the 3 business sectors.**
  - **Focus on compliance with the prohibition marketing and use of of non-authorised biocides**

Which companies

Selected from results obtained by a combined control on REACH and BPR requirements at 65 wholesalers in:

- **Pesticides and biocides**
- **Paints and pigments**
- **Detergents, cleaners and cleansing products**

Planning of the supply chain project

Steps

1. **Supply chain analysis: focus on distributors**
   - Databases from Chambers of Commerce, from customs, from other inspection divisions, from Bureau of Statistics
2. **Selection of companies; in 1st phase 65 companies**
   - Criterion: not member of trade associations, not visited before for REACH compliance, not located in residential areas.
3. **Conducting inspection visits**
4. **Follow-up supply chain analysis: focus on the suppliers of distributors, located in NL**
5. **Selection of suppliers: about 20 companies in the 2nd phase**
6. **Conducting inspection visits**

Observations with inspection visits in the 1st phase

- **15 of the 65 selected companies have been dropped. Reason:**
  - Were still member of a trade association
  - No products with organic solvents
  - Discontinued / merged / bankrupted
- **Totally 164 SDSs called (4 were identical)**
  - 26 SDSs for a substance
  - 127 SDSs for a mixture
  - 7 SDSs without classification (no SDS required)
- **Totally 153 SDSs checked**
  - 22 for pesticides and biocides (6 for a substance; 16 for a mixture)
  - 131 for other products (20 for a substance, 111 for a mixture)

Other observations in the 2st phase

- **Quality of SDSs from non-NL suppliers does not differ from SDSs from NL-suppliers**

- **SDSs drafted under own supervision (private label) score slightly better than SDSs from third parties**

Compliance of 153 checked SDSs in 1st phase (from 50 companies)

	Compliance:
• No SDS was completely correct	• 0%
• In national language (in Dutch)	• 95%
• Sector 1 (Identity product, supplier)	• 20%
• Sector 2 (Hazard identification)	• 33%
• Sector 3 (Composition, ingredients)	• 15%
• Sector 8 (Exposure control/personal protection)	• 33%
• Sector 15 (Regulatory information)	• 50%
• Sector 16 (Other information)	• 5%
• Classification	• 60%
• Labelling	• 30%

Red labelled sectors provide information on the safety of the downstream user; only 1/3 of SDSs are in compliance

Compliance of 21 checked SDSs in 2nd phase (12 of 50 companies)

	Compliance:
No SDS was completely correct	0%
In national language (in Dutch)	95%
Sector 1 (Identity product, supplier)	20%
Sector 2 (Hazard identification)	10%
Sector 3 (Composition, ingredients)	0%
Sector 8 (Exposure control/personal protection)	0%
Sector 15 (Regulatory information)	50%
Sector 16 (Other information)	5%
Classification	60%
Labelling	30%

Remarkably deviant from 1st phase
33%
15%
33%

Red labelled sectors provide information on the safety of the downstream user; few SDSs are in compliance

Most striking short-comings in 1st phase

- **Wrong classification**
  - Missing pictograms (8 times)
  - Missing info on presence of a certain hazardous substance (13 times)
  - Missing H-sentences (21 times)
  - Missing R-sentences (44 times)

- **Wrong format of SDS (16 sectors, cf REACH Annex II)**
  - Missing sub-sectors
  - USA type
  - Outdated SDS version (old arrangement)

Most striking short-comings in 1st phase – continued

- **Sector 1:**
  - Information concerning the Dutch National Poisoning Centre was incorrect, incomplete, or missing
- **Sector 2:**
  - Confusion about CLP (H- and S-sentences) and the “old C&L” system (R- and S-sentences)
- **Sector 3:**
  - See previous slide on classification
- **Sector 8:**
  - Applying wrong terminology (e.g. MAC-values)
  - Missing information (DNEL/PNEC)
  - Missing info on type of material, thickness, breakthrough time of gloves

Most striking short-comings in 1st phase – continued

- **Sector 15:**
  - Very often labelling was presented in this section
  - Missing information on Chemical Safety Assessment
- **Sector 16:**
  - Missing version number
  - Missing glossary and list of abreviations

Other learning points

- Announcing in advance to companies coming inspection visits and subsequently visiting many companies creates commotion within the branche
- Informing companies in advance about frequently observed short-comings promotes an active attitude
- Distributors have often no power to correct “faulty” SDSs, because of non-EU suppliers
- It was very difficult to trace the most interesting solvents. In company records often no entry to search for specific solvents.
- In the case of outsourcing evaluation of selected SDSs it is observed that the observations reported by external consultants need a check.
- Many companies are working with outdated or not up-to-date software. Consequently, many essential modifications and updates cannot be processed.

Questions / Comments ?

Thanks for your attention

Environment and Climate Regional Accession Network ECRAN

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

Basic Toxicology / Ecotoxicology

Martin Murín, MSc.

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E-mail: **ekotox@ekotox.sk**
www.ekotox.eu

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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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Basics In Risk Assessment

- **Hazard Assessment**

  Classification of chemicals and preparations

- **Effect Assessment / Exposure Assessment**
- **Generic Risk Assessment** (Local, Regional, Continental)
  - Ambient environment
  - Working environment
  - Consumers

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- **Effects Assessment**

Data: toxicological and ecotoxicological data incl. environmental fate

DNEL, DMEL / PNEC
ADI, TDI (RfD - US EPA)

- **Exposure Assessment**

Data: measured concentrations, monitoring, models

Exposure levels / PEC

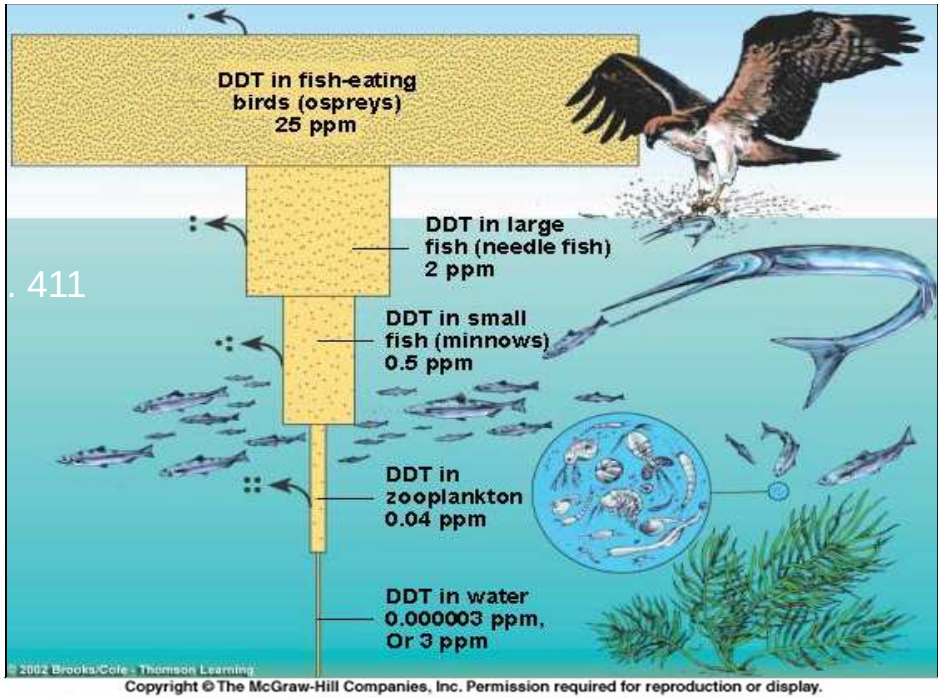
- **Generic Risk Assessment**

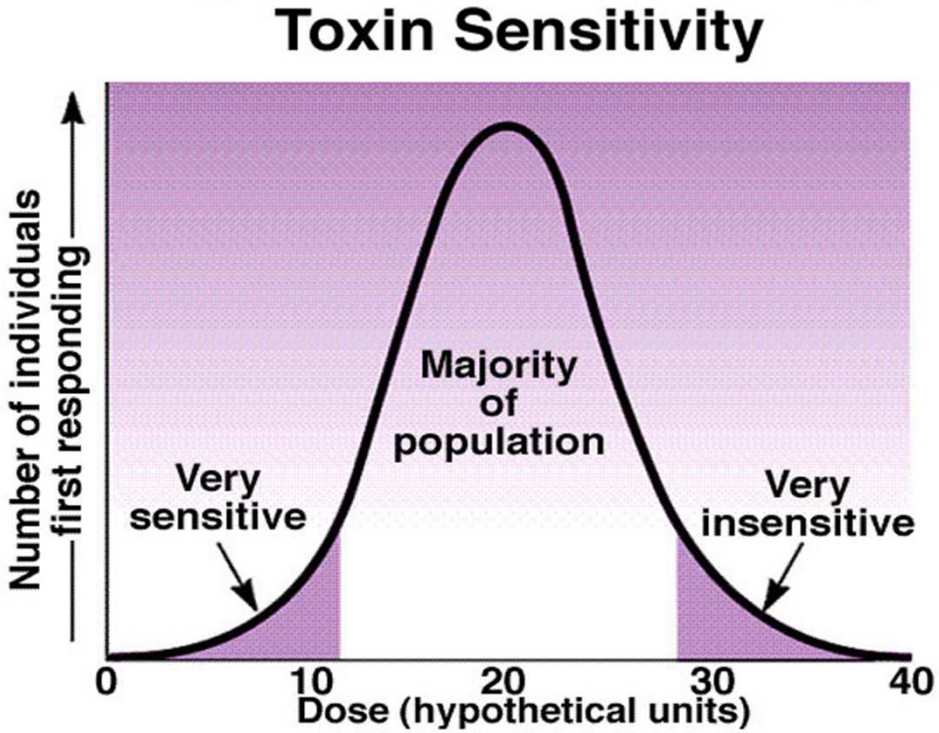
Data: toxicity / ecotoxicity, emissions into environment and exposure based on standardised conditions

GOAL: control and management of new and existing chemicals

Toxicology

- Toxicity
- Dosage
- Bioaccumulation
- Biomagnification
- Synergism
- Response
- Acute effect
- Chronic effect





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TOXICOLOGY: Assessing Chemical Hazards

Toxicity: measure of how harmful a substance is in causing injury, illness, or death to living organisms.

FACTORS AFFECTING TOXICITY:

1) Dose: the amount of substance ingested, inhaled or absorbed.

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Ecotoxicology

- **Fate and disposition**
  - ⇓ **Release into medium**
  - ⇓ **Pathways of migration, accumulation**
  - ⇓ **Biomodification**
  - ⇓ **Removal, degradation or precipitation**
- **Ecosystem health**
  - **change in population structure**
  - **health of individual species**
  - **damage to ecosystem**

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Toxicology and Ecotoxicology are similar but not identical.

Toxicology	***Ecotoxicology***
Absorption	Release into the environment
Distribution	Fate and Disposition
Metabolism	Metabolism
Elimination	No counterpart!

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Tox / Ecotox

Environment and Climate Regional Accession Network ECRAN

Toxicology

- Host defense mechanisms
- Individual susceptibility states
- Single effects
- Cumulative exposure

Ecotoxicology

- Bioaccumulation
- Bioconcentration (in water)
- Biomagnification
- (Never) single effects
- Movement between media (air, water)

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Generalizations in toxicology!

- **The dose makes the poison**
- **The most susceptible are the very young, the very old and the infirm**
- **Interaction and multiple effects may occur**
- **Occupational and environmental exposures never go away - they reappear in other settings.**

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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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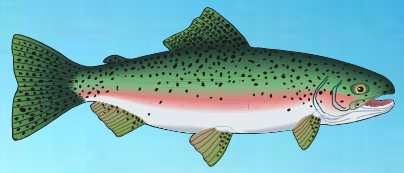
Ecotoxicology
Terrestrial
Aquatic

BASE SET REQUIREMENT

AQUATIC

ACUTE TOXICITY LC50

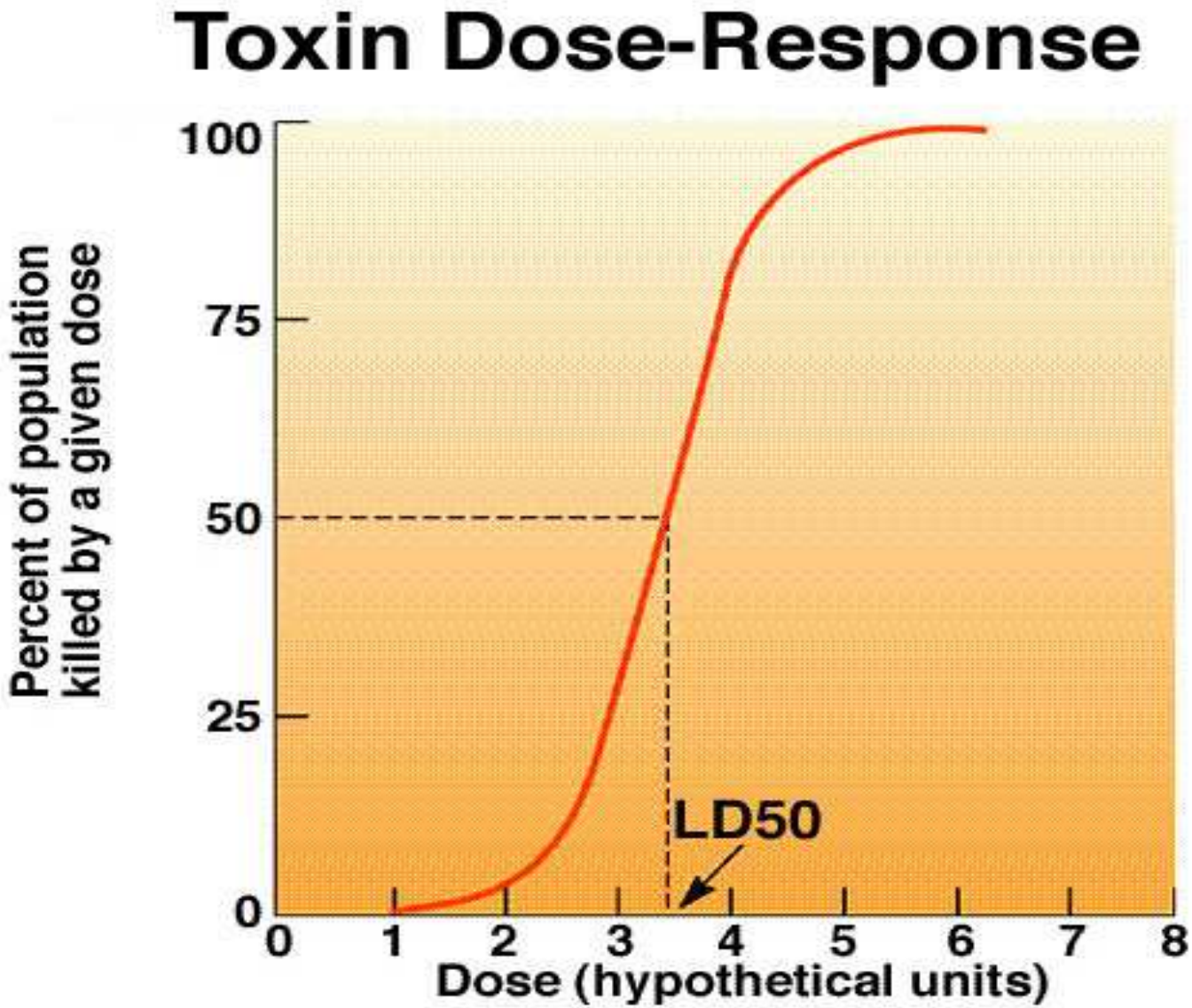


Fish

Algae

Daphnia:

CHEMICALS: Major Types of Toxicity



Dose-Response Curves

- Dose-response
- Nonthreshold
- Threshold

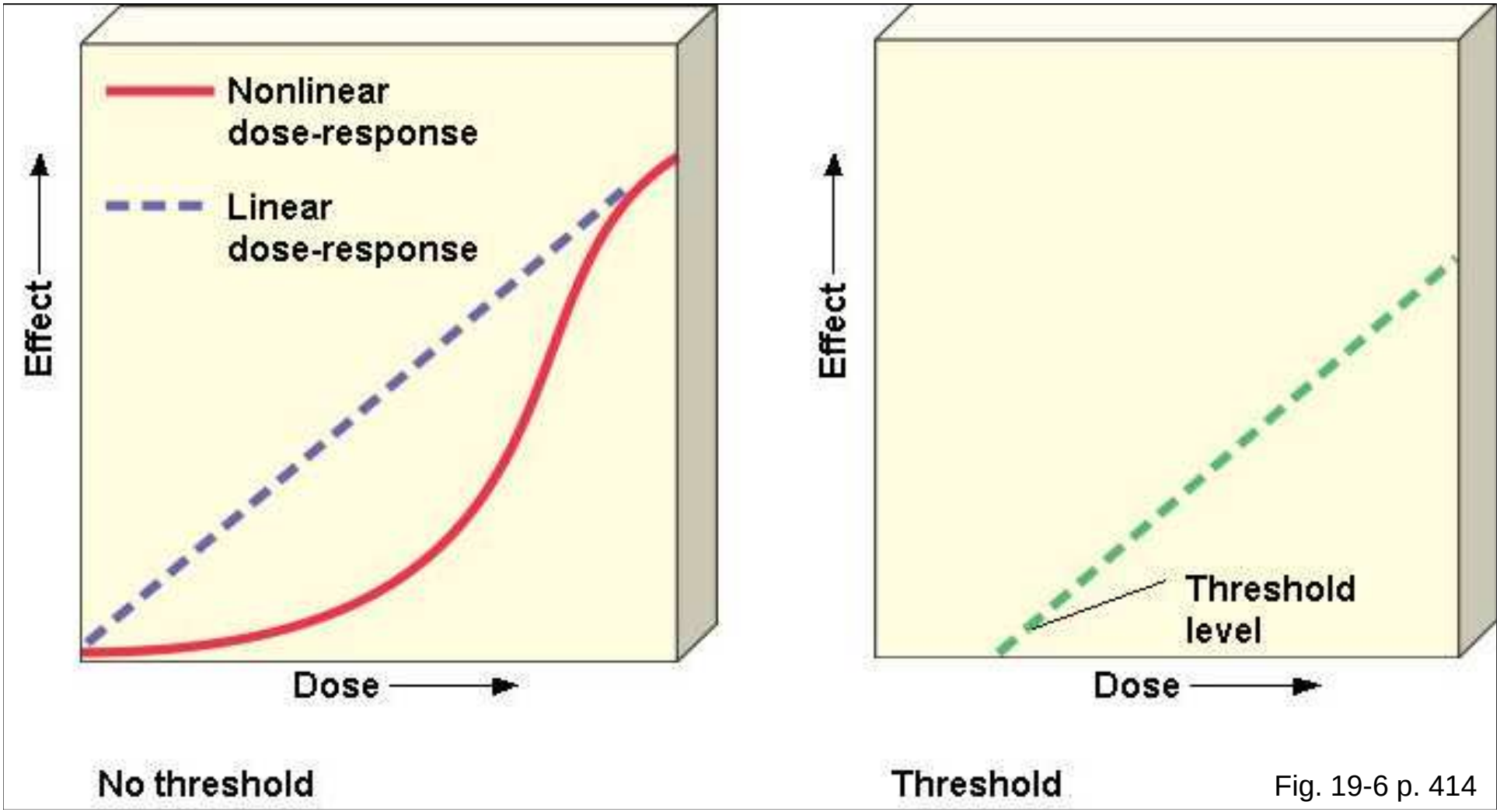
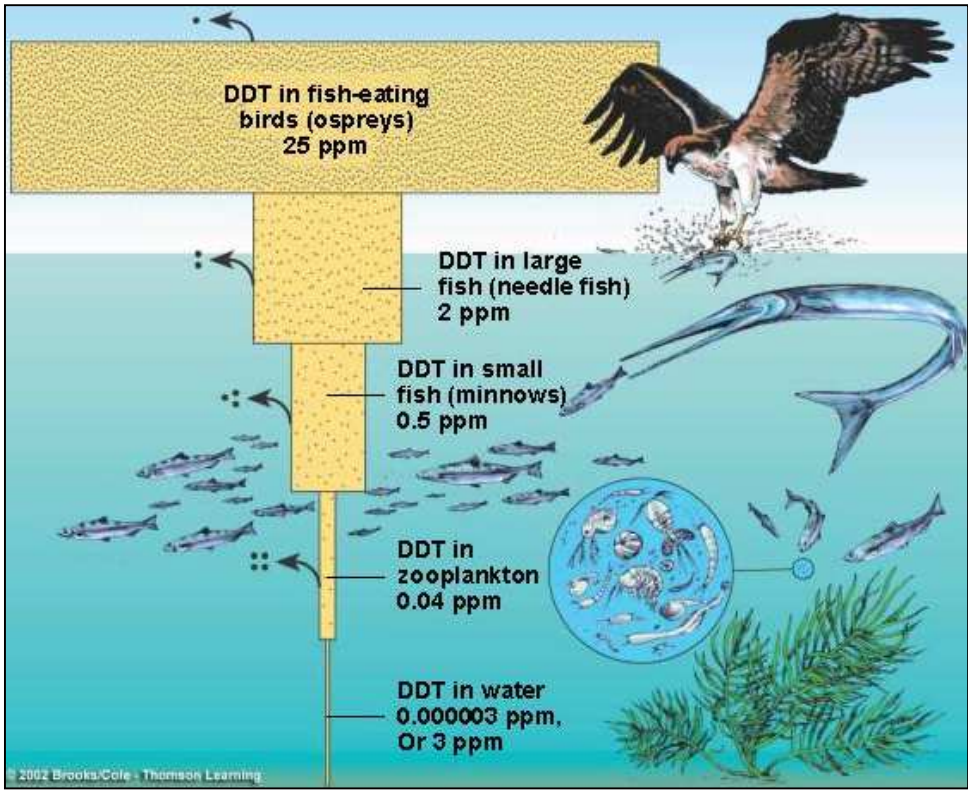


Fig. 19-6 p. 414

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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Transport and Fate of pollutants in Ecosystem

- Environmental pathways (distribution):
  - Chemical substances could be introduced into the environment for specific purposes and in defined ways.
  - These substances, however will move from their point of entry (environmental Phase: air, water and soil) to their final destination i.e. the environmental compartment for which they have more affinity.
  - If it is not a “sink” but a “reservoir”, the chemicals can be transferred again towards other compartments as thermodynamic equilibrium is approached.

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Transport & Fate

Environment and Climate Regional Accession Network ECRAN

- Transport and Fate in aquatic environment:
- Biodegrade
- Photodegrade
- Bioaccumulate in aquatic organisms
- Volatilize
- Contaminate plants, animals and well water
- Adsorb to suspended and bottom sediment

- Transport and Fate in air:
- Photodegrade
- Be inhaled
- Be absorbed through skin
- Fallout in non-contaminated environments

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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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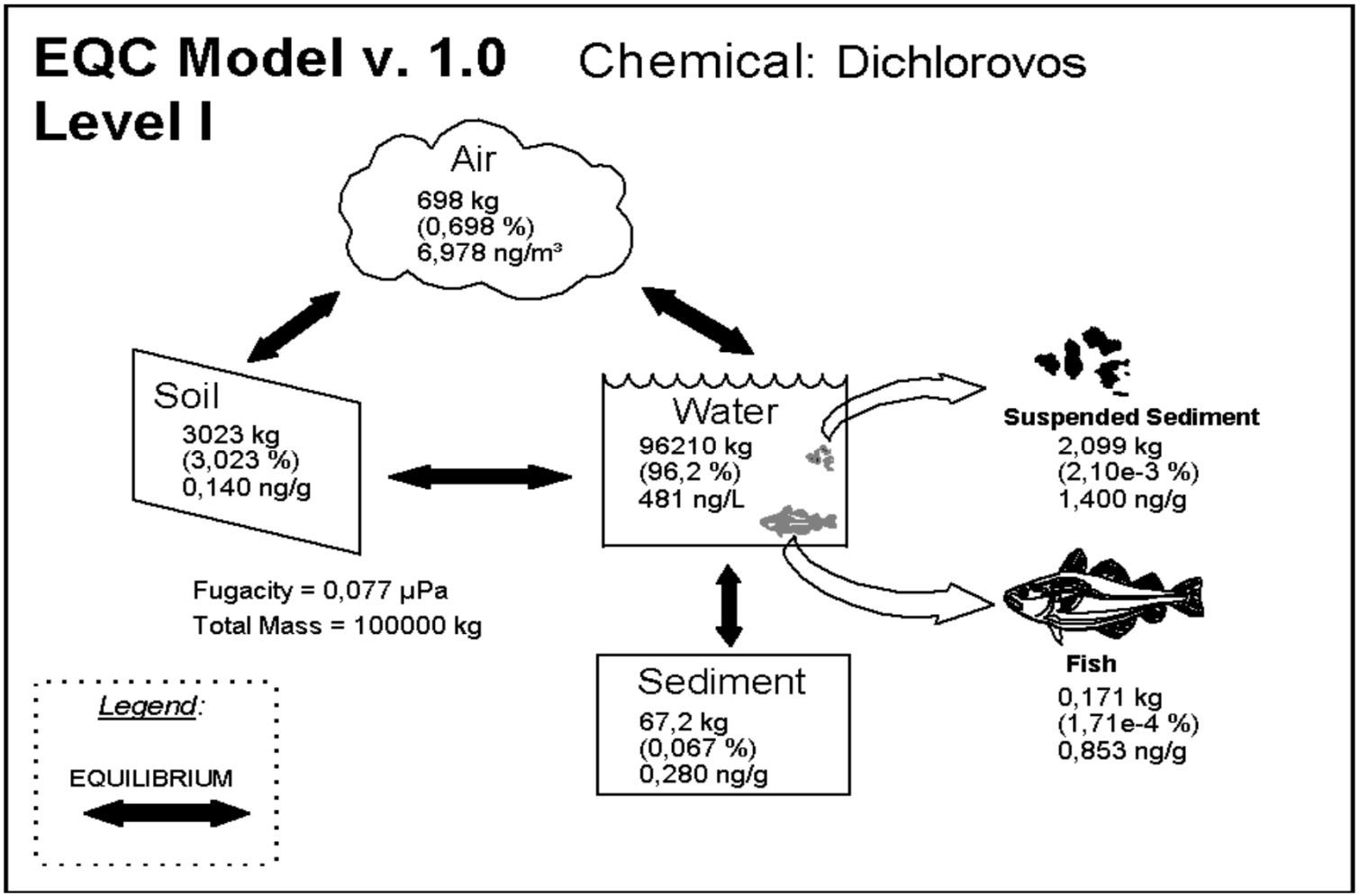
Fate in the environmental compartments - models

- Donald Mackay



This Project

Bio-concentration / accumulation

bio-concentration: - direct uptake from a medium e.g. air and water (phytoplankton)

- bio-accumulation:- indirect uptake through food
- bio-magnification: - build up along the food chain

BIOMAGNIFICATION:

- Why do we have bio-magnification?
- From the second law of thermodynamics, energy present in the chemical bonds of organisms at one level does not all end up as bond energy at the next level, because much of the energy is degraded to heat at each step.
- -mass of herbivores<<mass of plants they feed on.
- With each step upward in a food chain the biomass is reduced ("pyramid of the biomasses")
- - loss of pollutants from organisms does not follow the same pattern hence we have biomagnification

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Environmental fate

- The environmental fate of a compound is evaluated on the basis of the persistence of the compound, which can be degraded in natural conditions in various ways according to its molecular structure and the environmental compartment it exist (biota, water column, air soil, sediment and suspended particulate).

- Chemicals undergo transformation in every environmental compartment including biota. They also undergo bioconcentration/ bioaccumulation in biota.

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Individual vs. Population

- Capture and storage of toxicant at storage sites (blood plasma, liver , kidney, fat tissue and bone)
- Excretion (urine, bile, exhalation, feces, cerebral fluid, sweat, saliva and regurgitation from the stomach)
- Absorption
- Biotransformation/metabolism

- **POPULATION:** Changes in numbers
- **COMMUNITY:** DIVERSITY

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Tolerance

- Tolerance: ability to show reduces response to a specific dose of a chemical than was shown on a prior occasion from the same dose.

