ENIRONMENT 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
**Project summary**

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

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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, belgium).

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 “
Results to be achieved

**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.
**ECRAN Structure**

ECRAN Ministerial Meetings (political level)
ECRAN Steering Committee Meetings (technical level)

**ENVIRONMENT**
- Strategic planning and investments
- Approximation of environmental legislation and the accession negotiations

**CLIMATE ACTION**
- Climate Coordination Group

Public participation – NGOs Environment Forum

Cross-cutting activities
- Enforcement and compliance
- Progress Monitoring Exercise
- Legislative compliance checks
- Handbook on the Implementation of EU Climate Acquis

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### Planned activities

<table>
<thead>
<tr>
<th>EF Public Participation:</th>
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<tbody>
<tr>
<td>✓ Creation of regional Environment Forum with selected NGOs (minimum 1 and maximum 3 NGOs per country);</td>
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<td>✓ Organisation of annual meetings with the EC;</td>
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<td>✓ Design and delivery of tailor made training programme.</td>
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<tr>
<th>Enforcement and Compliance (ECENA):</th>
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<tr>
<td>✓ 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);</td>
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<tr>
<td>✓ External country assessments on the implementation and enforcement of the selected EU acquis in the country,</td>
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<tr>
<td>✓ Coordination and cooperation with other relevant networks (IMPEL, INECE, Interpol, etc.).</td>
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**Enhanced** public participation in environmental and climate planning and decisionmaking process

**Improved** skills in relation to enforcement of the legislation
**Planned activities**

- **Progress Monitoring:**
  - Tables of Concordance, Implementation Questionnaires and preparation of draft and final PM Reports for the years 17, 18 and 19;
  - Legislative compliance checks (legal assistance 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 and climate acquis

**Improved** institutional set-up and technical working arrangements established
Planned activities

- 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.
Planned activities

- **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 tariff settings in cooperation with the Strategic Planning and Investments Working Group;
  - Capacity building on the implementation and differences 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 and climate acquis; **Experience-sharing** and networking activities established.

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Planned activities

- 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 and climate acquis; Experience-sharing and networking activities established.
Planned activities

- 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.
Practical arrangements

**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

Website (www.ecranetwork.org)
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.
<table>
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<tr>
<th>No.</th>
<th>Date</th>
<th>Key outputs</th>
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<tbody>
<tr>
<td>1</td>
<td>end-January 2014/early February 2014</td>
<td>Training Needs Questionnaire and Training Needs Assessment. Proposals for pilot industries to be visited. TNA report</td>
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<tr>
<td>2</td>
<td>January - February 2014</td>
<td>Training Methodology, Training Programme and Training Materials</td>
</tr>
<tr>
<td>3</td>
<td>Training Workshop no. 1. Early May, 2014 13,14,15 May</td>
<td>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</td>
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<tr>
<td>4</td>
<td>Training Workshop 2,3,4 December 2014</td>
<td>Training (2). Procedures REACH/CLP (2). Training Report Tirana with site visit.</td>
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</table>
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 reports can be accessed through the Publication link in the Support section.
Thank you for your attention
General Introduction on REACH Regulation

Ike van der Putte
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

Scope:
- substances, in preparations, in certain articles
- mandatory data tonnage dependent
- Chemical safety report (> 10 tonnes)
- Safety data sheet

Main elements of REACH

Registration of all substances

Authorisation of certain hazardous substances

Restrictions for substances of concern

Evaluation by competent authorities
The registration process

- Who?
- What?
- When?
- How?
Registration: general

AIM:

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

Registration Dossier = Documentation

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

No formal acceptance - industry retains responsibility
Who Has to Register?

- EU Manufacturers & importers if they manufacture or import > 1 ton/ year of a substance:
  - as defined in Article 3 (1)
  - unless exempted from the registration scope (Article 2, Annexes IV and V)
  - irrespective of whether they are classified as dangerous or not

- Importers and Producers of articles (conditions of Article 7).
  - Intended release of substances only

- Manufactures of substances outside the EU may appoint an “only representative” to fulfil their REACH obligations.
  - “Only representative” relieves importers of their duties.
  - Importers are then considered DUs.
What Must Be Registered?

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

Are substances in articles to be registered?

Only if:
- the substances are intended to be released from the produced or imported article during normal/ reasonable foreseeable conditions of use, AND
- the total amount of the substance present in the articles with intended releases produced and/or imported by that actor exceeds 1 tonne per year per producer or importer
- The substance has not yet been registered for that specific use
Registration

And what if there is no intended release?

In that case there are no registration obligations.

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

If the first two criteria are met, the manufacturer/importer has to inform:
- the (professional) recipients without delay about the substance and the safe use
- on request, his customers within 45 working days (free of charge)
Registration – when?

1 June 2008

Deadlines for registration of phase in substances

- ≥1000 tonnes CMRs (≥1 tonne) very toxic to aquatic organisms (R50/53) (≥100 tonnes)
- 100-1000 tonnes
- 1-100 tonnes
- Non 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

Classification, labelling and packaging (CLP)

Registration, authorisation and restriction (REACH)

Substances in IED permitting and inspection

Prevention of emissions into air

Protection of national heritage

Nature protection

Avoidance of hazardous waste

Soil protection

Prevention of emissions to surface water / ground water (WFD)

Work safety
REACH Specifics
Roles & Responsibility

Outline:
A: Short refreshment on REACH
B: Roles in REACH
C: Responsibility at each role

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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

Restriction measures for substances of concern

Authorization of certain hazardous substances

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

Scope:
- manufacturers, importers, professional users
- substances, in preparations, in certain articles
- mandatory data tonnage dependent
- Chemical safety report
- Safety data sheet

Scope:
- carcinogenic, mutagenic, reprotoxic substances (CMR-substances)
- Endocrine disruptors
- Persistent Organic Pollutants (POPs)
- Persistent bioaccumulating toxic substances (PBTs or vPvBs)
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 \( \cong \) existing substances
  – Non phase-in \( \cong \) 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 foreseeable 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

- Risk reduction measures on site being implemented

- Proposal for additional testing (if > trigger level)

- Proposal C&L

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

- 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

• 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

**Manufacturer/Importer (M/I)**
- Data collection
- Risk Assessment
- Risk Reduction Strategy
- MSDS
- C&L proposal
- If applic. proposal “additional testing”

**Registration**

**Registration-database**

**Evaluation**

**Authorisation**

**Restriction measures**

**Downstream user (DU)**
- Exposure/Emission data
- Risk Assessment
- Risk Reduction Strategy
- If applic. MSDS product
- If applic. C&L preparation

**Industry**

**Authorities**
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

Commission → Agency → Industry

EU Member States

Competent authority
Enforcement authorities
Experts
Representatives

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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
REACH Specifics
Roles & Responsibility

Case studies
A: Clarifications
B: Case studies

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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

Outsde EU

Manufacturer 1

Manufacturer 2

Manufacturer 3

Appoint as OR

3t

5t

3t

5t

3t

EU

Importer 1

Importer 2

Importer 3

Importer 4

Distributor 4

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

Non EU
- Mixture AB
- Subst. Y

EU
- Mixture YZ
- Subst. X

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

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

Article C
- Subst. D
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

Outside EU

- Mixture VZ
- Non-EU Formulator D
- Mixture VZXY

EU

- Manufacturer A
  - Subst. X
  - Formulator C
- Manufacturer B
  - Subst. Y
- Importer E
  - Mixture VZXY
- Mixture XY

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
Exercise

Outside EU

- **Subst. X** 60t
- **Subst. Y** 60t

  - **Mixture XY** 60t + 60t

    - **Non-EU Formulator D**
      - **Mixture XY** 100t + 100t

EU

- **Manufacturer A**
  - **Subst. X** 40t

- **Manufacturer B**
  - **Subst. Y** 40t

  - **Formulator C**
    - **Mixture XY** 40t + 40t

    - **Importer E**
      - **Mixture XY** 100t + 100t

Registration obligations

- **Manufacturer A** registers 40t X and 40t Y.
- **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
REACH Specifics – Helpdesk

