

IED/Chemicals Working Group (Activity 2.8)

Training modules Results/Outputs/2014 Planning 2015

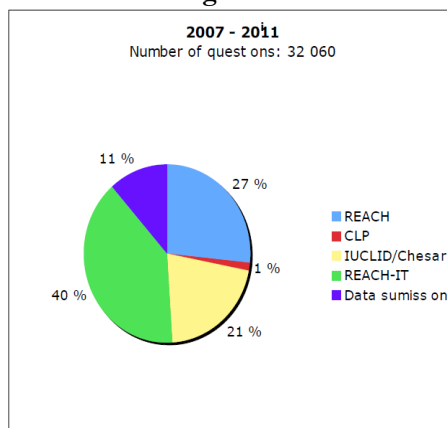


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REACH complemented by CLP is the most ambitious piece of chemicals legislation in the world



QUESTIONS RECEIVED BY THE ECHA HELPDESK BY TOPIC.

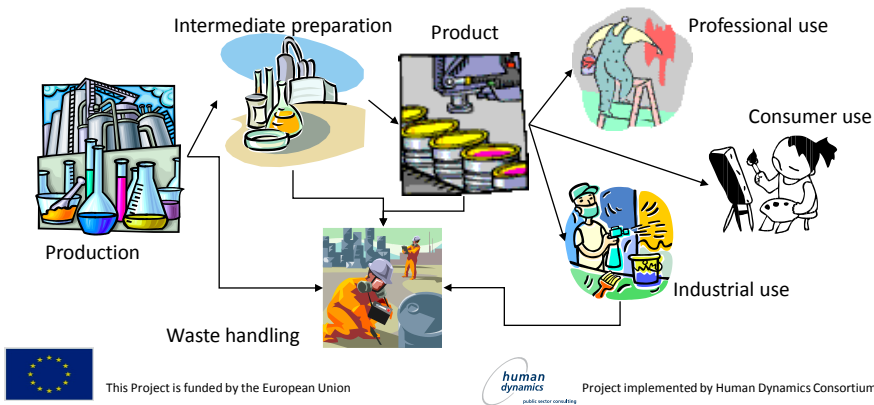


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Production & Use of chemicals



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

MODULE 1: 3 –days May 2014
General Introductory Module/Procedures
REACH specifics: Registration, Evaluation, Authorization and restriction
REACH Roles and responsibilities
Pre-SIEF,SIEF and consortia
REACH Chemicals risk assessment
Chemical Safety report (CSR)
Safety Data Sheets (SDS)
CLP general development
REACH IED interaction (general)
Site visit 1 (IPPC/SEVESO installation)



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A New EU Chemicals Policy

Registration, Evaluation and Authorisation of Chemicals



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REACH: KEY ELEMENTS

- Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances
- Key elements:
 - Registration by industry of manufactured/imported chemical substances > 1 tonne/year (staggered dead-lines over 11 years)
 - Increased information and communication throughout the supply chain
 - Evaluation of some registered substances (Agency and Member States)
 - Authorisation only for use of substances of very high concern
 - Restrictions: “Safety net” (Community wide action)
 - Chemicals Agency to efficiently manage the system

Focus on priorities:

- High volumes (chemicals with greatest likely exposure register first)
- Greatest concern (CMR and R50/53 register first)

Contents of REACH Regulation

TITLE I GENERAL ISSUES	Ch. 1 – 2	Art. 1 – Art. 4
TITLE II REGISTRATION OF SUBSTANCES	Ch. 1 – 5	Art. 5 – Art. 24
TITLE III DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING	Ch. 1 – 3	Art. 25 – Art. 30
TITLE IV INFORMATION IN THE SUPPLY CHAIN		Art. 31 – Art. 36
TITLE V DOWNSTREAM USERS		Art. 37 – Art. 39
TITLE VI EVALUATION	Ch. 1 – 4	Art. 40 – Art. 54
TITLE VII AUTHORISATION	Ch. 1 – 3	Art. 55 – Art. 66
TITLE VIII RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS	Ch. 1 – 2	Art. 67 – Art. 73



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Contents of REACH Regulation (continue)

TITLE IX FEES AND CHARGES		Art. 74
TITLE X AGENCY		Art. 75 – Art. 111
TITLE XI CLASSIFICATION AND LABELLING INVENTORY*		Art. 112 – Art. 116
TITLE XII INFORMATION		Art. 117 – Art. 120
TITLE XIII COMPETENT AUTHORITIES		Art. 121 – Art. 124
TITLE XIV ENFORCEMENT		Art. 125 – Art. 127
TITLE XV TRANSITIONAL AND FINAL PROVISIONS		Art. 128 – Art. 141

➤*C&L Inventory – Title XI; moved to CLP Title V

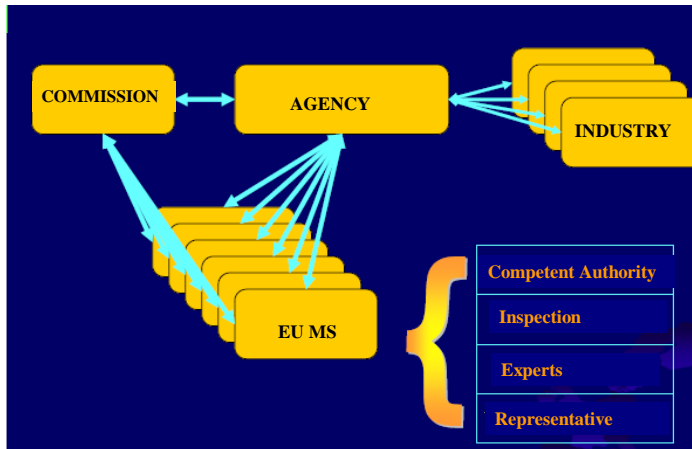


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REACH ORGANISATION



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Regional Accession Network **ECRAN**

Registration: general

AIM:

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

Registration Dossier = Documentation

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

No formal acceptance - industry retains responsibility



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Who Has to Register?