- Mechanism of tolerance:
  - **Failure to translocate,**
  - **biotransformation (detoxication),**
  - **excretion**

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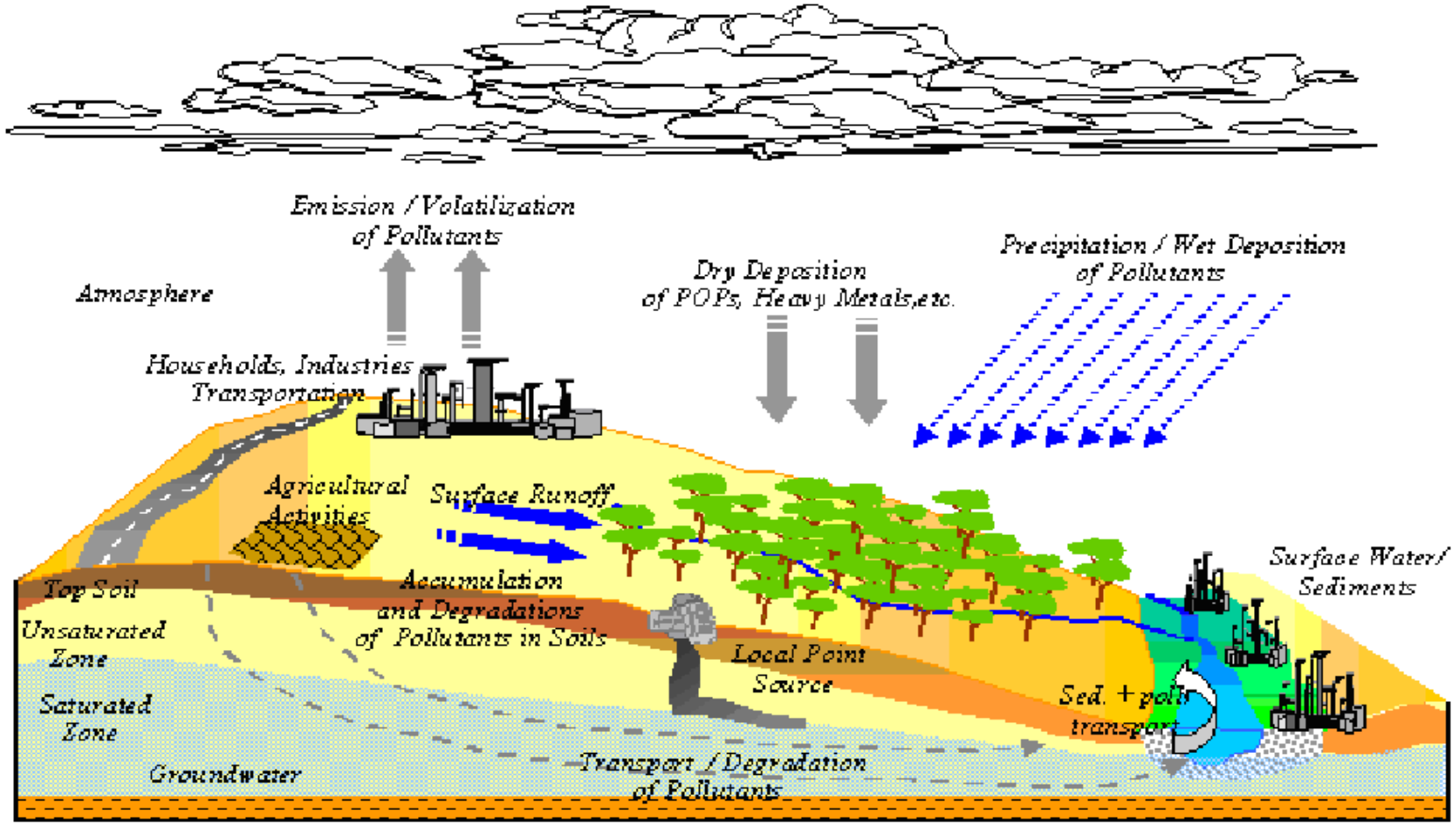
Contaminants pressure



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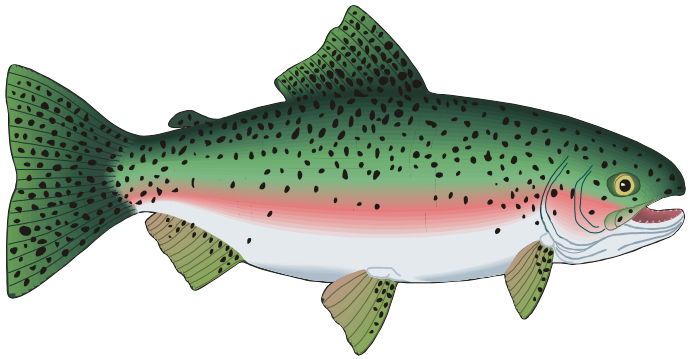
C.1. ACUTE TOXICITY FOR FISH

- LC = lethal concentration

acute lethal toxicity of a substance to fish in fresh water



- acute toxicity is expressed as the median lethal concentration (LC50), 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.

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C.1. Information need

- 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)
- Additional information (for instance structural formula, degree of purity, nature and percentage ofsignificant 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.

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C.1. Test principle

- A limit test may be performed at 100 mg per litre in order to demonstrate that the LC50 is greater than this concentration.
- The fish are exposed to the test substance added to water at a range of concentrations for a period of 96 hours.
- Mortalities are recorded at least at 24-hour intervals, and the concentrations killing 50% of the fish (LCso) at each observation time are calculated where possible.

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C.1. Quality Criteria

- The quality criteria shall apply to the limit test as well as the full test method.
- The mortality in the controls must not exceed 10% (or one fish if less than ten are used) by the end of the test.
- The dissolved oxygen concentration must have been more than 60% of the air-saturation value throughout.
- The concentrations of the test substance shall be maintained to within 80% of the initial concentrations throughout the duration of the test.
- The pH should not vary by more than 1 unit.
- For substances which dissolve easily in the test medium, yielding stable solutions i.e. those which will not to any significant extent volatilize, degrade, hydrolyze or adsorb, the initial concentration can be taken as being equivalent to the nominal concentration. Evidence shall be presented that the concentrations have been maintained throughout the test and that the quality criteria have been satisfied.

C.1. Quality Criteria

- For substances that are:
  - **(i) poorly soluble in the test medium, or**
  - **(ii) capable of forming stable emulsions or dispersions, or**
  - **(iii) not stable in aqueous solutions,**
- the initial concentration shall be taken as the concentration measured in solution (or, if technically not possible, measured in the water column) at the start of the test. The concentration shall be determined after a period of equilibration but before the introduction of the test fish.
- In any of these cases, further measurements must be made during the test to confirm the actual exposure concentrations or that the quality criteria have been met.

C.1. Test Procedures

- Static test:
  - Toxicity test in which no flow of test solution occurs. (Solutions remain unchanged throughout the duration of the test.)
- Semi-static test:
  - Test without flow of test solution, but with regular batchwise renewal of test solutions after prolonged periods (e.g. 24 hours).
- Flow-through test:
  - Toxicity test in which the water is renewed constantly in the test chambe rs, the chemical under test being transported with the water used to renew the test medium.

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C.1. Chemicals with low solubility

- Ultrasonic dispersion, organic solvents, emulsifiers or dispersants may be used as an aid to prepare stock solutions of substances with low aqueous solubility or to help to disperse these substances in the test medium.
- When such auxiliary substances are used, all test concentrations should contain the same amount of auxiliary substance, and additional control fish should be exposed to the same concentration of the auxiliary substance as that used in the test series. The concentration of such auxiliaries should be minimized, but in no case should exceed 100 mg per litre in the test medium.

C.1. Test conditions

- duration: 96 hours
- number of animals: at least 7 per concentration,
- test concentration: At least five concentrations differing by a constant factor not exceeding 2,2 and as far as possible spanning the range of 0 to 100 % mortality,
- light: 12 to 16 hours illumination daily,
- temperature: appropriate to the species (Appendix 2) but within ± 1 °C within any particular test,
- dissolved oxygen concentration: not less than 60 % of the air-saturation value at the selected temperature,
- feeding: none.

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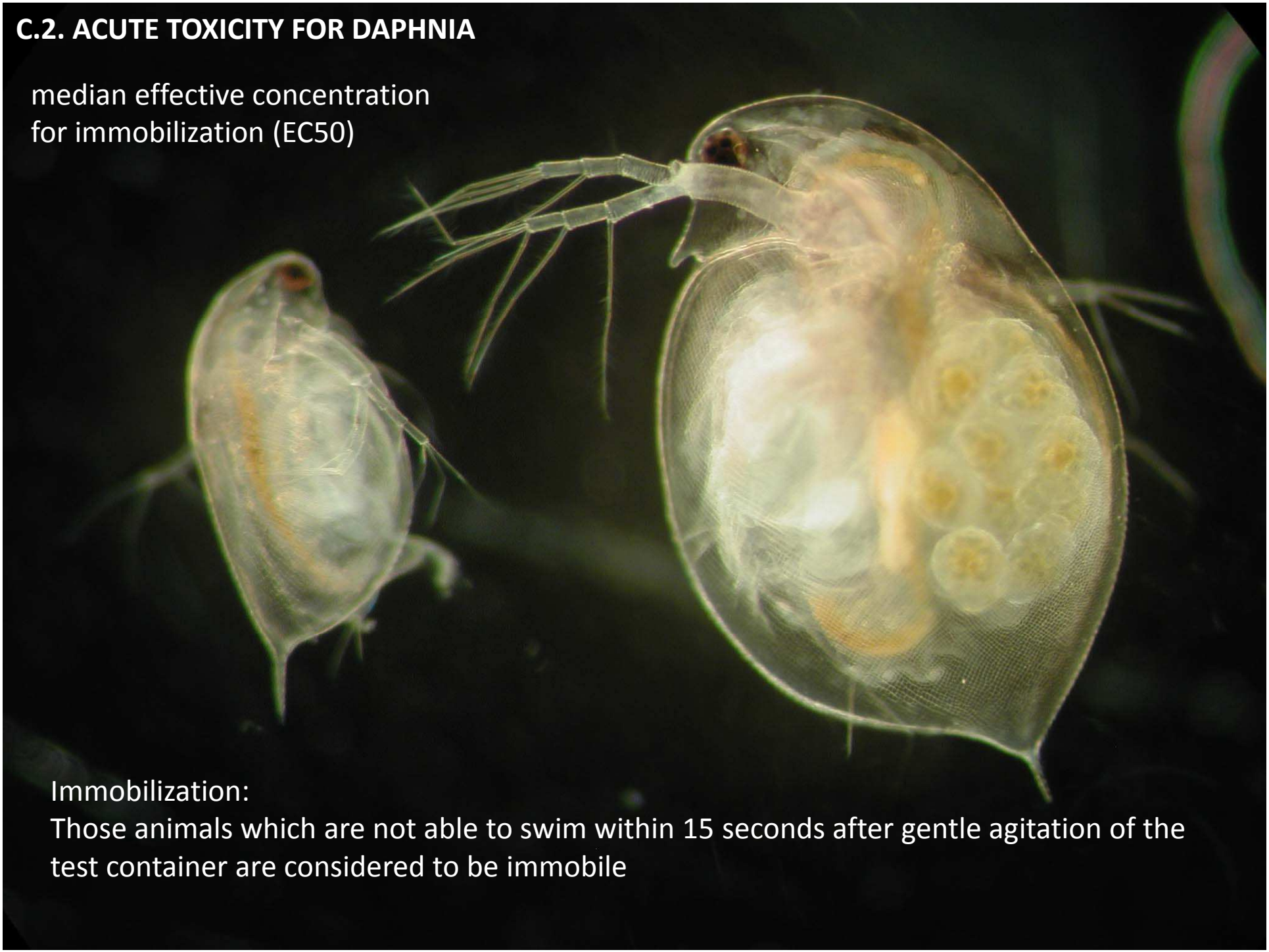
Recommended species	Recommended range of test temperature (°C)	Recommended total length of test animal (cm)
Brachydanio rerio (Teleostei, Cyprinidae) (Hamilton-Buchanan) Zebrab-fish	20 to 24	3,0 ±0,5
Pimephales promelas (Teleostei, Cyprinidae) (Rafinesque) Fathead minnow	20 to 24	5,0 ±2,5
Cyprinus carpio (Teleostei, Cyprinidae) (Linneaus 1758) Common carp	20 to 24	6,0 ±2,0
Oryzias latipes (Teleostei, Poeciliidae) Cyprinodontidae (Tomminck and Schlege 1850) Red killifish	20 to 24	3,0 ±1,0
Poecilia reticulata (Teleostei, Poeciliidae) (Peters 1859) Guppy	20 to 24	3,0 ±1,0
Lepomis macrochirus (Teleostei, Centrarchidae) (Rafinesque Linneaus 1758) Bluegill	20 to 24	5,0 ±2,0
Onchorhynchus mykiss (Teleostei, Salmonidae) (Walbaum 1988) Rainbow trout	12 to 17	6,0 ±2,0
Leuciscus idus (Teleostei, Cyprinidae) (Linneaus 1758) Golden Orfe	20 to 24	6,0 ±2,0

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.2. Information need

- water solubility, vapour pressure, chemical stability , dissociation constants and biodegradability of the substance before starting the test.
- Additional information (for instance structural formula, degree of purity, nature and percentage ofsignificant 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.

C.2. Test principle

- A limit test may be performed at 100 mg per litre in order to demonstrate that the EC50 is greater than
- this concentration.
- The *Daphnia* are exposed to the test substance added to water at a range of concentrations for 48 hours. If a shorter test is used, justification should be given in the test report.
- Under otherwise identical test conditions, and an adequate range of test substance concentrations, different concentrations of a test substance exert different average degrees of effect on the swimming ability of *Daphnia* . Different concentrations result in different percentages of *Daphnia* being no longer capable of swimming at the end of the test. The concentrations causing zero or 100 % immobilization are derived directly from the test observations whereas the 48-hour EC50 is determined by calculation if possible.

C.2. Quality Criteria

- Immobilization in the controls must not exceed 10% at the end of the test.
- Test *Daphnia* in the control groups must not have been trapped at the surface of the water.
- It is desirable that concentration of dissolved oxygen in the test vessels should remain above 3 mg l-1 throughout the course of the test. However, in no circumstances should the dissolved oxygen concentration fall below 2 mg l-1.
- The concentration of the test substance shall be maintained to within 80% of the initial concentration throughout the duration of the test.
- For substances which dissolve easily in the test medium, yielding stable solutions i.e. those which will not to any significant extent volatilize, degrade, hydrolyze or adsorb, the initial concentration can be taken as being equivalent to the nominal concentration.
- Evidence shall be presented that the concentrations have been maintained throughout the test and that the quality criteria have been satisfied.