Awareness and info dissemination

Shufan Keetlaer-Qi
Overview

*Helpdesks under REACH and CLP*

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

Scope
• no company specific advice
• ”WHAT” not ”HOW”
• no consultancy
Annual statistics of CLP and REACH
NHD’s activities 2013

Received by national helpdesks (28 MSs, Iceland, Liechtenstein, Norway, Serbia and Turkey)
Activities of national helpdesk besides replying to questions
Involvement of national helpdesk staff in activities and network of ECHA and the EC
Involvement of national helpdesk staff in international activities in 2013
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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Project implemented by Human Dynamics Consortium
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)
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.
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

Agency

Committees (MSC, RAC, SEAC)

Support to helpdesks
- Q&A database
- FAQ document

Agency “helpdesk”

Network
- Helpdesk exchange forum (IT based)
- Correspondents network

Agency acting as focal point

Stakeholder helpdesks

MS helpdesk

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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
National helpdesks contact details

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

Luxembourg

Malta

Netherlands

BPR helpdesk
CIGB - College voor de toelating van gewasbeschermingsmiddelen en biociden
Stadsbrink 5, 6707 AA Wageningen
Telephone: +31 0 317 47 18 10
Email: helpdesk (at) cigb.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

Ministry of Infrastructure and Environment

Policy, legal provisions

Trade organisations
Companies
Municipalities, Provinces, Police, Waterboards, Inspectorates

REACH Helpdesk

ADVISE

Awareness raising
Answering questions
Position of Dutch CLP Helpdesk

Ministry of Health, Welfare and Sport

Policy, legal provisions

Advice

CLP Helpdesk

Awareness raising
Answering questions

Trade organisations
Companies
Municipalities, Provinces, Police, Waterboards, Inspectorates
Organisation

Level 1:
Telephone operator

Level 2:
Specialist, daily shift

Level 3:
Expert, consultation for specialists.

Top desk information management system

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

Products

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

75% of the questions concern:

- Labelling
- Classification in general (translation)
- Information campaign
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
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
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
Discussion
• What will be the role and tasks of the REACH and CLP helpdesks in your country?
• Who are the customers of the REACH and CLP helpdesk in your country?
• What are the products in your country which can be relevant for REACH?
Enforcement of the REACH and CLP Regulations in EU Member States

Ike van der Putte
PART 2 Practical Consequences
REACH Enforcement
REACH Organisation

- COMMISSION
- AGENCY
- INDUSTRY
- EU MS
- Competent Authority
  - Inspection
  - Experts
  - Representative

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## Registration & Testing Costs

REACH Regulation (1907/2006)

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

* Excluding Chemical Safety Report

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

*** Average costs
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
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
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.
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

1. Legislation
2. Not. C&L, SDS, Permit
3. Implementation
4. Enforcement
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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.
Lessons learned
Past initiative Chemicals Legislation - Notification

**NONS**
- 4000 substances
  - 305 not identified
  - 163 existing
  - 142 new
  - 53 not notified

**SENSE**
- 1905 substances
  - 100 not identified
  - 1572 existing
  - 233 new
  - 11 not notified
Lessons learned
Past initiative Chemicals Legislation – C&L and MSDS

SENSE Project

Labelling

1805 substances
513 (28%) correctly labelled

Classification

1905 substances
1252 MSDS available
1004 correct
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
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
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
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
Inspection – An impression of the field work
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
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
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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Project implemented by Human Dynamics Consortium
CHECKLIST FOR THE INSPECTIONS 4

Former Chemicals legislation

Preparation of the inspection

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
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
## Time needed per company inspection 2

<table>
<thead>
<tr>
<th>Country</th>
<th>Time needed per inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium, Denmark, Finland, Netherlands, Sweden</td>
<td>Less than 3 days</td>
</tr>
<tr>
<td>Germany, Greece, Italy, Norway, United Kingdom</td>
<td>3 - 9 days</td>
</tr>
<tr>
<td>Austria, France, Ireland, Portugal, Spain</td>
<td>More than 9 days</td>
</tr>
</tbody>
</table>
## Competent authorities (CA) and enforcement authorities (EA) chemicals legislation

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

This Project is funded by the European Union

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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
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 substance (＞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
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
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
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 between the 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 = REACH Information Portal for Enforcement; October 2011 vs 1.1 released
REACH Enforcement in UK

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.**
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.
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
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.
Results of the Forum coordinated REACH enforcement project on registration, pre-registration 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.
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 imported.
Background

The project was carried out by 29 Member States 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.
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.
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.
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...
  - Territory - country / region
  - Authority and legal instrument
Aims and Objectives

• To get information / basic knowledge about chemicals on the market:
  – imported
  – manufactured
  – used

• for legal purpose
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)
Chemicals inventory relevance

- 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.
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
<table>
<thead>
<tr>
<th>Original Name</th>
<th>HPVC OECD</th>
<th>EU Prior</th>
<th>EHC</th>
<th>IRIS</th>
<th>Haz Environ</th>
<th>Endo Dis</th>
<th>WFD</th>
<th>CMR</th>
<th>PBT</th>
<th>PT</th>
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<td>ethanol; ethyl alcohol</td>
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</table>
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
Implementation **Tools** of Regulation 793/93

1. Data Collection

**HEDSET**

**IUCLID**
Implementation **Tools** of Regulation 793/93

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

2. **Priority Setting**: EURAM
   EU Ranking Method
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
This Project is funded by the European Union

EURAM - Programme
EU Risk Ranking Method

Ranking of all Substances in IUCLID ordered by degree of potential adverse effects

Comments by Competent Authorities and Industry

Expert Judgement Stage creates adjusted Ranking

Commission Proposal for Priority List, Discussion with Member States, OECD, Industry

Meeting for Final Decision, Publication in Official Journal

1st Priority List
2nd Priority List
3rd Priority List
4th Priority List

Project implemented by Human Dynamics Consortium
Priority Setting Existing Substances EU before REACH

140 Priority Substances

> 2000 HPVCs

> 100,000 EINECS substances
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 ongoing = legal issues are taken through an import/export)
Safety Data Sheets as communication instrument

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

Arnold van der Wielen
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

This Project is funded by the European Union
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"

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

Means in this context, that it is not sufficient to simply offer the SDS via the Internet!

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

1. Check SDS/ES
   - Use covered?
     - yes: Comply with ES?
       - yes: Okay
       - no: Make use/use conditions known to supplier
     - no: identify alternative suppliers

2. Comply with ES?
   - yes: Implement supplier’s ES
   - no: Conditions in place to meet at least supplier’s ES

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Project implemented by Human Dynamics Consortium
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:

- Section 2 Hazards identification
- Section 9 Physical and Chemical properties
- Section 3 Composition/information on ingredients
- Section 10 Stability and Reactivity
- Section 11 Toxicological information
- Section 12 Ecological information
SDS sections 14 & 15 needs to be checked for consistency with the following sections:

- Section 9 Physical and Chemical properties
- Section 11 Toxicological information
- Section 12 Ecological information
- Section 15 Regulatory information

Section 14 Transport information
THANKS FOR YOUR ATTENTION

QUESTIONS?
Controlling SDS
Experience in practise

NL project in 2013 in supply chain working with organic solvents

Arnold van der Wielen
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 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 2nd 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)

- No SDS was completely correct
- In national language (in Dutch)
- Sector 1 (Identity product, supplier)
- Sector 2 (Hazard identification)
- Sector 3 (Composition, ingredients)
- Sector 8 (Exposure control/personal protection)
- Sector 15 (Regulatory information)
- Sector 16 (Other information)
- Classification
- Labelling

**Compliance:**

- 0%
- 95%
- 20%
- 33%
- 15%
- 33%
- 50%
- 5%
- 60%
- 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 2\textsuperscript{nd} phase (12 of 50 companies)

- No SDS was completely correct
- In national language (in Dutch)
- Sector 1 (Identity product, supplier)
  - Sector 2 (Hazard identification)
  - Sector 3 (Composition, ingredients)
  - Sector 8 (Exposure control/personal protection)
  - Sector 15 (Regulatory information)
  - Sector 16 (Other information)
- Classification
- Labelling

Compliance:
- 0%
- 95%
- 20%
- 10%
- 0%
- 50%
- 5%
- 60%
- 30%

Remarkably 33% deviant from 15% 1\textsuperscript{st} phase 33%

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

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Project implemented by Human Dynamics Consortium
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 1\textsuperscript{st} 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 1\textsuperscript{st} 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 abbreviations
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 shortcomings 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
Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED

Basic Toxicology / Ecotoxicology

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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
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
• **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
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.
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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Project implemented by Human Dynamics Consortium
Toxicology and Ecotoxicology are similar but not identical.

**Toxicology**

- Absorption
- Distribution
- Metabolism
- Elimination

**Ecotoxicology**

- Release into the environment
- Fate and Disposition
- Metabolism
- No counterpart!

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Tox / Ecotox

**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)
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.
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
This Project is funded by the European Union

Ecotoxicology

Terrestrial

Aquatic
BASE SET REQUIREMENT

ACUTE TOXICITY  LC50

Fish

Algae

Daphnia:
CHEMICALS: Major Types of Toxicity
Dose-Response Curves

- Dose-response
- Nonthreshold
- Threshold

Figure 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
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.
Transport & Fate

- 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

This Project is funded by the European Union

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Chemicals behaviour

• 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)
Fate in the environmental compartments - models

- Donald Mackay

**EQC Model v. 1.0**

**Level I**

**Chemical: Dichlorovos**

- *Air*
  - 698 kg (0.698 %)
  - 6,978 ng/m²

- *Soil*
  - 3023 kg (3.023 %)
  - 0.140 ng/g
  - Fugacity = 0.077 μPa
  - Total Mass = 100000 kg

- *Water*
  - 96210 kg (96.2 %)
  - 481 ng/L

- *Sediment*
  - 67.2 kg (0.067 %)
  - 0.280 ng/g

- *Suspended Sediment*
  - 2,099 kg (2.10e-3 %)
  - 1,400 ng/g

- *Fish*
  - 0.171 kg (1.71e-4 %)
  - 0.853 ng/g

Legend:

- EQUILIBRIUM
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
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.
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
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
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.
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 of significant impurities, presence and amounts of additives, and n-octanol/water partition coefficient) should be taken into consideration in both the planning of the test and interpretation of the results.
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.
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 chambers, the chemical under test being transported with the water used to renew the test medium.
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, 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.
<table>
<thead>
<tr>
<th>Recommended species</th>
<th>Recommended range of test temperature (°C)</th>
<th>Recommended total length of test animal (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Brachydanyio rerio</em> (<em>Teleostei, Cyprinidae</em>) (Hamilton-Buchanan) Zebrab-fish</td>
<td>20 to 24</td>
<td>3.0 ± 0.5</td>
</tr>
<tr>
<td><em>Pimephales promelas</em> (<em>Teleostei, Cyprinidae</em>) (Rafinesque) Fathead minnow</td>
<td>20 to 24</td>
<td>5.0 ± 2.5</td>
</tr>
<tr>
<td><em>Cyprinus carpio</em> (<em>Teleostei, Cyprinidae</em>) (Linnaeus 1758) Common carp</td>
<td>20 to 24</td>
<td>6.0 ± 2.0</td>
</tr>
<tr>
<td><em>Oryzias latipes</em> (<em>Teleostei, Poeciliidae</em>) Cyprinodontidae (Tomminck and Schlegle 1850) Red killifish</td>
<td>20 to 24</td>
<td>3.0 ± 1.0</td>
</tr>
<tr>
<td><em>Poecilia reticulata</em> (<em>Teleostei, Poeciliidae</em>) (Peters 1859) Guppy</td>
<td>20 to 24</td>
<td>3.0 ± 1.0</td>
</tr>
<tr>
<td><em>Lepomis macrochirus</em> (<em>Teleostei, Centrarchidae</em>) (Rafinesque Linnaeus 1758) Bluegill</td>
<td>20 to 24</td>
<td>5.0 ± 2.0</td>
</tr>
<tr>
<td><em>Onchorhynchus mykiss</em> (<em>Teleostei, Salmonidae</em>) (Walbaum 1988) Rainbow trout</td>
<td>12 to 17</td>
<td>6.0 ± 2.0</td>
</tr>
<tr>
<td><em>Leuciscus idus</em> (<em>Teleostei, Cyprinidae</em>) (Linnaeus 1758) Golden Orfe</td>
<td>20 to 24</td>
<td>6.0 ± 2.0</td>
</tr>
</tbody>
</table>
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 of significant impurities, presence and amounts of additives, and n-octanol/water partition coefficient) should be taken into consideration in both the planning of the test and interpretation of the results.
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 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.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.
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 of significant impurities, presence and amounts of additives, and n-octanol/water partition coefficient) should be taken into consideration in both the planning of the test and interpretation of the results.
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.
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.
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. 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,
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

<table>
<thead>
<tr>
<th>Test</th>
<th>Analytical Method</th>
<th>suitability for substances which are:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>poorly soluble</td>
</tr>
<tr>
<td>DOC Die-Away</td>
<td>Dissolved organic carbon</td>
<td>-</td>
</tr>
<tr>
<td>Mod. OECD Die-Away</td>
<td>Dissolved organic carbon</td>
<td>-</td>
</tr>
<tr>
<td>CO₂ Evolution</td>
<td>Respirometry: CO₂ evolution</td>
<td>+</td>
</tr>
<tr>
<td>Manometric Respirometry</td>
<td>Manometric respirometry: oxygen consumption</td>
<td>+</td>
</tr>
<tr>
<td>Closed Bottle</td>
<td>Respirometry: dissolved oxygen</td>
<td>+/−</td>
</tr>
<tr>
<td>MITI</td>
<td>Respirometry: oxygen consumption</td>
<td>+</td>
</tr>
<tr>
<td>Test</td>
<td>DOC Die-Away</td>
<td>CO₂Evolution</td>
</tr>
<tr>
<td>------</td>
<td>--------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Concentration of Test Substance as mg/l</td>
<td>10-40</td>
<td>10-20</td>
</tr>
<tr>
<td>mg DOC/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mg ThOD/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concentration of Inoculum (in cells/l, approximatively)</td>
<td>≤ 30 mg/l SS or ≤ 100 ml effluent/l (10^7-10^8)</td>
<td>0,5 ml secondary effluent/l (10^5)</td>
</tr>
<tr>
<td>Concentration of elements in mineral medium (in mg/l)</td>
<td>P</td>
<td>116</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>1,3</td>
</tr>
<tr>
<td></td>
<td>Na</td>
<td>86</td>
</tr>
<tr>
<td></td>
<td>K</td>
<td>122</td>
</tr>
<tr>
<td></td>
<td>Mg</td>
<td>2,2</td>
</tr>
<tr>
<td></td>
<td>Ca</td>
<td>9,9</td>
</tr>
<tr>
<td></td>
<td>Fe</td>
<td>0,05-0,1</td>
</tr>
<tr>
<td>pH</td>
<td>7,4 ± 0,2</td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>22 ± 2 °C</td>
<td></td>
</tr>
</tbody>
</table>

**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. If either of these conditions is not met, the test should be repeated.

- 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.
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.
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;
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.
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.
Intermittent 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.