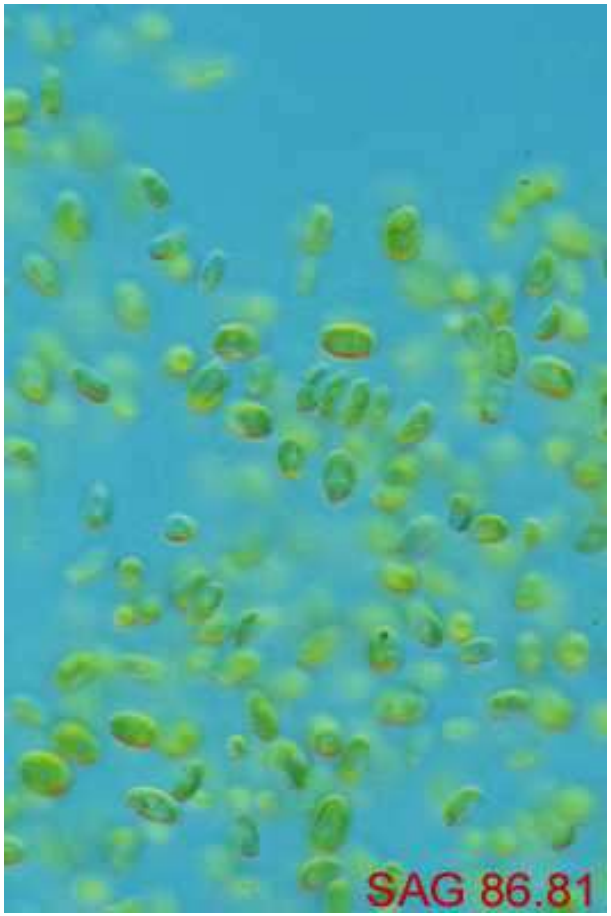
C.2. Quality Criteria

- For substances that are:
  - **(i) poorly soluble in the test medium, or**
  - **(ii) capable of forming stable emulsions or dispersions, or**
  - **(iii) not stable in aqueous solutions,**
- the initial concentration shall be taken as the concentration measured in solution (or, if technically not possible, measured in the water column) at the start of the test. The concentrat ion shall be determined after a period of equilibration but before the introduction of the test fish.
- In any of these cases, further measurements must be made during the test to confirm the actual exposure concentrations or that the quality criteria have been met.

C.2. Test conditions

- duration: 48 hours
- number of animals: at least 20 animals at each test concentration preferably divided into four batches
- test concentration: the test solution should be prepared immediately before introduction of the *Daphnia*, preferably without using any solvent other than water. The concentrations are made up in a geometric series, at a concentration ratio not exceeding 2.2. Concentrations sufficient to give 0 and 100% immobilization after 48 hours and a range of intermediate degrees of immobilizations permitting calculation of the 48 hour EC50 should be tested together with controls,
- light: a light-dark cycle is optional,
- temperature: temperature: the test temperature should be between 18 and 22 °C, but for each single test it should be constant within ± 1 °C,
- aeration: the test solutions must not be bubble-aerated,
- Volatile compounds should be tested in completely filled closed containers, large enough to prevent lack of oxygen.
- feeding: none.

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.3. Information need

- water solubility, vapour pressure, chemical stability , dissociation constants and biodegradability of the substance before starting the test.
- Additional information (for instance structural formula, degree of purity, nature and percentage ofsignificant 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.

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C.3. Test principle

- A limit test may be performed at 100 mg per litre in order to demonstrate that the EC50 is greater than this concentration.
- Exponentially-growing cultures of selected green algae are exposed to various concentrations of the test substance over several generations under defined conditions.
- The test solutions are incubated for a period of 72 hours, during which the cell density in each solution is measured at least every 24 hours. The inhibition of growth in relation to a control culture is determined.

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C.3. Quality Criteria

- The cell density in the control cultures should have increased by a factor of at least 16 within three days.
- The concentrations of the test substance shall be maintained to within 80 % of the initial concentrations/ throughout a time corresponding to the duration of the test.
- For substances which dissolve easily in the test medium, yielding stable solutions i.e. those which will not to any significant extent volatilize, degrade, hydrolyze or adsorb, the initial concentration can be taken as being equivalent to the nominal concentration. Evidence shall be presented that the concentrations have been maintained throughout the test and that the quality criteria have been satisfied.

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C.3. Test conditions

- duration: 72 hours
- For the test, at least five concentrations are made up in a geometric series at a concentration ratio not exceeding 2,2. The lowest concentration tested should have no observed effect on the growth of the algae. The highest concentration tested should inhibit growth by at least 50 % relative to the control and, preferably, stop growth completely.
- Test cultures containing the desired concentrations of test substance and the desired quantity of algal inoculum are prepared by adding aliquots of stock solutions of the test substance to suitable amounts of algal pre-cultures (see Appendix 1).
- The culture flasks are shaken and placed in the culturing apparatus. The algal cells are kept in suspension by shaking, stirring or bubbling with air, in order to improve gas exchange and reduce pH variation in the test solutions. The cultures should be maintained at a temperature in the range of 21 to 25 °C, controlled at ± 2 °C.
- The cell density in each flask is determined at least at 24, 48 and 72 hours after the start of the test. Filtered algal medium containing the appropriate concentration of the test chemical is used to determine the background when using cell density measurements other than direct counting methods.

Test organisms

- It is suggested that the species of green algae used be a fast -growing species that is convenient for culturing and testing. The following species are preferred:
- -*Selenastrum capricornutum* , e.g. ATCC 22662 or CCAP 278/4,
- -*Scenedesmus subspicatus*, e.g. 86.81 SAG,

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C.4. DETERMINATION OF 'READY' BIODEGRADABILITY

- A solution, or suspension, of the test substance in a mineral medium is inoculated and incubated under aerobic conditions in the dark or in diffuse light. The amount of DOC in the test solution due to the inoculum should be kept as low as possible compared to the amount of DOC due to the test substance.
- Allowance is made for the endogenous activity of the inoculum by running parallel blank tests with inoculum but without test substance, although the endogenous activity of cells in the presence of the substance will not exactly match that in the endogenous control. A reference substance is run in parallel to check the operation of the procedures.

C.4. DETERMINATION OF 'READY' BIODEGRADABILITY

- In order to select the most appropriate method, information on the chemical's **solubility, vapour pressure** and **adsorption** characteristics is essential.
- The chemical structure or formula should be known in order to calculate theoretical values and/or check measured values of parameters, e.g. ThOD, ThCO2, DOC, TOC, COD (see Annexes I and II).

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.

Environmental compartments

the environmental compartments considered for the inland environment:

- **the aquatic and terrestrial ecosystem,**
- **top predators,**
- **microbial activity in a STP,**
- **and the atmosphere.**

This means that for each of these compartments a PNEC **has to be derived.**

A PNEC is regarded as a concentration below which an unacceptable effect will most likely not occur. In principle, the PNEC is calculated by dividing the lowest short-term L(E)C50 or long-term NOEC value by an appropriate assessment factor.

The assessment factors reflect the degree of uncertainty in extrapolation from laboratory toxicity test data for a limited number of species to the 'real' environment.

Assessment factors applied for long-term tests are smaller as the uncertainty of the extrapolation from laboratory data to the natural environment is reduced.

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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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Criteria for data reliability 1

refer to accepted standards:

- **a complete test report is available or the test has been described in sufficient detail and the test procedure is in accordance with generally accepted standards. These data are considered valid and can be used for risk assessment;**
- **the validity of the data cannot be fully established or the test method differs in some respects from the guidelines and the generally accepted scientific standards. Experts must decide in each case whether the test result can be taken into consideration in the risk assessment or is regarded as not valid;**

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Criteria for data reliability 2

- it is clearly evident that the data are not valid because critical pieces of information are not available and cannot be sourced retrospectively (e.g. it is not possible to establish the identity of the test substance). These data are not considered to be valid for the risk assessment. However, they may be used as an aid in the design of an appropriate test.

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Relevance of data

In order to evaluate the relevance of the available data, it is necessary to judge, *inter alia*, if the appropriate endpoints are studied under relevant conditions and if the substance tested is representative of the substance being assessed.

To be able to assess the latter it is essential that the substance is properly described and any significant impurities are identified.

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Intermittend releases

Many substances are released to the environment from industrial sources as a result of batch, rather than continuous processes.

In extreme cases, substances may only be emitted a few times a year. Since the PECs associated with industrial releases can take into account both the amount released and the number of days of emission, the magnitude of the PECs in the risk assessment should not be affected.

PEClocal is always calculated on the basis of a daily release rate, regardless of whether the discharge is intermittent or continuous. It represents the concentration expected at a certain distance from the source on a day when discharge occurs. The discharge is always assumed to be continuous over the 24-hour period.

On the other hand, PECregional is calculated using the annual release rate. It represents the steady-state concentration to be expected, regardless of when the discharge occurred.

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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]

Eff Ass for Intermittent Releases

to derive a PNECwater**, intermittent for such situations, an assessment factor of 100 be normally applied to the lowest L(E)C50 of at least three short-term tests from three trophic levels.**

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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

PNECsed

- **when no toxicity test results are available for sediment organisms, the equilibrium partitioning method is applied to identify a potential risk to sediment organisms. This method is regarded as "screening approach" and is explained in Section 3.5.3;**
- **when only acute toxicity test results for benthic organisms are available (at least one) the risk assessment is performed both on the basis of the test result of the most sensitive species using an assessment factor of 1000 and on the basis of the equilibrium partitioning method. The lowest PNECsed is then used for the risk characterisation;**
- **when long-term toxicity test data are available for benthic organisms the PNECsed is calculated using assessment factors for long-term tests and this result should prevail in the risk assessment.**

This Project is funded by the European Union

human dynamics public sector consulting

Project implemented by Human Dynamics Consortium

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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Goals of Chemical Safety Assessment

- To ensure that risks to workers, consumers and the environment are controlled (and identify and apply the appropriate measures accordingly
- Shall address all identified uses of the M/I or DU
- Develop exposure scenarios if substances are classified as dangerous or considered to be a PBT/vPvB
- Document the assessment in the chemical safety report (CSR), including listing of the exposure scenarios, covering Risk Management Measures (including C&L and down stream consequences)
- To communicate information using the safety data sheet according to REACH

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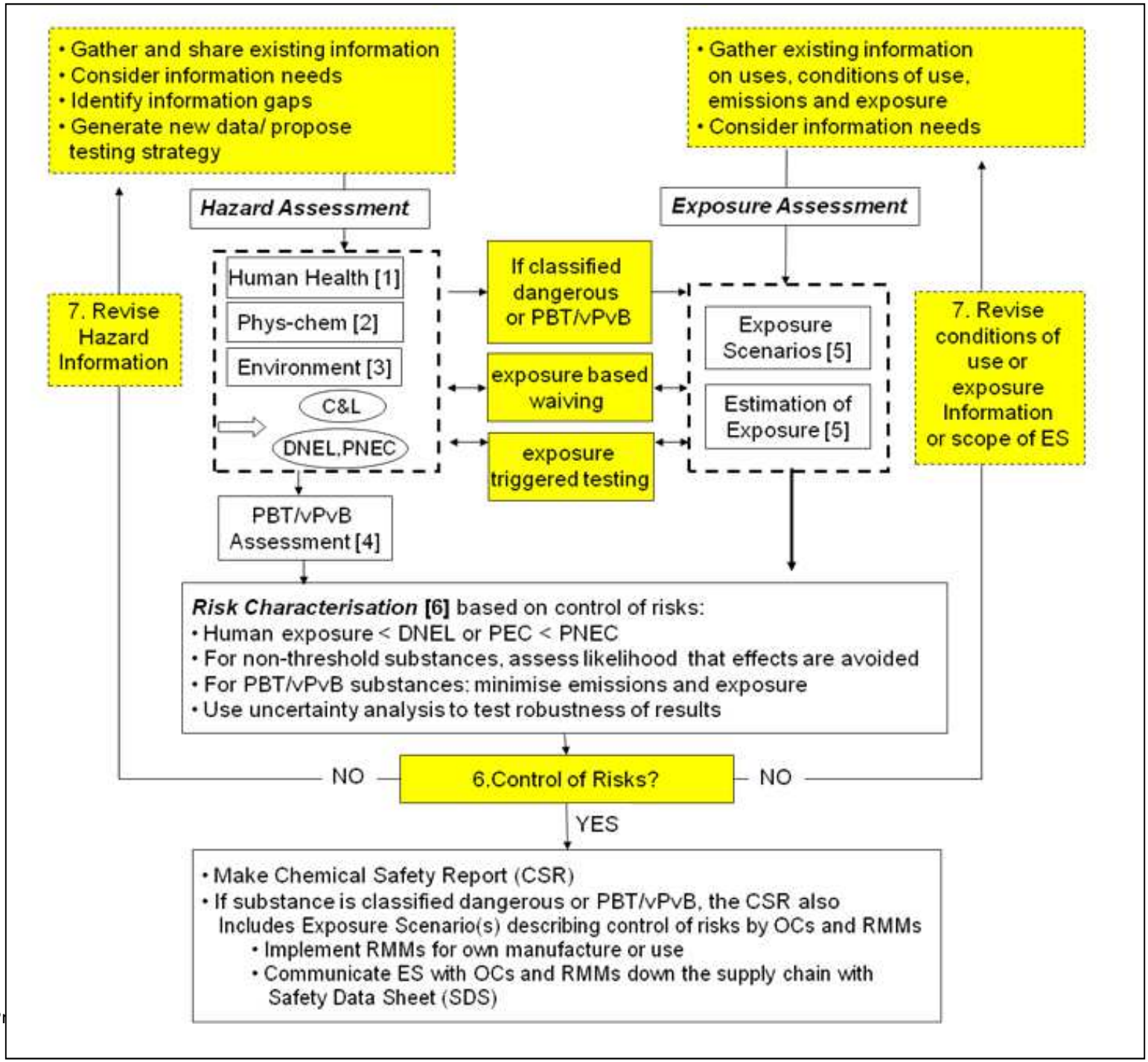
• Gather and share existing information
• Consider information needs
• Identify information gaps
• Generate new data/ propose testing strategy
• Gather existing information on uses, conditions of use, emissions and exposure
• Consider information needs
Hazard Assessment
Exposure Assessment
Human Health [1]
Phys-chem [2]
Environment [3]
C&L
DNEL,PNEC
If classified dangerous or PBT/vPvB
exposure based waiving
exposure triggered testing
Exposure Scenarios [5]
Estimation of Exposure [5]
7. Revise Hazard Information
7. Revise conditions of use or exposure Information or scope of ES
PBT/vPvB Assessment [4]
Risk Characterisation [6] based on control of risks:
• Human exposure < DNEL or PEC < PNEC
• For non-threshold substances, assess likelihood that effects are avoided
• For PBT/vPvB substances: minimise emissions and exposure
• Use uncertainty analysis to test robustness of results
NO
6.Control of Risks?
NO
YES
• Make Chemical Safety Report (CSR)
• If substance is classified dangerous or PBT/vPvB, the CSR also Includes Exposure Scenario(s) describing control of risks by OCs and RMMs
• Implement RMMs for own manufacture or use
• Communicate ES with OCs and RMMs down the supply chain with Safety Data Sheet (SDS)

This Pr

Environmental Classification & Hazard Assessment

CASE STUDY

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Environmental Hazard / Risk Assessment – Case Study

Goal of the Case Study is brief practical introduction into a proces of **„Generic Risk Assessment“**.