PEC\textsubscript{local} 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, PEC\textsubscript{regional} is calculated using the annual release rate. It represents the steady-state concentration to be expected, regardless of when the discharge occurred.
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.
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).
Table 16  Assessment factors to derive a PNEC<sub>aquatic</sub>

<table>
<thead>
<tr>
<th>Available data</th>
<th>Assessment factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one short-term L(E)C50 from each of three trophic levels of the base-set (fish, Daphnia and algae)</td>
<td>1000 &lt;sup&gt;a)&lt;/sup&gt;</td>
</tr>
<tr>
<td>One long-term NOEC (either fish or Daphnia)</td>
<td>100 &lt;sup&gt;b)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)</td>
<td>50 &lt;sup&gt;c)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels</td>
<td>10 &lt;sup&gt;d)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Species sensitivity distribution (SSD) method</td>
<td>5-1</td>
</tr>
<tr>
<td>(to be fully justified case by case)</td>
<td></td>
</tr>
<tr>
<td>Field data or model ecosystems</td>
<td>Reviewed on a case by case basis &lt;sup&gt;f)&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
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.
## Effects Assessment for Microorganisms

### Table 17 Test systems for derivation of PNEC\textsubscript{microorganisms}

<table>
<thead>
<tr>
<th>Test</th>
<th>Available value</th>
<th>Assessment factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiration inhibition tests</td>
<td>NOEC or EC10</td>
<td>10</td>
</tr>
<tr>
<td>EU Annex V C.11; OECD 209 (1984f) ISO 8192 (1986)</td>
<td>EC50</td>
<td>100</td>
</tr>
<tr>
<td><strong>Inhibition control in standardised biodegradation tests</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Ready biodegradability tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Inherent biodegradability tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhibition of nitrification</td>
<td>NOEC or EC10</td>
<td>1</td>
</tr>
<tr>
<td>ISO-9509 (1989)</td>
<td>EC50</td>
<td>10</td>
</tr>
<tr>
<td>Ciliate growth inhibition tests</td>
<td>NOEC or EC10</td>
<td>1</td>
</tr>
<tr>
<td>(preferably with <em>Tetrahymena</em>, cf. OECD, 1998a) ¹)</td>
<td>EC50</td>
<td>10</td>
</tr>
<tr>
<td>Activated sludge growth inhibition tests</td>
<td>NOEC or EC10</td>
<td>10</td>
</tr>
<tr>
<td>ISO-15522</td>
<td>EC50</td>
<td>100</td>
</tr>
</tbody>
</table>
## Effects Assessment for Microorganisms in Sewage Treatment Plants (STP)

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

### 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.
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.
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 downstream consequences)
• To communicate information using the safety data sheet according to REACH
This Project is funded by the European Union

Project implemented by Human Dynamics Consortium

---

**Hazard Assessment**

- Gather and share existing information
- Consider information needs
- Identify information gaps
- Generate new data/propose testing strategy

**Exposure Assessment**

- Gather existing information on uses, conditions of use, emissions and exposure
- Consider information needs

---

**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

---

6. Control of Risks?

- 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)

---

7. Revise Hazard Information

7. Revise conditions of use or exposure information or scope of ES
Environmental Hazard / Risk Assessment – Case Study

Goal of the Case Study is brief practical introduction into a process of "Generic Risk Assessment".

Tasks:
1. Classify chemical substances (caprolactam, 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 (RQ).
6. Make proposals for future factory production / limitations - RMMs.

WWW.ekotox.sk
E-mail: ekotox@ekotox.sk
Tel/Fax: (02) 45943712/45945223
Tomášikova 10F, 821 03 Bratislava
Ekotoxikologické centrum Bratislava s.r.o.

Martin Murník, MSc.

CASE STUDY

Environmental Classification & Hazard Assessment
Results

Environmental Hazard / Risk Assessment – Case Study

Existing production

Caprolactame

Classification GHS Pictogram

Signal Word

Hazard Statement

Effects assessment

PNEC

Exposure assessment

Endangered compartments

PEC – aquatic environment

Risk Quotients RQ

Proposals / comments:

Diphenylamine

PEC – aquatic environment

Proposals / comments:

Dioctylphthalate

PEC – aquatic environment

Proposals / comments:
### Estimates for the emission factors (fractions released)

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Emmision factors to:</th>
<th>Solubility (mg/l)</th>
<th>Vap. (Pa)</th>
<th>Air</th>
<th>Waste water</th>
<th>Soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 100</td>
<td>≤ 1</td>
<td>&lt; 100</td>
<td>&lt; 100</td>
<td>0.65</td>
<td>0.25</td>
<td>0.0005</td>
</tr>
<tr>
<td>100 – 1000</td>
<td>≥ 1</td>
<td>100 – 1000</td>
<td>100 – 1000</td>
<td>0.80</td>
<td>0.10</td>
<td>0.0025</td>
</tr>
<tr>
<td>≥ 1 000</td>
<td>&gt; 1</td>
<td>≥ 1 000</td>
<td>≥ 1 000</td>
<td>0.95</td>
<td>0.05</td>
<td>0.001</td>
</tr>
<tr>
<td>&lt; 100</td>
<td>≤ 1</td>
<td>&lt; 100</td>
<td>&lt; 100</td>
<td>0.40</td>
<td>0.50</td>
<td>0.005</td>
</tr>
<tr>
<td>100 – 1000</td>
<td>≥ 1</td>
<td>100 – 1000</td>
<td>100 – 1000</td>
<td>0.55</td>
<td>0.35</td>
<td>0.0025</td>
</tr>
<tr>
<td>≥ 1 000</td>
<td>&gt; 1</td>
<td>≥ 1 000</td>
<td>≥ 1 000</td>
<td>0.65</td>
<td>0.25</td>
<td>0.001</td>
</tr>
<tr>
<td>&lt; 100</td>
<td>≤ 1</td>
<td>&lt; 100</td>
<td>&lt; 100</td>
<td>0.25</td>
<td>0.65</td>
<td>0.005</td>
</tr>
<tr>
<td>100 – 1000</td>
<td>≥ 1</td>
<td>100 – 1000</td>
<td>100 – 1000</td>
<td>0.35</td>
<td>0.55</td>
<td>0.0025</td>
</tr>
<tr>
<td>≥ 1 000</td>
<td>&gt; 1</td>
<td>≥ 1 000</td>
<td>≥ 1 000</td>
<td>0.50</td>
<td>0.40</td>
<td>0.001</td>
</tr>
<tr>
<td>≥ 10 000</td>
<td>&lt; 1</td>
<td>≥ 10 000</td>
<td>≥ 10 000</td>
<td>0.05</td>
<td>0.85</td>
<td>0.005</td>
</tr>
<tr>
<td>100 – 1000</td>
<td>≥ 1</td>
<td>100 – 1000</td>
<td>100 – 1000</td>
<td>0.10</td>
<td>0.80</td>
<td>0.0025</td>
</tr>
</tbody>
</table>

### Overall emissions concerning production volume:

- < 1000 per annum – 0.02 – 0.002
- > 1000 per annum – 0.002 – 0.0005

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

- **Affinity**
  - **WATER**
  - **AIR**
  - **SOIL**
  - **PLANT BIOTA**
  - **ANIMAL BIOTA**

<table>
<thead>
<tr>
<th>S</th>
<th>Affinity</th>
<th>H</th>
<th>log Koc</th>
<th>log Kow</th>
<th>log Koa</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>High</td>
<td>&gt; 10</td>
<td>&gt; 10</td>
<td>&gt; 5</td>
<td>&gt; 5</td>
</tr>
<tr>
<td>M</td>
<td>Medium high</td>
<td>10 – 100</td>
<td>10 – 10</td>
<td>5 – 4</td>
<td>5 – 3.5</td>
</tr>
<tr>
<td>L</td>
<td>Medium low</td>
<td>100 – 10</td>
<td>10 – 10</td>
<td>4 – 2</td>
<td>3 – 1.5</td>
</tr>
<tr>
<td>LL</td>
<td>Low</td>
<td>&lt; 100</td>
<td>&lt; 100</td>
<td>&lt; 1</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

### Units recalculation

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

---

### P-CHE Tables
Formalised criteria (simplified scheme) for classification of chemical substances

Valid only for the aquatic environment

<table>
<thead>
<tr>
<th>aquatic environment (adverse effects in the aquatic environment)</th>
<th>F, D, A: Fish, Daphnia, Algae</th>
<th>Sw = water solubility.</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>+</td>
<td>I &gt; 10-100 and</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>I &gt; 1-10 and</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>I &gt;</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>S = water solubility.</td>
</tr>
</tbody>
</table>

Formalised criteria (simplified scheme) for classification of chemical substances

Ekotoxikologické centrum Bratislava s.r.o.

REACH Course

ERAs Case Study
Classification categories for hazardous to the aquatic environment


of 16 December 2008

Acute (short-term) aquatic hazard

**Acute Category 1 (Note 1)**

96 hr LC₅₀ (for fish) \(\leq 1\) mg/l and/or
48 hr EC₅₀ (for crustacea) \(\leq 1\) mg/l and/or
72 or 96 hr ErC₅₀ (for algae or other aquatic plants) \(\leq 1\) mg/l. (Note 2)

**Acute Category 2**

96 hr LC₅₀ (for fish) > 1 to \(\leq 10\) mg/l and/or
48 hr EC₅₀ (for crustacea) > 1 to \(\leq 10\) mg/l and/or
72 or 96 hr ErC₅₀ (for algae or other aquatic plants) > 1 to \(\leq 10\) mg/l (Note 2)

**Acute Category 3**

96 hr LC₅₀ (for fish) > 10 to \(\leq 100\) mg/l and/or
48 hr EC₅₀ (for crustacea) > 10 to \(\leq 100\) mg/l and/or
72 or 96 hr ErC₅₀ (for algae or other aquatic plants) > 10 to \(\leq 100\) mg/l (Note 2)

**Chronic Category 1 (Note 1)**

and the substance is not rapidly degradable and/or the experimentally determined BCF > \(500\) (or if absent, the log Kow \(\geq 4\)). Indicate a potential to bioaccumulate.

**Chronic Category 2**

96 hr LC₅₀ (for fish) > 1 to \(\leq 10\) mg/l and/or
48 hr EC₅₀ (for crustacea) > 1 to \(\leq 10\) mg/l and/or
72 or 96 hr ErC₅₀ (for algae or other aquatic plants) > 1 to \(\leq 10\) mg/l (Note 2)

**Chronic Category 3**

96 hr LC₅₀ (for fish) > 10 to \(\leq 100\) mg/l and/or
48 hr EC₅₀ (for crustacea) > 10 to \(\leq 100\) mg/l and/or
72 or 96 hr ErC₅₀ (for algae or other aquatic plants) > 10 to \(\leq 100\) mg/l (Note 2)

**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 or reliably determined chronic NOECs (Note 3), and which are not rapidly degradable and have an experimentally determined BCF > \(500\) (or if absent, a log Kow \(\geq 4\)), 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.

**Safety net classification**

When classifying substances, the appropriate M-factor (see Table 5.1.3) must be indicated. When classifying substances, the appropriate M-factor (see Table 5.1.3) must be indicated. When classifying substances, the appropriate M-factor (see Table 5.1.3) must be indicated. When classifying substances, the appropriate M-factor (see Table 5.1.3) must be indicated. When classifying substances, the appropriate M-factor (see Table 5.1.3) must be indicated.

**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 5.1.3).

**Note 2**

Classification shall be based on the ErC₅₀ (growth rate). In circumstances where the ErC₅₀ is not specified or no ErC₅₀ is recorded, classification shall be based on the lowest EC₅₀ available.

**Note 3**

'No acute toxicity' is taken to mean that the LC₅₀ (s) is/are above the water solubility. Also for poorly soluble substances, where the acute test does not provide a true measure of the intrinsic toxicity.
**ECOLOGICAL STUDY**

**5.2 Water organisms 5.2.1 Short-term studies**

<table>
<thead>
<tr>
<th>Taxonomic Group</th>
<th>Species</th>
<th>Effect Parameter</th>
<th>Test Duration</th>
<th>Toxicity</th>
<th>Effect</th>
<th>Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Algae</strong></td>
<td>Selenastrum capric.</td>
<td>EC50 &gt; 0.1 mg/l</td>
<td>96 h</td>
<td>YES</td>
<td>LC50</td>
<td>&gt; 64 mg/l</td>
<td>24 h</td>
<td>[IUC132]</td>
</tr>
<tr>
<td><strong>Gymnodinium breve</strong></td>
<td>Gymnodinium breve</td>
<td>LC50 100 g/l</td>
<td>96 h</td>
<td>YES</td>
<td>EC50</td>
<td>&gt; 31 g/l</td>
<td>96 h</td>
<td>[IUC139]</td>
</tr>
</tbody>
</table>

**5.2.2 Long-term studies**

<table>
<thead>
<tr>
<th>Taxonomic Group</th>
<th>Species</th>
<th>Effect Parameter</th>
<th>Test Duration</th>
<th>Toxicity</th>
<th>Effect</th>
<th>Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Crustaceans</strong></td>
<td>Daphnia magna</td>
<td>LC50 &gt; 0.32 mg/l</td>
<td>96 h</td>
<td>YES</td>
<td>EC50</td>
<td>&gt; 64 mg/l</td>
<td>24 h</td>
<td>[IUC128]</td>
</tr>
<tr>
<td><strong>Daphnia magna</strong></td>
<td>Daphnia magna</td>
<td>LC50 9.4 mg/l</td>
<td>48 h</td>
<td>YES</td>
<td>EC50</td>
<td>&gt; 31 g/l</td>
<td>96 h</td>
<td>[IUC129]</td>
</tr>
</tbody>
</table>

**5.2.3 Hydrophobicity**

<table>
<thead>
<tr>
<th>Log Kow</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.60 [EPIWin v.2.0]</td>
<td>[IUC104]</td>
</tr>
</tbody>
</table>

**5.2.4 Biodiversity**

**5.2.5 Microorganisms**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 1400 mg/l</td>
<td>[IUC141]</td>
</tr>
<tr>
<td>LC0</td>
<td>100 mg/l</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>

**5.2.6 Soil organisms**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>= 0.32 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.32 mg/l</td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>

**5.2.7 Water environments 5.2.1 Short-term studies**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>= 0.3 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC130]</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
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</table>

**5.2.8 Hydrophobicity**

<table>
<thead>
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<th>Literature</th>
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<tbody>
<tr>
<td>6.00 [EPIWin v.2.0]</td>
<td>[IUC104]</td>
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</table>

**5.2.9 Biodiversity**

**5.2.10 Microorganisms**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
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<tr>
<td>LC0</td>
<td>100 mg/l</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>

**5.2.11 Soil organisms**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>= 0.32 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.32 mg/l</td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>

**5.2.12 Water environments 5.2.1 Short-term studies**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>= 0.3 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC130]</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>

**5.2.13 Hydrophobicity**

<table>
<thead>
<tr>
<th>Log Kow</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.00 [EPIWin v.2.0]</td>
<td>[IUC104]</td>
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</tbody>
</table>

**5.2.14 Biodiversity**

**5.2.15 Microorganisms**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
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<tr>
<td>LC0</td>
<td>100 mg/l</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>

**5.2.16 Soil organisms**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>= 0.32 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.32 mg/l</td>
<td></td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
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</tr>
</tbody>
</table>

**5.2.17 Water environments 5.2.1 Short-term studies**

<table>
<thead>
<tr>
<th>Effect Parameter</th>
<th>Effective Concentration</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>= 0.3 mg/l</td>
<td>[IUC126]</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC130]</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 0.3 mg/l</td>
<td>[IUC124]</td>
</tr>
</tbody>
</table>
### Ecotoxicological properties