Tasks:

1. Classify chemical substances (caprolactame, diphenylamine, dioctylphthalate) for environmental hazard
2. Define endangered environmental compartments based on P-CH properties
3. Perform effects assessment – calculate Predicted No Effect Concentration (**PNEC**)
4. Calculate Predicted Environmental Concentration (**PEC**)
5. Explain (calculate) **Risk Quotients**
6. Make proposals for future factory production / limitations - RMMs

Environmental Hazard / Risk Assessment – Case Study

Results

Existing production

Caprolactame		
Classification	GHS Pictogram	
	Signal Word	
	Hazard Statement	
Effects assessment		
	PNEC	
Exposure assessment	Endangered env. ompartments	
	PEC – aquatic environment	
Risk Quotients	$RQ_{surface\ water}$	
Proposals / comments:		

Diphenylamine		
Classification	GHS Pictogram	
	Signal Word	
	Hazard Statement	
Effects assessment		
	PNEC	
Exposure assessment	Endangered env. ompartments	
	PEC – aquatic environment	
Risk Quotients	$RQ_{surface\ water}$	
Proposals / comments:		

New production

Dioctylphthalate		
Classification	GHS Pictogram	
	Signal Word	
	Hazard Statement	
Effects assessment		
	PNEC	
Exposure assessment	Endangered env. ompartments	
	PEC – aquatic environment	
Risk Quotients	$RQ_{surface\ water}$	
Proposals / comments:		

P-CH Tables

Estimates for the emission factors (fractions released)

Conditions		Emmision factors to:		
Solubility (mg/l)	**Vap. (Pa)**	**Air**	**Waste water**	**Soil**
<100	< 100	0.65	0.25	0.0005
	100 – 1 000	0.8	0.1	0.0025
	≥ 1 000	0.95	0.05	0.001
100 – 1000	< 100	0.4	0.5	0.005
	100 – 1 000	0.55	0.35	0.002
	≥ 1 000	0.65	0.25	0.001
1 000 - 10 000	< 100	0.25	0.65	0.005
	100 – 1 000	0.35	0.55	0.002
	≥ 1 000	0.5	0.4	0.001
≥ 10 000	< 100	0.05	0.85	0.005
	100 – 1 000	0.1	0.8	0.002
	≥ 1 000	0.25	0.65	0.001

Overall emmisions concerning production volume:
< 1000 per annum – 0,02
> 1000 per annum – 0,002 – 0,0005

Classes of affinity of chemicals for the different environmental compartments in relation to the phzsico-chemical characteristics of the molecules

Affinity	**WATER**	**AIR**	**SOIL**	**ANIMAL BIOTA**	**PLANT BIOTA**
	S v mg/l	H v Pa m^3/mol	log Koc	log Kow	log Koa
high	> 10 000	> 10	> 5	> 5	> 8
medium high	10 000 – 100	$10 – 10^{-1}$	5 – 4	5 – 3.5	8 – 7
medium	100 – 10	$10^{-1} – 10^{-2}$	4 – 2	3.5 – 3	7 – 5
medium low	10 – 0,1	$10^{-2} – 10^{-4}$	2 – 1	3 – 1	> 4
low	< 0,1	$< 10^{-4}$	< 1	< 1	< 4

S = water solubility
H = Henry law constant
Koc = Soil Adsorptive Coefficient
Kow = octanol/water distribution coefficient
Koa = oktanol/air distribution coefficient

Units recalculation

1 atm = 1013 mbar = 1013 hPa = 101300 Pa = 760 mmHg
1 mmHg = 133,3 Pa

Formalised criteria (simplified scheme) for classification of chemical substances

Valid only for the aquatic environment

Acute toxicity: min. F, D, A: L(E)C_{50} (mg/l)	**No readily biodegradable**	**Potential for bioaccumulation: Log P_{ow}>3 or BCF > 100**	**Classification: Hazard symbol R-phrases**
< 1	**-**	**-**	 **N** **R50 (very toxic...)**
< 1	**+ and / or**	**+**	 **N** **R50/53 (very toxic... and may cause long-term adverse effects in the aquatic environment)**
1-10 and	**+ and / or**	**+**	 **N** **R51/53 (toxic... and may cause long-term adverse effects in the aquatic environment)**
10-100 and	**+ and**	**+/ -**	**R52/53* (Harmful... and may cause long-term adverse effects in the aquatic environment)**
-, but S_w< 1	**+ and**	**+**	**R53* (May cause long-term adverse effects in the aquatic environment)**

F, D, A: Fish, Daphnia, Algae = fish, Daphnia, algae; S_w = water solubility.
* without classification in case when substance has documented abilitt for ready degradability in the water environment, or NOEC (long-term) for fish or Daphnia ≥ 1 mg/l (R52) or higher then Sw (R53).

Classification categories for hazardous to the aquatic environment

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008

Acute (short-term) aquatic hazard

Acute Category 1 (Note 1)

96 hr LC50 (for fish) ≤ 1 mg/l and/or

48 hr EC50 (for crustacea) ≤ 1 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) ≤ 1 mg/l. (Note 2)

Chronic (long-term) aquatic hazard

Chronic Category 1 (Note 1)

96 hr LC50 (for fish) ≤ 1 mg/l and/or

48 hr EC50 (for crustacea) ≤ 1 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) ≤ 1 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4).

Chronic Category 2

96 hr LC50 (for fish) > 1 to ≤ 10 mg/l and/or

48 hr EC50 (for crustacea) > 1 to ≤ 10 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) > 1 to ≤ 10 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4), unless the chronic toxicity NOECs are > 1 mg/l.

Chronic Category 3

96 hr LC50 (for fish) > 10 to ≤ 100 mg/l and/or

48 hr EC50 (for crustacea) > 10 to ≤ 100 mg/l and/or

72 or 96 hr ErC50 (for algae or other aquatic plants) > 10 to ≤ 100 mg/l (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4) unless the chronic toxicity NOECs are > 1 mg/l.

Safety net' classification

Chronic Category 4

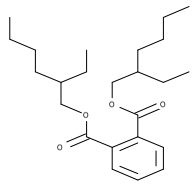
Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility (note 3), and which are not rapidly degradable and have an experimentally determined BCF ≥ 500 (or, if absent, a log Kow ≥ 4), indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or evidence of rapid degradation in the environment.

Note 1
When classifying substances as Acute Category 1 and/or Chronic Category 1 it is necessary at the same time to indicate an appropriate M-factor (see table 4.1.3).

Note 2
Classification shall be based on the ErC_{50} [= EC_{50} (growth rate)]. In circumstances where the basis of the EC_{50} is not specified or no ErC_{50} is recorded, classification shall be based on the lowest EC_{50} available.

Note 3
'No acute toxicity' is taken to mean that the $L(E)C_{50}$(s) is/are above the water solubility. Also for poorly soluble substances, (water solubility < 1 mg/l), where there is evidence that the acute test does not provide a true measure of the intrinsic toxicity.

DIOCTYLPHTHALATE



CAS No.:	**117-81-7**
EINECS/ELINCS No.:	**204-211-0**
Formula:	**C24-H38-O4**
Molecular weight:	**390,54 g/mol**
Form:	light colored liquid; colorless oily liquid; sl

Melting point:	-50 °C	**Boiling point:**	230 °C pri 5mm Hg
Flash point:	215 °C (open cup)		[R 13]
Autoignition temperature:	390 °C		[R 13]
Vapor pressure:	1,32 mm Hg pri 200 °C; 9,75x10^{-6} mm Hg pri 25 °C		[HSDB]
Henry constant:	1,1x10^{-5} atm x m^3 /mol; log H (Pa.m^3.mol^{-3}) = -2,8		
Density:	0,9861 at 20 °C		[HSDB]
Water solubility:	less then 0,01% at 25 °C 0,340 mg/l at 25 °C		[HSDB] [HSDB]
Solubility in org. solvents:	miscible with mineral oil and hexane		
Log Kow:	7,60 [EPIWinv.2,0]	**BCF:**	640 [IUCL104]
Ready biodegradability:	No		
Inherent biodegradability:	Yes		
Soil Adsorptive Coefficient	Koc = 165400; logKoc = 5,219 [EPIWin v.2.0]		
Half-life of deg.	7 days (model. river), 60 days (model. lake)		
Photolysis			
Hydrolysis	half-live: at pH 8 = 195 days; at pH 7 = 5 years		

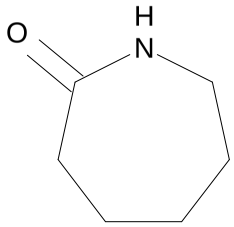
5. Ecotoxicology 5.1 Microorganisms

Taxonomic group	Sp.	Effect	Parameter	Effective conc.	Units	Test duration	Lit.
Bacteria	*Pseudomonas putida*		EC10	>1400	mg/l	6 h	[IUC141]
	Fauschlamm		EC0	100	mg/l	30 d	[IUC142]

5.2 Water organisms 5.2.1 Short-term studies

Taxon. group	Sp.	Effect	Parameter	Effective conc.	Units	Test duration	Lit.
Fish	*Gasterosteus aculeatus*	NOEC LC0 LC50 EC50	> = 0,3 > = 0,3 > 0,3 > 0,3	mg/l mg/l mg/l mg/l		96 h 96 h 96 h 96 h	[IUC126]
	Jordanella floridae	NOEC LC50	> = 0,32 > 0,32	mg/l mg/l		96 h 96 h	[IUC126]
	Leuciscus idus	LC0 LC50	22 61	mg/l mg/l		48 h 48 h	[IUC124]
	Leuciscus idus	LC0 LC50	11 533	mg/l mg/l		48 h 48 h	[IUC124]
Crustations	*Daphnia magna*	LC50	> 0,32	mg/l		48 h	[IUC86]
	Daphnia magna	LC50 LC50	11 > 64	mg/l mg/l		48 h 24 h	[IUC128]
	Daphnia magna	LC50	9,4	mg/l		48 h	[IUC129]
	Daphniapulex	LC50	> 0,4	mg/l		96 h	[IUC131]
Algae	*Selenastrum capric.*	EC50	> 0,1	mg/l		96 h	[IUC132]
	Gymnodinium breve	LC50	100	g/l		96 h	[IUC139]
	Gymnodinium breve	EC50 LC50	31 100	g/l g/l		96 h 96 h	[IUC139]

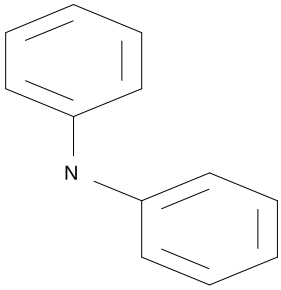
Ecotoxicological properties
Caprolactame



2H-Azepin-2-one, hexahydro-

Substance	caprolactame
CAS No.	105-60-2
EC No.	203-313-2
Formula	$C_6H_{11}ON$
Molecular weight [g/mol]	113.16
Relative density [g/cm^2]	1.014
Melting point [^oC]	69 –71
Boiling point [^oC]	270
Water solubility [mg/l]	820000 2000
Vapore pressure [mm Hg]	0.001
Henryho constant [atm×m3/mol]	evaporation not significant
log K_{ow}	- 0.19
Hydrolysis, $t_{1/2}$ [days]	n.a.
Photolysis, $t_{1/2}$ [days]	n.a.
Ready biodegradability [%]	82 (MITI I test) 95 – 100 (14 days)
Bioaccumulation, BCF	< 1
Toxicity, microorganisms [mg/l]	EC10 = 1740 *(Pseudomonas)* EC50 = 4200 *(Pseudomonas)*
Toxicity, algae [mg/l]	EC50 = 130 *(Scenedesmus subspicatus*)
Toxicity, crustations [mg/l]	EC50 > 500 *(Daphnia magna)*
Toxicity, fish [mg/l]	LC50 = 930 *(Lepomis macrochirus)* Toxicity = 5000 – 10000 NOEC = 1000
Soil Adsorptive Coefficient	Koc = 57,35; logKoc = 1,759

Ecotoxicological properties
Diphenylamine



Benzenamine, N-phenyl-

Substance	Diphenylamine
CAS No.	122-39-4
EC No.	204-539-4
Formula	$C_{12}H_{11}N$
Molecular weight [g/mol]	169.22
Relative density [g/cm^2]	
Melting point [^oC]	53 –54
Boiling point [^oC]	302
Water solubility [mg/l]	200 - 300 40
Vapore pressure [mm Hg]	1.61×10^{-4} (20^oC) 0.11
Henryho constant [atm×m3/mol]	0.90×10^{-6}
log K_{ow}	3.5 3.62
Hydrolysis, $t_{1/2}$ [days]	
Photolysis, $t_{1/2}$ [days]	0.08 – 1.4 (reaction product: karbazol)
Ready biodegradability [%]	0 (MITI I)
Bioaccumulation, BCF	51 – 253 *(Cyprinus carpio)* 30 *(Pimephales promelas)* 70
Toxicity, microorganisms [mg/l]	Inhibition > 10 (saprophytic microflora) NOEC = 100 *(Nitrosomonas sp.)* NOEC = 1000 *(Pseudomonas fluorescens)*
Toxicity, algae [mg/l]	EC50 = 0.048 *(Scenedesmus)*
Toxicity, crustations [mg/l]	EC50 = 2.3 *(Daphnia magna)* EC0(21 days) = 0.16 *(Daphnia magna)* EC70(21 days) = 0.5 *(Daphnia magna)*
Toxicity, fish [mg/l]	LC50 = 1 – 100 LC50(48 h) = 5.1 *(Oryzias lapites)*
Toxicity, earthworms [mg/kg]	LC50(14 days) = 269 NOEC(14 days) = 178
Soil Adsorptive Coefficient	Koc = 1887; logKoc = 3,276

HYPOTHETICAL CASE STUDY
Environmental risk calculation

Accidental spill at Duslo a.s. in Šal'a (Váh)

- dibuthylphthalate
- xylene
- diazinon (OP ester)

TASKS:

- Calculation of PEC (predicted environmental concentration)
- Use of assessment factors
- Selection of adequate toxicity data (use: IUCLID or other: acquire US EPA ecotox database: http://cfpub.epa.gov/ecotox/ or ECHA: http://echa.europa.eu/ and echemportal: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)
- Calculation of PNEC (predicted no-effect concentratiobn)
- Calculation of Environmental risk downstream

Case Study: Environmental risk calculation for chemicals release due to a calamity

Purpose: To learn how to calculate environmental concentrations in a river; how to select toxicity data for risk assessment, how to calculate a PNEC. What is the risk for aquatic organisms 55 km down stream of Titu, near Bucharest.

HYPOTHETICAL CASE STUDY: Factory DUSLO a.s., located 55 km upstream of Bucharest, near Titu

Duslo a.s. produces various chemicals including industrial fertilisers, plant production agents, rubber chemicals, polyvinylacetate dispersions and dispersion glues as well as special products of organic and inorganic chemistry. Due to a fire in the factory depot 30 kg dibutylphthalate, 10 kg of xylene and 3 kg of diazinon were spilled with the fire extinguishing water into the river Dambovita.