**Caprolactame**

**Substance**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAS No.</strong></td>
<td>105-60-2</td>
</tr>
<tr>
<td><strong>EC No.</strong></td>
<td>203-313-2</td>
</tr>
<tr>
<td><strong>Formula</strong></td>
<td>C (<em>6)H (</em>{11})O</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>113.16 g/mol</td>
</tr>
<tr>
<td><strong>Melting point</strong></td>
<td>69 – 71 °C</td>
</tr>
<tr>
<td><strong>Boiling point</strong></td>
<td>270 °C</td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>820,000 mg/l</td>
</tr>
<tr>
<td><strong>Henry’s constant</strong></td>
<td>1.014 g/cm²·cm²/mmol</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>1.13 g/cm³</td>
</tr>
<tr>
<td><strong>pK(_{ow})</strong></td>
<td>-0.19</td>
</tr>
</tbody>
</table>

#### Ecotoxicological properties

**EC50 for Pseudomonas**
- EC10 = 1740 mg/l
- EC50 = 4200 mg/l

**EC50 for Scenedesmus subspicatus**
- EC50 = 130 mg/l

**EC50 for Daphnia magna**
- EC50 > 500 mg/l

**LC50 for Lepomis macrochirus**
- LC50 = 930 mg/l

**Bioaccumulation, BCF**
- Bioconcentration factor > 1

**Ready biodegradability**
- 82% (MITI I test)

**Bioadsorptive Coefficient**

<table>
<thead>
<tr>
<th>KC</th>
<th>NoEC</th>
<th>Toxicity, fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1000</td>
<td>Toxicity, crustations</td>
</tr>
<tr>
<td>1</td>
<td>0000</td>
<td>Toxicity, algae</td>
</tr>
</tbody>
</table>

**Soil Adsorptive Coefficient**

<table>
<thead>
<tr>
<th>KOC</th>
<th>Toxicity, crustations</th>
</tr>
</thead>
<tbody>
<tr>
<td>5735</td>
<td>Toxicity, algae</td>
</tr>
</tbody>
</table>

**EC50 for Pseudomonas**
- EC50 = 130 mg/l

**EC50 for Scenedesmus subspicatus**
- EC50 = 100 (14 days)

**Bioconcentration, BCF**
- Bioconcentration factor > 1

**Ready biodegradability**
- 82% (MITI I test)

**Bioadsorptive Coefficient**

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<td>5735</td>
<td>Toxicity, algae</td>
</tr>
</tbody>
</table>
Ecotoxicological properties

**Diphenylamine**

**Substance**

- CAS No.: 122-39-4
- EC No.: 204-539-4

**Formula**: C$_{12}$H$_{11}$N

**Molecular weight**: [g/mol] 169.22

**Boiling point**: [°C] 302

**Density**: [g/cm$^3$] 1.16 - 1.07 (20°C)

**Water solubility**: [mg/l] 0.06 - 0.10

**pK$_a$**: 3.5

**Henry's constant**: [atm × m$^3$/mol] 0.90 × 10$^{-6}$

**Bioaccumulation, BCF**:

- NOEC = 100 (Pseudomonas fluorescens)
- NOEC = 100 (Nitrosomonas sp.)
- Inhibition > 10 (saprophytic microflora)

**Biodegradability, MITI I**

0.08 – 1.4 (reaction product: carbazol)

**Bioaccumulation, BCF**:

- NOEC = 100 (Pseudomonas fluorescens)
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- NOEC = 100 (Pseudomonas fluorescens)
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**Ready biodegradability**: [%] 0

**Biodegradation half-life [days]**

- Photolysis, t$_{1/2}$: 0.08 – 1.4 (reaction product: carbazol)
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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)
- Calculation of PNEC (predicted no-effect concentration)
- Use of assessment factors
- Use of assessment factors
- Calculation of PEC (predicted environmental concentration)

Environmental risk calculation

HYPOTHETICAL CASE STUDY
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 downstream 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 fertilizers, plant protection 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 xyylene 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.

### Calculation of the predicted environmental concentration:
Dilution of a spilled quantity may be calculated by the equation:

\[ C_{\text{max}} = \frac{1.36 \times 10^{-4} \times M}{D} \]

Where:
- \( C_{\text{max}} \) = maximum concentration at some distance downstream in (mg/l)
- \( M \) = discharge quantity in kg
- \( D \) = dispersion coefficient in m²/s
- \( t \) = time in days

This simplification is derived from the Gaussian relationship:

\[ C_{\text{max}} (t) = \frac{\sqrt{\pi}}{4} \frac{D \cdot A \cdot e^{-kt}}{t} \]

The following parameter values were used:
- \( k = 0 \) (no degradation)
- \( A = 500 \) m²
- \( D = 50 \) m²/s = 432 \times 10^{-4} \) m²/day
- \( t = 0.8 \) days

\[ C_{\text{max}} = \frac{1.36 \times 10^{-4} \times M}{D} \]

\[ C_{\text{max}} = 0.45 \times 10^{-4} \]

Hydrological data:
- Time between Titu and Bucharest: 8.5 hours
- Discharge: 0.45 m³/s
- River width: 1 m
- Distance between discharge point and some distance downstream = 2.4 D³
- First order removal rate (l/day) = k
- Removal = e⁻ᵏᵗ
- Dilution by increased water quantity = d
- Discharge quantity in kg = M
- Maximum concentration at some distance downstream in (mg/l) = \( C_{\text{max}} (t) \)

\[ C_{\text{max}} (t) = \frac{\sqrt{\pi}}{4} \frac{D \cdot A \cdot e^{-kt}}{t} \]

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

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

**Conclusion:**

The risk coefficient calculated for the chemicals released shows that the risk is low, and the toxic effects on aquatic organisms are minimal.

**Deposit:**

The chemicals released into the river Dambovita may pose a risk to aquatic life and the surrounding ecosystem. It is important to monitor the river for any adverse effects and take necessary precautions to prevent future releases.
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 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:

<table>
<thead>
<tr>
<th>Available data</th>
<th>Assessment factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term PECs from at least three species (normally fish, Daphnia, algae)</td>
<td>1000</td>
</tr>
<tr>
<td>Two long-term PECs from species representing two trophic levels</td>
<td>100</td>
</tr>
<tr>
<td>One long-term PEC (either fish or Daphnia)</td>
<td>50</td>
</tr>
<tr>
<td>At least one short-term (EC50) from each of three trophic levels of the ecosystem</td>
<td>10</td>
</tr>
<tr>
<td>Field data or model ecosystems</td>
<td>Case by case</td>
</tr>
</tbody>
</table>

Apply the following classification is used:

Classification PEC/PNEC

Serious risk >10
Unacceptable risk 1-10
Acceptable risk 0.01-1
Negligible risk <0.01

4 Calculate the risk coefficient

The environmental risk of a substance can be estimated by the PEC/PNEC coefficient. The

PEC/PNEC = Ratio Lowest LC50 of NOEC and an selected assessment factor.
### Acute data for dibutylphthalate (CAS no. 84-74-2)

<table>
<thead>
<tr>
<th>Group</th>
<th>Species</th>
<th>Criterion</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Scenedesmus subsp.</td>
<td>EC50 (72 h)</td>
<td>1.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gymnodium breve</td>
<td>EC50 (96 h)</td>
<td>0.2 mg/l</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>LC50 (48 h)</td>
<td>3.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Artemia salina</td>
<td>LC50 (72 h)</td>
<td>1.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gammarus pseudolim.</td>
<td>LC50 (96 h)</td>
<td>2.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Nitocra spinipes</td>
<td>LC50 (96 h)</td>
<td>1.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Mysidopsis bahia</td>
<td>LC50 (96 h)</td>
<td>0.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Pimephales promelas</td>
<td>LC50 (96 h)</td>
<td>0.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Percina flavescens</td>
<td>LC50 (96 h)</td>
<td>0.46 mg/l</td>
</tr>
<tr>
<td></td>
<td>Lepomis macrochirus</td>
<td>LC50 (96 h)</td>
<td>1.6 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Oncorhynchus mykiss</td>
<td>LC50 (96 h)</td>
<td>0.8 mg/l</td>
</tr>
<tr>
<td>Other species</td>
<td>-</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Chronic data for dibutylphthalate

<table>
<thead>
<tr>
<th>Group</th>
<th>Species</th>
<th>Criterion</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Selenastrum capricorn.</td>
<td>NOEC (10 d)</td>
<td>0.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Dunaliella parva</td>
<td>NOEC (8 d)</td>
<td>0.2 mg/l</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>NOEC (10 d)</td>
<td>1.05 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gammarus pulex</td>
<td>NOEC (7 d)</td>
<td>0.10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Dugesia japonica</td>
<td>NOEC (5 d)</td>
<td>0.54 mg/l</td>
</tr>
<tr>
<td></td>
<td>Leptodora succincta</td>
<td>NOEC (5 d)</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Pimephales promelas</td>
<td>NOEC (5 d)</td>
<td>0.10 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Oncorhynchus mykiss</td>
<td>LC50 (99 d)</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td>Other species</td>
<td>-</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Acute data for xylene (CAS no. 1330-20-7)

<table>
<thead>
<tr>
<th>Group</th>
<th>Species</th>
<th>Criterion</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Cyclotella breve</td>
<td>EC50 (72 h)</td>
<td>2.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Oscillatoria sinensis</td>
<td>EC50 (72 h)</td>
<td>1.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gymnodium breve</td>
<td>EC50 (72 h)</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>EC50 (72 h)</td>
<td>1.5 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Oncorhynchus mykiss</td>
<td>LC50 (96 h)</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td>Other species</td>
<td>-</td>
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<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Species</th>
<th>Criterion</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Scenedesmus subsp.</td>
<td>EC50 (96 h)</td>
<td>1.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gymnodium breve</td>
<td>EC50 (96 h)</td>
<td>0.2 mg/l</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>LC50 (48 h)</td>
<td>3.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Artemia salina</td>
<td>LC50 (72 h)</td>
<td>1.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gammarus pseudolim.</td>
<td>LC50 (96 h)</td>
<td>2.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Nitocra spinipes</td>
<td>LC50 (96 h)</td>
<td>1.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Mysidopsis bahia</td>
<td>LC50 (96 h)</td>
<td>0.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Pimephales promelas</td>
<td>LC50 (96 h)</td>
<td>0.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Percina flavescens</td>
<td>LC50 (96 h)</td>
<td>0.46 mg/l</td>
</tr>
<tr>
<td></td>
<td>Lepomis macrochirus</td>
<td>LC50 (96 h)</td>
<td>1.6 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Oncorhynchus mykiss</td>
<td>LC50 (96 h)</td>
<td>0.8 mg/l</td>
</tr>
<tr>
<td>Other species</td>
<td>-</td>
<td></td>
<td></td>
</tr>
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</table>

Chronic data for dibutylphthalate are:

<table>
<thead>
<tr>
<th>Group</th>
<th>Species</th>
<th>Criterion</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Selenastrum capricorn.</td>
<td>NOEC (10 d)</td>
<td>0.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Dunaliella parva</td>
<td>NOEC (8 d)</td>
<td>0.2 mg/l</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>NOEC (10 d)</td>
<td>1.05 mg/l</td>
</tr>
<tr>
<td></td>
<td>Gammarus pulex</td>
<td>NOEC (7 d)</td>
<td>0.10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Dugesia japonica</td>
<td>NOEC (5 d)</td>
<td>0.54 mg/l</td>
</tr>
<tr>
<td></td>
<td>Leptodora succincta</td>
<td>NOEC (5 d)</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Pimephales promelas</td>
<td>NOEC (5 d)</td>
<td>0.10 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Oncorhynchus mykiss</td>
<td>LC50 (99 d)</td>
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<tr>
<td>Other species</td>
<td>-</td>
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</tr>
<tr>
<td>Group</td>
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<td>Criterion</td>
<td>Result</td>
</tr>
<tr>
<td>-------------</td>
<td>------------------------------</td>
<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Algae</td>
<td>Selenastrum capricornutum</td>
<td>EC50 (73 h)</td>
<td>4.36 mg/l</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Ceriodaphnia dubia</td>
<td>NOEC (7 days)</td>
<td>1.17 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Salmo gairdner</td>
<td>LC50 (96 h)</td>
<td>2.6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Bryocoronaecus</td>
<td>LC50 (96 h)</td>
<td>9.94 mg/l</td>
</tr>
<tr>
<td></td>
<td>Selenastrum capricornutum</td>
<td>NOEC (73 h)</td>
<td>0.44 mg/l</td>
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<tr>
<td>Other species</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>Selenastrum capricornutum</td>
<td>NOEC (73 h)</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Ceriodaphnia dubia</td>
<td>NOEC (7 days)</td>
<td>1.17 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Salmo gairdner</td>
<td>LC50 (56 d)</td>
<td>1.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Bryocoronaecus</td>
<td>LC50 (96 h)</td>
<td>2.6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Selenastrum capricornutum</td>
<td>NOEC (73 h)</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td>Other species</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>Selenastrum capricornutum</td>
<td>EC50 (73 h)</td>
<td>4.36 mg/l</td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Ceriodaphnia dubia</td>
<td>NOEC (7 days)</td>
<td>1.17 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>Salmo gairdner</td>
<td>IC 50 (24 h)</td>
<td>1.0 mg/l</td>
</tr>
<tr>
<td></td>
<td>Bryocoronaecus</td>
<td>LC50 (96 h)</td>
<td>9.94 mg/l</td>
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<td></td>
<td>Selenastrum capricornutum</td>
<td>NOEC (73 h)</td>
<td>0.44 mg/l</td>
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<tr>
<td>Other species</td>
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### Acute data for diazinon (CAS no 333-41-5)

<table>
<thead>
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<th>Group</th>
<th>Species</th>
<th>Criterion</th>
<th>Result (24h)</th>
<th>Data quality</th>
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<tbody>
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<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>LC50 (24h)</td>
<td>0.00035 mg/l</td>
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<td></td>
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<tr>
<td>Fish</td>
<td>Rainbow trout (Oncorhynchus mykiss)</td>
<td>NOEC (24h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>EC50 (48h)</td>
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### Chronic data for diazinon are:

<table>
<thead>
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<th>Group</th>
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<th>Criterion</th>
<th>Result (21d)</th>
<th>Data quality</th>
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<td>NOEC</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>NOEC</td>
<td>0.00015 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Fish</td>
<td>Rainbow trout (Oncorhynchus mykiss)</td>
<td>LC50 (21d)</td>
<td>0.60 mg/l</td>
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<td></td>
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<tr>
<td>Invertebrates</td>
<td>Daphnia magna</td>
<td>LC50 (24h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other species</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mixture or Article
Obligations

Date: 29.11.2014

Dr. Gisela Holzgraefe
Ministry for Energy, Agriculture, the Environment and Rural Areas of Land Schleswig-Holstein (Germany)
Content

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

- **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.
**Mixture or article?**

- **object**
  - **Main function?**
    - yes: provision of substance?
      - yes: see ECHA Guidance on substances in articles
      - no: object = article
    - no: form, shape, design more important than chemical composition
      - yes: see ECHA Guidance on substances in articles
      - no: object = substance resp. mixture
  - Decision not clear

- Substance / mixture in a container
- Object = article
- See ECHA Guidance on substances in articles
- Object = substance resp. mixture
Decision article or preparation / mixture

Object

Step 1: Identify the function of the object

Yes

Step 2: Are shape, surface and design more relevant for the function than the chemical composition?