1. Calculate the predicted environmental concentration (PEC) at Bucharest
2. Calculate the predicted No effect Concentration (PNEC)
3. Calculate the risk coefficient at Bucharest
4. What are your conclusions based on the calculated risk coefficient.
5. Take a closer look at the assumptions, are they legitimate for this situation.

1. Calculation of the predicted environmental concentration:

Dilution of a spilled quantity may be calculated by the equation:

$$\mathbf{C_{max} = 1.36 \times 10^{-4} \times M}$$

C_{max}	=	maximum concentration at Bucharest (mg/l)
M	=	discharge quantity in kg

This simplification is derived from the Gausian relationship:

$$C_{max}(t) = \frac{M}{2.A.\sqrt{\pi \,.\, D \,.\, t}} \,.\, \Theta d \,.\, e^{-kt}$$

C_{max} (t)	=	maximum concentration at some distance downstream in (mg/l)
M	=	discharge quantity in kg
d	=	dilution between discharge point and some distance downstream caused by increased water quantity
e^{-kt}	=	removal
-k	=	first order removal rate (l/day)
t	=	time (day)
2.A .D.t	=	volume of water that contains the chemical
A	=	cross section area of the river (m^2)
D	=	dispersion coefficient (m^2/sec)
t	=	time (sec.)

The following parameter values were used:

k	=	0	(no degradation)
A	=	500	m^2
D	=	50	m^2/s 432 x 10^4 m^2/day
t	=	0.8	days between Titu and Bucharest
~~Θ~~d	≈	0.45	for Titu to Bucharest

The formula used in this dispersion model is based on the following assumptions:
- The substances are highly soluble.
- Decrease in concentration in the water is solely caused by dispersion without degradation, evaporation and adsorption to floating particles is not taken into account.
- Complete mixing of spills within the water body (river Dambovita).

2 Calculation of the Predicted No Effect Concentration PNEC:

The PNEC can be calculated using toxicity data and by applying an assessment factor. Gather toxicity data on dibutylphthalate, diphenylamine and zineb in IUCLID (or other sources).

3 Select the right assessment factor

Select the right assessment factor on the basis of the following scheme:

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
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	Case by case

PNEC = ratio lowest LC50 or NOEC and an selected assessment factor

4.Calculate the risk coefficient

The environmental risk of a substance can be estimated by the PEC/PNEC coefficient. the following classification is used:

Classification	PEC/PNEC
Serious risk	>10
Unacceptable risk	1-10
Acceptable risk	0.01-1
Negligible risk	<0.01

Acute data for dibutylphthalate (CAS no. 84-74-2) are:

Group	Species	Criterion	Result	Data quality
Algae	Scenedesmus subsp. Gymnodium breve	EC50 (72 h) EC50 (96 h)	1.2 mg/l 0.2 mg/l	
Invertebrates	Daphnia magna Artemia salina Gammarus pseudolim. Nitocra spinipes Mysidopsis bahia	EC50 (48 h) LC50 (24 h) LC50 (96 h) LC50 (96 h) LC50 (96 h)	3.4 mg/l 8.0 mg/l 2.1 mg/l 1.7 mg/l 0.8 mg/l	
Fish	Pimephales promelas Lepomis macrochirus Ictalurus punctatus Oncorhynchus mykiss Perca flavescens	LC50 (96 h) LC50 (96 h) LC50 (96 h) LC50 (96 h) LC50 (96 h)	0.9 mg/l 0.7 mg/l 0.46 mg/l 1.6 mg/l 0.35 mg/l	
Other species	-			

Chronic data for dibutylphthalate are:

Group	Species	Criterion	Result	Data quality
Algae	Selenastrum capricorn. Dunaliella parva	NOEC (10 d) NOEC (8 d)	0.8 mg/l 0.2 mg/l	
Invertebrates	Daphnia magna Gammarus pulex Dugesia japonica	NOEC (21 d) NOEC (10 d) NOEC (7 d)	1.05 mg/l 0.10 mg/l 0.54 mg/l	
Fish	Oncorhynchus mykiss	NOEC (99 d)	0.1 mg/l	
Other species	-			

Acute data for xylene (CAS no 1330-20-7) are:

Group	Species	Criterion	Result	Data quality
Algae	Selenastrum capricornutum	EC50 (growth rate) (73 h)	4.36 mg/l	Klimisch 1
Invertebrates	Daphnia Magna	IC 50 (24 h)	1.0 mg/l	Klimisch 2
Fish	Salmo gairdneri Bryoconamericus iheringii Salmo gairdneri	LC50 (96 h) LC50 (96 h) LC50 (96 h)	2.6 mg/l 9.94 mg/l 7.6 mg/l	Klimisch 2 Klimisch 2 Klimisch 2
Other species				

Chronic data for xylene are:

Group	Species	Criterium	Result	Data quality
Algae	Selenastrum capricornutum	NOEC (73h)	0.44 mg/l	Klimisch 1
Invertebrates	Ceriodaphnia dubia	NOEC (7 days)	1.17 mg/l	Klimisch 1
Fish	Salmo gairdneri	NOEC (56 d)	1.3 mg/l	Klimisch 2
Other species				

Acute data for diazinon (CAS no 333-41-5) are:

Group	Species	Criterion	Result	Data quality
Algae	No data			
Invertebrates	Water flea Moina macrocopa Daphnia magna	LC50 (24h) EC50 (48h)	0.01mg/l 0.00035 mg/l	
fish	Salmo trutta (ssp Lacustris) Cutthroat Trout (Oncorhynchus clarki	LC50 (96h) LC50 (96h)	0.60 mg/l 1.70 mg/l	
Other species				

Chronic data for diazinon are

Group	Species	Criterium	Result	Data quality
Algae	No data			
invertebrates	Daphnia magna	NOEC (21d)	0.00015 mg/l	
fish	Rainbow trout (Oncorhynchus mykiss)	NOEC (28d)	0.2 mg/l	
Other species				

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

Mixture or Article

Obligations

Date: 29.11.2014

Dr. Gisela Holzgraefe

Ministry for Energy, Agriculture, the Environmant and Rural Areas

of Land Schleswig-Holstein (Germany)

Content

- Mixture or article?
- obligations for registration
- obligations for notification
- Examples

Article or Mixture?

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

- **Preparation**: means a mixture or solution composed of two or more substances
- any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency (Art 6 (1) REACH)
- **Article**: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
- Example: table = article. It may be made out of wood, metal, plastics. The most important is the function not out of which material it is made.
- Example: text marker = mixture in a container

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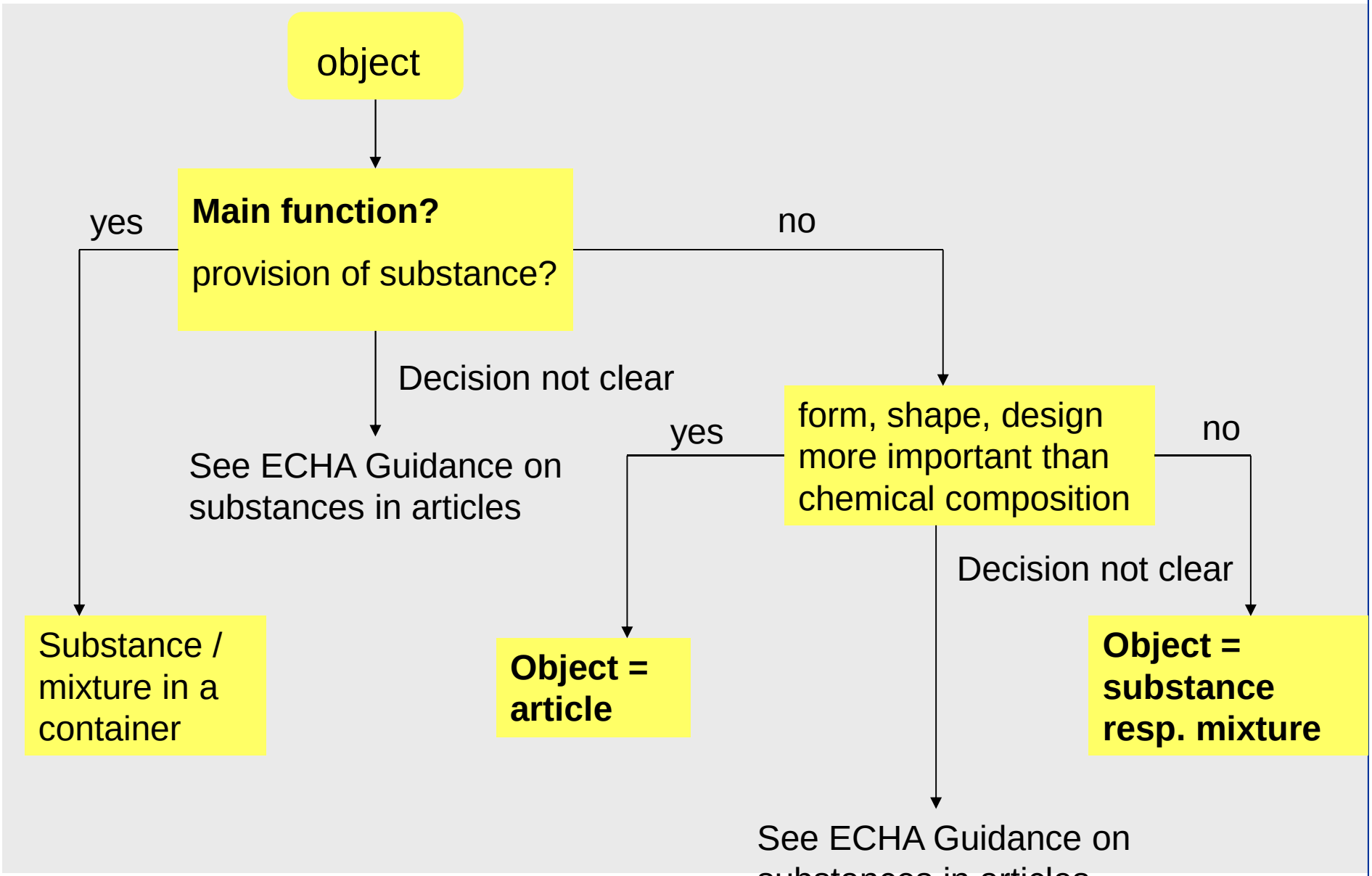
Mixture or article?



Decision article or preparation / mixture

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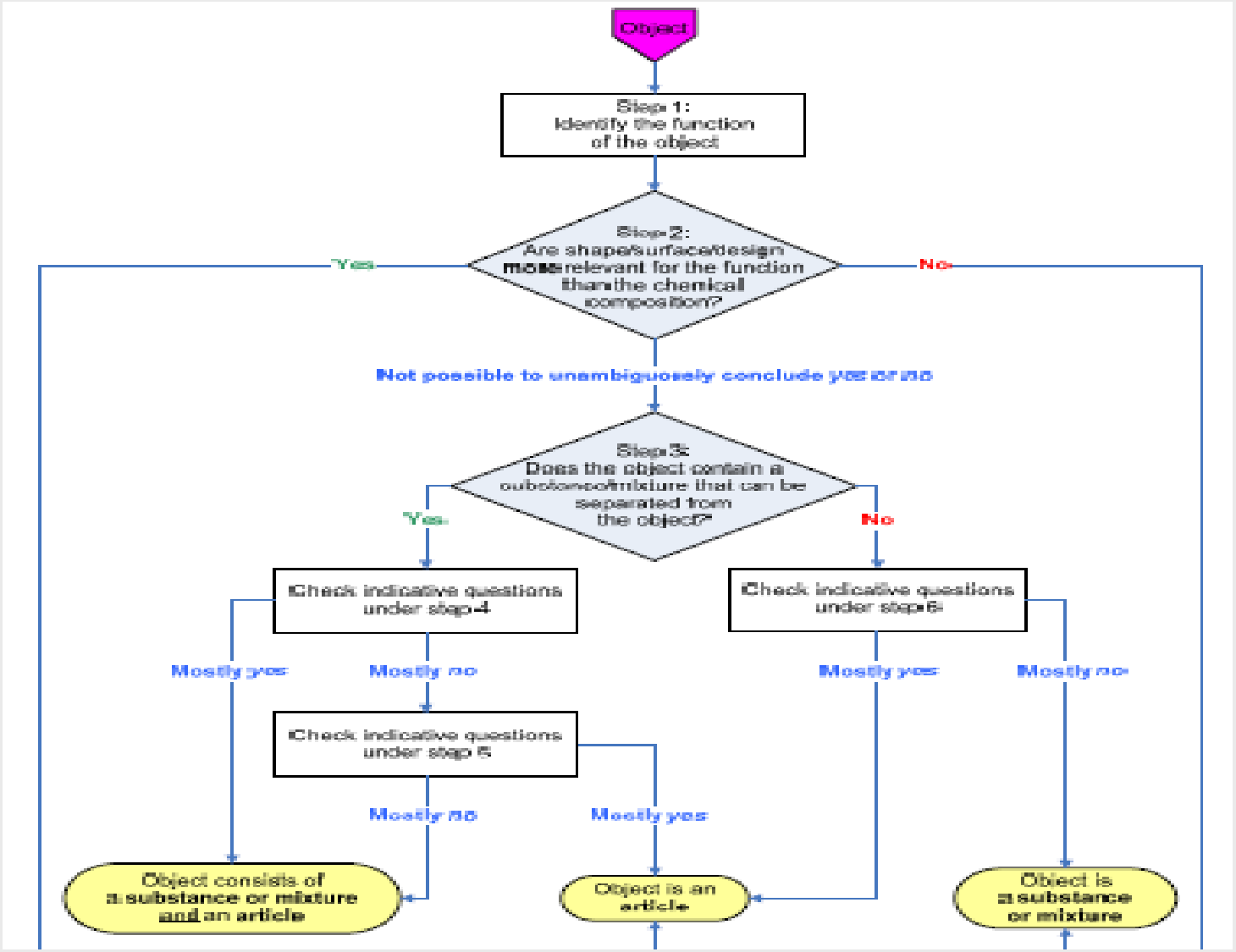

duties

- Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

  (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year and

  (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use. (Art 7 (1) REACH)
  (Example: print cartridge or text marker = mixture in a container)

duties

- Any producer or importer of articles shall notify the Agency, if a substance meets the criteria in Article 57 (SVHC) and is identified and put on the Candidate List), if both the following conditions are met:

  (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

  (b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w). (Article 7 (2) REACH)

- Exception: producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

- Notification of substances in articles to be made at the latest 6 months after it has been included into the SVHC candidate list.