No

Not possible to unambiguously conclude yes or no

Step 3: Does the object contain a sub-component or a mixture that can be separated from the object?

Yes

Check indicative questions under step 4

Mostly yes

Check indicative questions under step 5

Mostly no

Object consists of a substance or a mixture and an article

Mostly no

Mostly yes

Object is an article

No

Check indicative questions under step 6

Mostly yes

Mostly no

Object is a substance or a mixture
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)
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

no registration of substances in articles

- subst > 1 t/a
  - yes: intended release
  - no: no
- article
  - yes: registration
    - Art. 6, 17, 18
  - no: no further duties
- SVHC
  - yes: communication
    - Art. 33
  - no: no further duties
- > 0.1% w/w
  - yes: no further duties
  - no: no further duties
- t > 1 t/a
  - yes: no further duties
  - no: no further duties
Preparation - Article

- 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 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of 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.
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.
Example bicycle

- saddle
- steering link
- handle
- handle bar
- saddle pillar
- bicycle chain bar
- pedal
- bicycle frame
- spokes
- bicycle basket
- bicycle fork
- tyres
Laptop

- different articles in a laptop, easy to identify: screen, computer case (housing), keyboard, 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/condenser and each resistor?
- The German competent authority for chemicals BAuA does not give general advice.
Example: Computer components
Nicotine in e-cigarettes

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**

<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Hazard statement</th>
<th>pictogram</th>
<th>Hazard statement Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>nicotine</td>
<td>Acute Tox. 1</td>
<td>H310</td>
<td>H310</td>
</tr>
<tr>
<td></td>
<td>Acute Tox 3*</td>
<td>H301</td>
<td>H301</td>
</tr>
<tr>
<td></td>
<td>Aquatc Chronic 2</td>
<td>H411</td>
<td>H411</td>
</tr>
</tbody>
</table>

**no specific concentration limits**

**legally binding classification**

- Skull and crossbones: Environment
- Danger: Skull and crossbones
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 BÄuA:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Hazard class</th>
<th>Hazard statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 0,16 %</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>0,17 – 1 %</td>
<td>Acute Tox. 4</td>
<td>H 302</td>
</tr>
<tr>
<td>1,1 - &lt; 6,5 %</td>
<td>Acute Tox 3</td>
<td>H 301</td>
</tr>
<tr>
<td>6,5 – 65,9 %</td>
<td>Acute Tox. 2</td>
<td>H 300</td>
</tr>
<tr>
<td>&gt; 66 %</td>
<td>Acute Tox. 1</td>
<td>H 300</td>
</tr>
</tbody>
</table>
E-cigarettes

- **pharmaceutical product**: some courts decided for that, recent decision of higher court: no evidence that they support 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?
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 Environment 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

Permit writers / inspectors assess the substances processed and unintentionally generated during the process (e.g. dioxins, SO₂ …)
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 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 with 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
Substances in IED permitting

Classification, labelling and packaging (CLP)

Registration, authorisation and restriction (REACH)

Prevention of emissions into air

Protection of national heritage

Nature protection

Avoidance of hazardous waste

Prevention of emissions to surface water / ground water (WFD)

work safety

Soil protection

Substances in IED permitting and inspection
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 approach 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 – permitting
- 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)

<table>
<thead>
<tr>
<th>IED ref.</th>
<th>Obligation</th>
<th>Information source in REACH</th>
</tr>
</thead>
</table>
| 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)

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

Dr. Gisela Holzgraefe, November 2014
### REACH – IED Synergies (operators/DU)

<table>
<thead>
<tr>
<th>IED ref.</th>
<th>Obligation</th>
<th>Information source in REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Article 13 BAT BREF docs</strong></td>
<td>Info exchange on installation performance and emissions</td>
<td>ES: to support the identification of release routes relevant for the industrial sector</td>
</tr>
<tr>
<td></td>
<td>BAT identification Annex III IED</td>
<td>ES: to identify RMM resulting in adequate control of risks</td>
</tr>
</tbody>
</table>
| **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 |
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<td>BAT - criterion 2 (use of less hazardous substance)</td>
<td>Information on alternatives from SVHC or restriction dossier: can provide information on potential alternative substance and or technology</td>
</tr>
<tr>
<td><strong>Article 20</strong></td>
<td>Substantial change</td>
<td>ext-SDS: to help identify whether change of substance is relevant to qualify as &quot;substantial change&quot;</td>
</tr>
<tr>
<td><strong>Article 22</strong></td>
<td>Potential contamination of soil and groundwater at the site</td>
<td>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)</td>
</tr>
<tr>
<td><strong>Article 23</strong></td>
<td>Environmental risk appraisal for inspection planning</td>
<td>ext-SDS: to help identify relevant hazardous substances and their possible release route for input in environmental risk assessments</td>
</tr>
</tbody>
</table>
## Specific IED to REACH feed

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

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<tbody>
<tr>
<td>Emerging techniques described in BREF (can provide information on potential alternatives in terms of techniques and/or substances to be used)</td>
<td>Support for substitution of hazardous substances with less hazardous or with alternative techniques. In particular substances included in the Candidate List and Annex XIV</td>
</tr>
<tr>
<td>Permit granted under IED</td>
<td>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</td>
</tr>
</tbody>
</table>
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 to 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 understanding 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 understanding 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

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

- 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 – authorities 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

- 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)

<table>
<thead>
<tr>
<th>Name of chemical substance / mixture / article</th>
<th>total amount (t)</th>
<th>Composition, content (weight %)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Name of component</td>
</tr>
<tr>
<td>calorific value (MJ/kg)</td>
<td>EWC code</td>
<td>input material</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Dutch SVHC list and guidance

- 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
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 parenthesis 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
<table>
<thead>
<tr>
<th>description</th>
<th>legislation</th>
<th>evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>supplier</td>
<td>Supplier of the SDS</td>
<td></td>
</tr>
<tr>
<td>From outside EU</td>
<td>yes/no</td>
<td></td>
</tr>
<tr>
<td>name</td>
<td>Name of product</td>
<td></td>
</tr>
<tr>
<td>use</td>
<td>Use of product (e.g. lubricant)</td>
<td></td>
</tr>
<tr>
<td>department</td>
<td>e.g. foundry</td>
<td></td>
</tr>
<tr>
<td>SDS compliant</td>
<td>Yes / no</td>
<td></td>
</tr>
<tr>
<td>notes</td>
<td>Reason for negative judgement</td>
<td></td>
</tr>
<tr>
<td>Actions to be taken</td>
<td>e.g. request for updated SDS</td>
<td></td>
</tr>
</tbody>
</table>
Example 2: flowsheet → worktool (NO)

Identification of chemicals which are subject to permission for industrial activity - August 2013

Application for a permit (new/modification) for an industrial activity

Action 1: Identify relevant chemicals
- Name, group name, CAS no., EU no., Safety Data Sheet (SDS), quantity

Action 2: Identify where the chemicals end up
- Emission to air/water
- Oil phase
- Waste
- Disposal site
  - Deliver to approved waste facilities
  - Specific conditions

Action 3: Check if the substance is covered by?
- REACH 1)
  - Candidate List
  - Annex XIV List of substances subject to authorisation
  - Annex XVII List of restrictions
- Biodieses regulation 7)
- Product regulation 6)
- Classification and Labelling
  - CLP 4)

National list of priority substances 3)

Consider emission limit values (ELVs) and program for substitution

Triggers different obligations

Is authorisation granted for this specific use according to REACH?

Banned or limited use?

CLP 4)

SDS

Evaluation of the application (setting emission limit values, specific conditions, requirements for waste disposal/landfills)
Example 2: Flowsheet - explanation

- **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 concerning 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.