duties concerning articles

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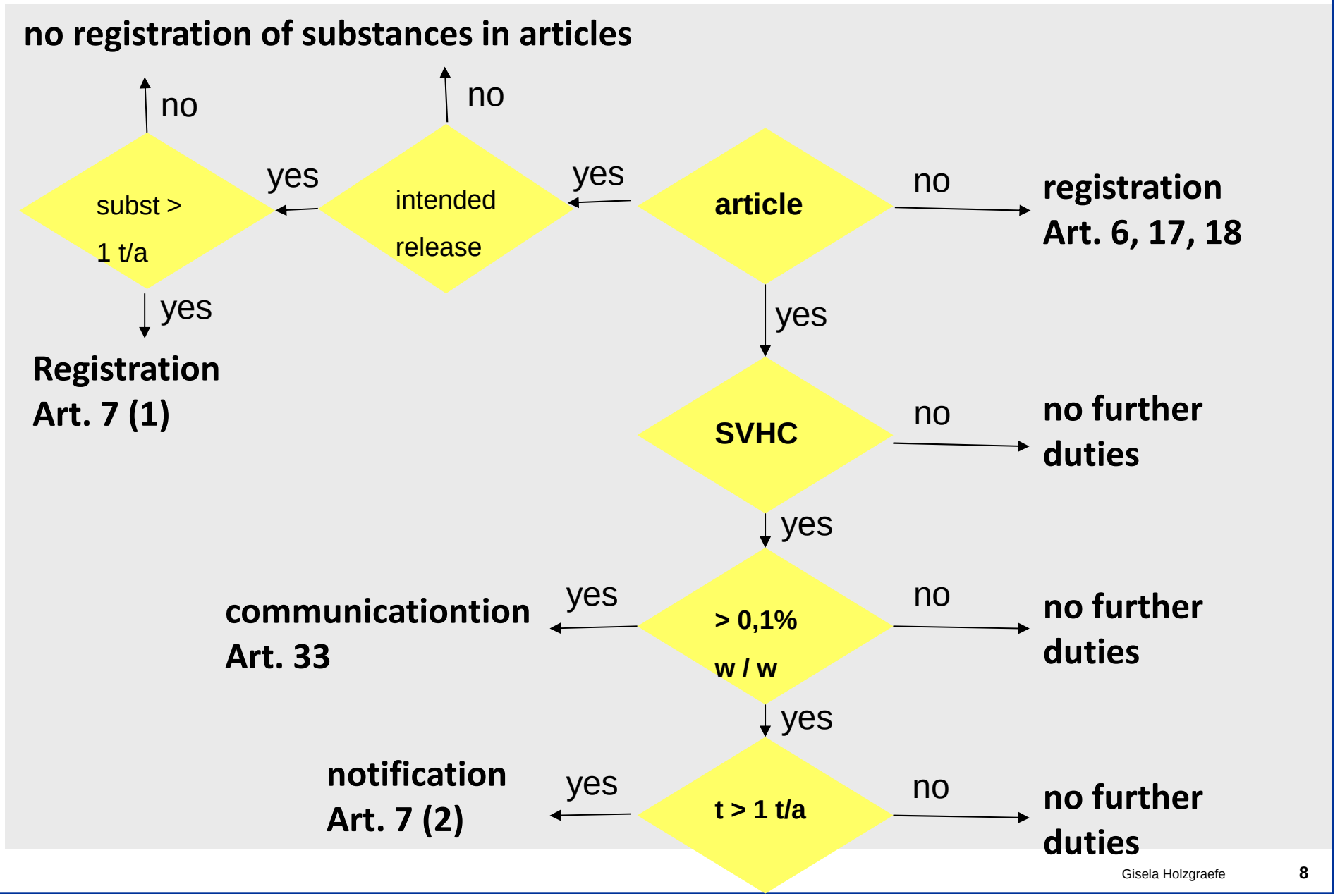

Preparation - Article

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- Article 33 REACH: *Duty to communicate information on substances in articles.*

➢ Any supplier of an article containing a SVHC substance in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

➢ On request by a consumer any supplier of an article containing a substance meeting the criteria of Art 57 (SVHC) and put on the candidate list in a concentration above 0.1 % wight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe useof the article including, as a minimum, the name of that substance.

➢ Relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Reference for 0,1 % w/w

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- **Dissenting view:**
  - COM and most of the EU/EEA memberstates consider every article, even if it is consisting of different and separately produced components as one article. → reference is the whole article
  - Others (AT, BE, DE, FR, SE, DK, NO) follow the principle „once an article, always an article“. The SVHC percentage is calculated with reference to the individual subcomponent.

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Example bicycle

Laptop

- different articles in a laptop, easy to identfy: screen, computer case (housing), keybord, cable, plug, computer circuit board …
- some of them consist of different articles, e.g. the circuit board
- Do we have to assess the amount of SVHC substances or substances on the candidate list of each capacitor / condensor and each resistor?
- The German competent authority for chemicals BAuA does not give general advice.

Example: Computer components

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Nicotine in e-cigarettes

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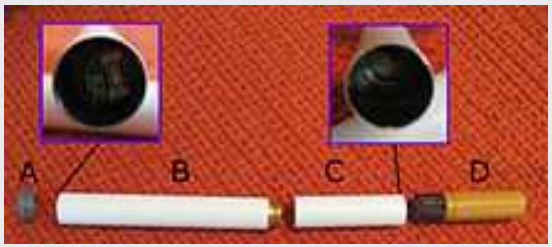
Construction



Disassembled cigarette-styled electronic cigarette.
A. LED light cover
B. battery (also houses circuitry)
C. atomizer (heating element)
D. cartridge (mouthpiece)

Classification / labelling nicotine

Harmonised classification and labelling acc. to (EC)1272/2008

	Hazard class	Hazard statement	pictogram	Hazard statement Code(s)
nicotine	Acute Tox. 1 Acute Tox 3* Aquatc Chronic 2	H310 H301 H411	GHS06 GHS09 Dgr	H310 H301 H411

no specific concentration limits

legally binding classification

Skull and crossbones

Environment

danger

e-cigarettes

Present situation: Under which legislation are e-cigarettes?

a) **Mixture of substances?** Propylene glycol (PG), glycerin (G) and/or polyethylene glycol 400 (PEG 400), sometimes different levels of alcohols mixed with flavourings and optionally a variable concentration of tabacco derived nicotine. Most liked e-liquids contain 18 mg/ml nicotine.

Classification (if nicotine is the only relevant substance) acc. to German BAuA :

	Hazard class	**Hazard statement**
0 – 0,16 %	No	No
0,17 – 1 %	Acute Tox. 4	H 302
1,1 - < 6,5 %	Acute Tox 3	H 301
6,5 – 65,9 %	Acute Tox. 2	H 300
> 66 %	Acute Tox. 1	H 300

E-cigarettes

- **pharmaceutical product:** some courts decided for that, recent decision of higher court: no
  no evidence that they suport to quit smoking
  no evidence that they produce less addicts than cigarettes
- Directive on **tobacco and related products** 2014/40/EU (to be implemented until 20 May 2016): Title III regulates electronic cigarettes.
  - the nicotine containing liquid shall not exceed 20 mg / ml.


Thank you for your attention!
Any questions?

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Interlinks of the REACH Regulation with IED

IMPEL project 2013 and results 2014

ECRAN – 58142, Workshop Tirana
Date: 2 – 4 December 2014

Dr. Gisela Holzgraefe

Ministry for Energy, Agriculture, the Environmant and Rural Areas

of Land Schleswig-Holstein (Germany)

Content

- REACH and IED – different aims
- Interlink analyses REACH / IED
- REACH – IED Synergies (operators/DU)
- Work in practice – permitting
- Work in practice – inspection
- Obligations / duties of operators
- Cooperation of authorities
- Supporting tools for authorities

Aims of REACH and IED

- **Directive 2010/75/EU on industrial emissions (IED):**
  - to prevent pollution by taking an integrated approach and
  - where that is not practicable to reduce emissions from installations and industrial activities into air, water and land in order to achieve a high level of protection of the environment as a whole.
  - IED sets the regulatory framework for permitting, monitoring and inspection of industrial installations.
  - Activities covered by IED: Annex I of IED – emissions and processing of chemical substances
  - Requirements: BREF documents with BAT conclusions
  - IED regulates the emissions of certain polluting substances
- Perrmit writers / inspectors assess the substances processed and unintentionally generated during the process (e.g. dioxins, SO_2 …)

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Aims of REACH and IED

- **REACH Regulation (REACH):**
  - to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals
  - REACH establishes procedures for for collecting and assessing information on the properties and hazards of substances and for defining the measures needed to manage the risks.
  - Processes under REACH: registration, authorisation, restrictions
  - REACH applies to all substances
  - Obligation of the operator to comply wit the requirements

→ **IED and REACH** have different aims and different ways of action. Operators of industrial installations manufacturing and or using chemical substances in their activities have obligations under both IED and REACH. Operators – key actors for safe use and avoiding releases to the environment

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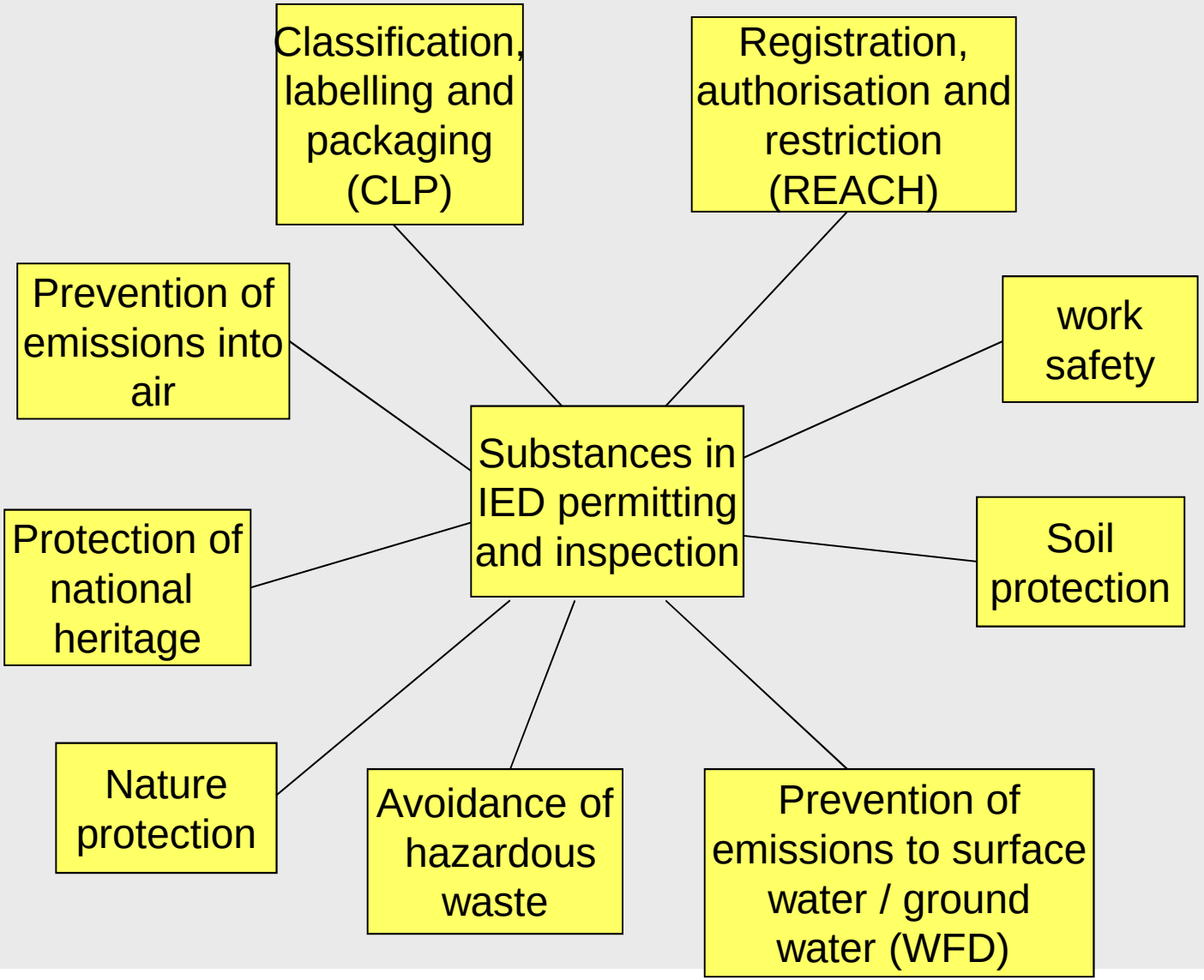
Substances in IED permitting



Substances in permit applications

- IED, national legislation and guidance for applicants provide requirements concerning the documents and data applicants have to submit.
- Authority needs a complete inventory of substances used, produced and stored on site
  - Raw material, educts or groups of educts,
  - Intermediates, by-products and products
  - Waste produced on site
  - Identifiers for substances
  - Information about physical, chemical and physicochemical, toxic properties and degradability of each substance
  - Possible releases or reactions in case of hazards
  - Kind and amount of substances in the raw waste gas and clean gas ….

Substances in permit applications

- Information about protection and prevention measures
  – measures for protection of human health and the environment as well as work safety measures.
- Applicants can use information generated for compliance with other legal duties e.g. with REACH requirements
- Applicants often use safety data sheets (SDS) for this purpose
- Problem: quality

➢ For decision making and setting permit conditions permit authority has to check the information and make a documentation of decisions and the reasoning

➢ A systematic appraoch is highly recommended → benefit for permit writers and inspectors as well as cooperating authorities

➢ For the assessment of chemical substances close cooperation between competent authorities for IED, work safety and REACH enforcement is highly recommended.

- **How can permit writers benefit from REACH information? - Interlink analyses REACH / IED**
- **Interaction REACH and IED (operators/DU)**
- **Work in practice – permiting**
- **Work in practice - inspection**

Interlink analysis - method

The analysis of interlinks in the use of data between the two pieces of legislations was conducted by

- taking into account the input of other relevant projects
- making an inventory of the downstream user (DU)/operator obligations under IED legislation
- identifying REACH generated information helping with compliance of identified obligations
- building “synergy” tables

The information interaction considered goes from REACH to the IED but a reciprocal interaction can be envisaged in most cases. Where specific “one-way” information interactions were identified they have been listed separately.

REACH – IED Synergies (operators/DU)

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IED ref.	Obligation	Information source in REACH
Article 11 General obligations of the operator	Preventive measures against pollution	Exposure Scenario (ES) to help/support: - identify possible release route - quantify release - identify risk management measures (RMM) required to achieve adequate control of risks
	Application of BAT	ES: to identify RMM required to achieve in adequate control of risks (cf. criteria 10 of Annex III of IED)
	Reducing waste and waste impact	SDS: section 13 Disposal considerations
	Accident prevention	SDS: section 2 Hazards identification and 7 Handling and storage
	Accident mitigation	SDS: sections 4 First aid measures, 5 Firefighting measures and 6 Accidental release measures

REACH – IED Synergies (operators/DU)

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IED ref.	Obligation	Information source in REACH
Article 12 Application for permit	Description of installation and activities	ext-SDS: identified uses of substance, OC and RMM to contribute to description of activities
	Description of substances	SDS: classification and hazard information on substances ECHA dissemination site: search for extra/missing info, data source
	Baseline report	SDS: to identify relevant hazardous substances ES: to identify possible release route (what substance for which environmental compartment)
	Foreseeable emissions and significant effects	SDS: to identify relevant hazardous substances ES: to identify possible release route (what substance for which environmental compartment and what effect)

REACH – IED Synergies (operators/DU)

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IED ref.	Obligation	Information source in REACH
Article 12 Application for permit	Waste management plan	ES: waste stage of the substance SDS: section 13 Disposal considerations
	Monitoring plan of the emissions to the environment	SDS: to identify relevant hazardous substances for monitoring ES: to identify possible release routes (what substance to what environmental compartment)
	If SEVESO compliance also needed	SDS: section 15 lists other legislations relevant to the substance ext-SDS: altogether to identify relevant hazardous substances for the preparation of the safety report

REACH – IED Synergies (operators/DU)

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IED ref.	Obligation	Information source in REACH
<u>Article 13</u> BAT **BREF docs**	Info exchange on installation performance and emissions	ES: to support the identification of release routes relevant for the industrial sector
	BAT identification Annex III IED	ES: to identify RMM resulting in adequate control of risks
	BAT - criterion 2 (use of less hazardous substance)	– Registry of intentions (early information of substances which may be subject to harmonised classification, authorisation or restriction) – Candidate List and Authorisation List (substances which should be replaced as soon as technically and economically feasible alternatives are available) – Analysis of alternatives section of the application for authorisation dossier: can provide information on potential alternative substance and or technology

REACH – IED Synergies (operators/DU)

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IED ref.	Obligation	Information source in REACH
	BAT - criterion 2 (use of less hazardous substance)	– Information on alternatives from SVHC or restriction dossier: can provide information on potential alternative substance and or technology
Article 20 Change by operator	Substantial change	ext-SDS: to help identify whether change of substance is relevant to qualify as "substantial change"
Article 22 Site closure / baseline report	Potential contamination of soil and groundwater at the site	ext-SDS: to help identify relevant hazardous substances and their possible release route for site evaluation planning upon closure of the site (what substance to what compartment and what fate)
Article 23 Inspection	Environmental risk appraisal for inspection planning	ext-SDS: to help identify relevant hazardous substances and their possible release route for input in environmental risk assessments

Specific IED to REACH feed

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Information provided by IED at DU level	Potential use for REACH compliance
Environmental permit application information such as • inventory of chemicals needed and their use	• DU obligations ✓ checking own use against ext-SDS ✓ communication in the supply chain if relevant ✓ communication to ECHA if relevant
Monitoring data such as •environmental monitoring •emission monitoring •waste production and management •raw material - chemicals and energy consumption •industrial activity	"Real life" data can be useful if performing own DU CSR
Environmental risk assessment	DU CSR

Specific IED to REACH feed

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Information provided by IED at DU level	Potential use for REACH compliance
Emerging techniques described in BREF (can provide information on potential alternatives in terms of techniques and/or substances to be used)	Support for substitution of hazardous substances with less hazardous or with alternative techniques. In particular substances included in the Candidate List and Annex XIV
Permit granted under IED	In the case of a DU applying for a REACH authorisation, according to REACH Art 62(5) the applicant can consider to use an IED permit granted to the installation as a justification for not considering the risks to human health and the environment arising from emissions of a substance from the installation

conclusions

- Operators can benefit from the information generated under REACH and IED for cross-legislation compliance in many different situations.
- It is a benefit for all parties if the information generated under one legislative regime can be used by industrial operators/downstream users to facilitate compliance under a second regime.
- It is a benefit for authorities for the assessment of applications, assessing the substances used, produced or imported.
- There is a need raise awareness and provide all the actors having a role in cross-legislation issues with guidance and tools on how to deal with and use the synergies identified.
- Objectives of IMPEL project 2014
  - dissemination of results and best practice examples and
  - exploring the practical work with REACH requirements in permitting and inspection by using a questionnaire (17 MS were involved)

I. work in practice - permitting

- **Support for permit writers and inspectors necessary**
- **Awareness for Interlink IED and REACH is growing**
- **Link between IED and REACH in legislation of MS → 6 MS have either a direct or indirect link in their legislation**
  - ➢ Link provides a common understandig and makes it easier for permit writers and inspectors
- **Guidance for dealing with REACH in permitting → 6 MS have it in place, either generic or as tools like flowsheets or checklists for permitting and inspection**
  - ➢ Guidance provides common understandig and makes it easier for permit writers and inspectors
- **Procedures for setting ELVs in permitting → 9 answers yes, others no, but all: reference to BAT and BAT conclusions, plus EQS for water**
  - ➢ This is the basic requirement acc. to IED and WFD

I. work in practice - permitting

- Generally **the national legislation allows for taking up permit conditions for imposing necessary measures due to the use of chemical substances** (e.g. related to storage, spill containment, fire-fight waters, surface materials of soil …)
- **Setting other conditions including substances regulated under REACH → half yes / half no**
  - Awareness of REACH relevance not yet very high. Permit writers have to check and to assess if the chemicals are under REACH in general or under restriction or authorisation regime.
- **Use of specific information from ES and SDS for setting conditions:**
  - Information from SDS is used but quality has to improve. In ext. SDS it is difficult to find the identified use and for work with ES well trained staff necessary. For improvement and harmonisation on company side ECHA has established ENES Network – Exchange Network on Exposure Scenarios (ECHA, DUCC and CEFIC ..)

I. work in practice - permitting

- **Use of PNECs from SDS for setting ELVs: few countries use them as additional information for setting ELVs, several organisations check how to handle it in future.**
  - Question: How reliable are PNECSs– defined by companies?
- **Reference to Annex XIV and XVII in the permit: more than half of the countries require information about these substances in the permit application.**
  - If an application covers activities that are an offence against restriction or authorisation requirements the permit cannot be granted. For this reason it has to be checked. Experience must grow.
- **Reference to authorisations granted or rejected for substances under REACH Annex XIV in the permit**
  - Countries are aware of it. Due to rare cases up to now there is not much experience with ist.

II. work in practice - inspection

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- **Most countries have general guidance for dealing with REACH in inspection in place**
  - several countries use the manuals / checklists of the FORUM REACH EN-FORCE-projects,
  - others have own checklists for REACH in inspections in place.
  - Remained unclear whether they are used in joint IED / REACH inspections or in REACH inspections
- **Most authorities check whether the company activities are covered by ES, but it seems that is not done systematically**
- **Adapted training for IED inspectors and permit writers is recommended for activities related to REACH**
  - Many countries use the manuals of the FORUM REACH-En-Force projects (REF) for this purpose too.

III. Obligations / duties of operators

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- **Operators have to comply with REACH and IED**
- **Operators have to inform the permit authority about all substances in the process chain (raw material, products, intermediates, waste ect.) (IED requirement)**
- **Enterprises should have to send relevant documents to the authorities (SDS, ecopsure scenarios, …) as part of the application.**
- **Information of the permit authority explicitly about substances regulated by REACH – authities should require this**
- **Duty to inform the authority about changes in the use of REACH relevant substances – if not in legislation it should be in a permit condition**

IV. Cooperation of authorities

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- **For dealing with REACH in IED permitting and inspection well trained staff is necessary.**
- **For producing good and coherent harmonised results**
  - ➢ IED permitting and IED inspection authorities should closely cooperate with REACH authorities
  - a) by allowing access to permits e.g. via databases
  - b) by providing information about relevant results of inspections
  - c) by taking up colleagues into mailing lists for information exchange
  - d) meetings for information exchange should be carried out
- **This may be a problem when authorities belong to different organisations (e.g. ministries)**

V. Supporting tools for authorities

- **guidance and checklists for applicants, e.g. template of Schleswig-Holstein and several other German federal states (extract, 1 of 5 pages, full version see presentation May 2014)**

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

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

Dutch SVHC list and guidance

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- **Basis criteria set out in Article 57 of REACH and on:**
  - EU CLP Regulation
  - REACH candidate list of substances
  - EU persistent organic pollutants (POPs) Regulation
  - Water Framework Directive (WFD) and
  - Convention for the protection of the marine environment of the North-East Atlantic (Ospar convention)
- **Aims:**
  - identification of priority substances
  - support for authorities which grant environmental permits
  - Minimise emissions of these substances into the environment
- **List will be updated regularly**

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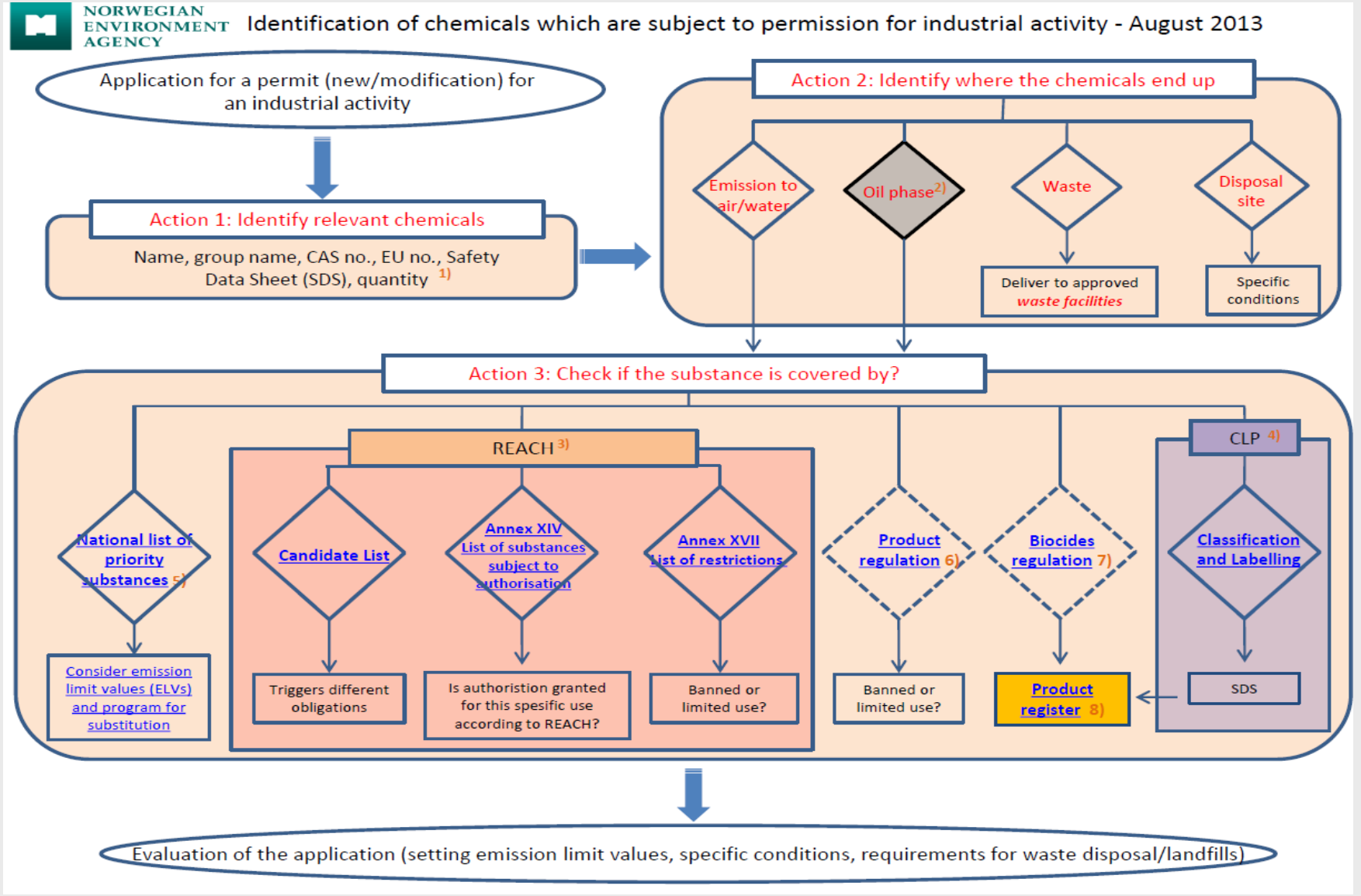
Checklist for SDS

- Many checklists for SDS are offered by industrial associations – not all reflect the latest version, good approach for quality improvement
- The IMPEL project „Linking the IED and the REACH Regulation I“ showed that authorities develop or use already electronic tools for the systematic assessment of substances for IED purposes
- **Example 1**: systematic assessment of SDS (Region Marche IT) electronic database is used for assessment of SDS submitted by manufacturer / downstream user / importer or generally the operator
- Negative result is noted in the database in paranthesis below the name of the supplier → all involved parties know that something is not o.k.
- Growing content of database – growing benefit for authorities
- Needed is expertise in chemical legislation and capacity
- Establishment of expert team for this task

1. SDS - Assessment Tool (Region Marche IT)

	description	legislation	evaluation
supplier	Supplier of the SDS		
From outside EU	yes/no		
name	Name of product		
use	Use of product (e.g. lubrificant)		
department	e.g. foundry		
…..			
SDS compliant	Yes / no		
notes	Reason for negative judgement		
Actions to be taken	e.g. request for updated SDS		

Example 2: flowsheet → worktool (NO)



Example 2: Flowsheet - explanation

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- **Action 1:** identification of relevant chemicals
- **Action 2:** identification where chemicals end up
- **Action 3:** identification of requirements in legislation
- **Action 4:** evaluation of the application → setting ELVs, specific conditions, requirements cóncerning waste

- an electronic tool has been developed, the flow sheet is linked to relevant databases
- It is used by all relevant parties: IED permit writers and inspectors, REACH authorities and competent authority for work safety.
- All these authorities have access to a database with the information on the companies (permits, inspection reports etc.)
- The tool will be explained in detail in the final report of the IMPEL project „Linking the Directive on Industrial Emissions (IED) and REACH Regulation (II)“

Comments

- the integrated approach of the IED requires close cooperation of different authorities
- both REACH and IED are very complex
- IED authorities still learn how to deal with REACH requirements in their daily work
- the authorities use different approaches
- guidance and tools should be provided for supporting authorities and streamlining procedures


Thank you for your attention.