- Manufacturers and importers.
 - DUs may notify non-pre-registered substances of interest
 - By doing so DU obliged to submit “light”-registration dossier
- Producers of articles (conditions of Article 7).
 - Intended release of substances only
- Manufactures of substances outside the EU may appoint an “only representative” to fulfil their REACH obligations.
 - “Only representative” relieves importers of their duties.
 - Importers are then considered DUs.



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Substances/Mixtures/Articles/containers?

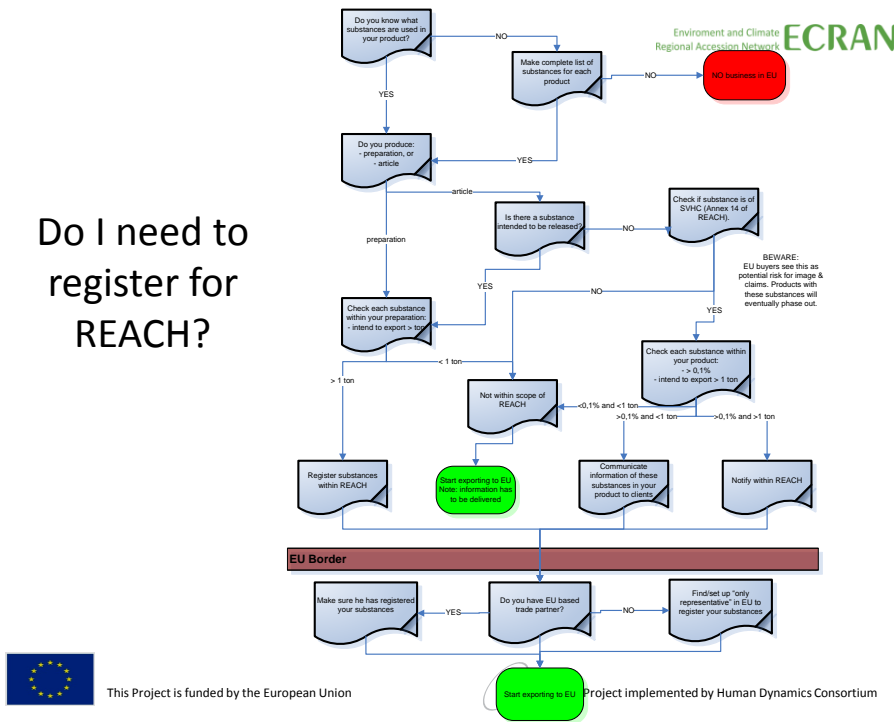


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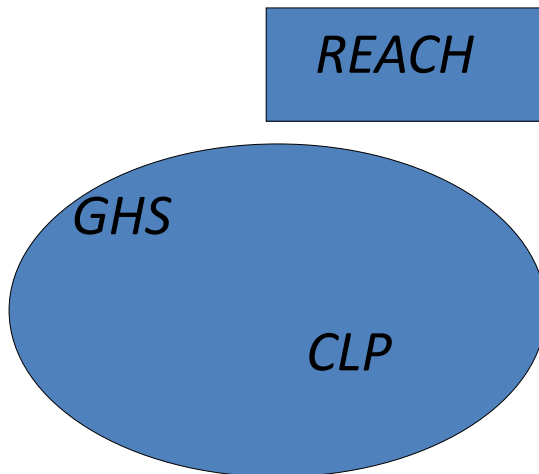


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Do I need to register for REACH?



INTERCONNECTIONS



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What is CLP?

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- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packing (CLP) of **substances** and **mixtures**, amending and repealing Directive 67/548/EEC (i.e.DSD) and 1999/45/EC (i.e DPD) and amending Regulation No 1907/2006 (i.e. REACH) came into force on 20 January 2009
- **Implements Globally Harmonised System (GHS) of Classification and labelling in the EU**
- Covers all 27 EU and EEA countries
- GHS sets optional building blocks from which countries can choose



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Why do we need GHS?

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Substance - oral toxicity LD₅₀ = 257 mg/kg

GHS	Danger (Skull & Cross Bones)
Transport	liquid: slightly toxic; solid: not classified
EU	Harmful (St Andrew's Cross)
US	Toxic
CAN	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
Thailand	Harmful
New Zealand	Hazardous
China	Not Dangerous
Korea	Toxic



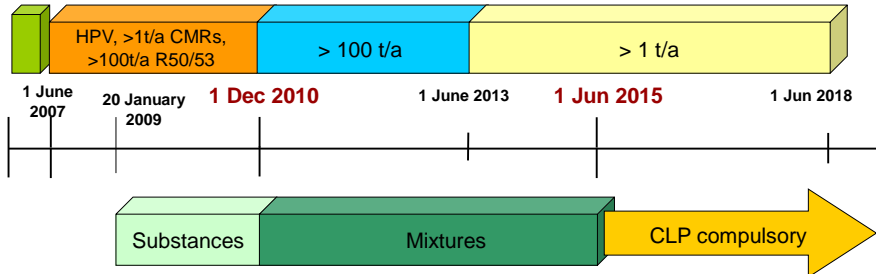
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CLP & REACH Timelines Compared

REACH: registration deadlines (substances)



CLP Regulation



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LINK IED and REACH

SUBSTANCES

REACH/CLP

IED

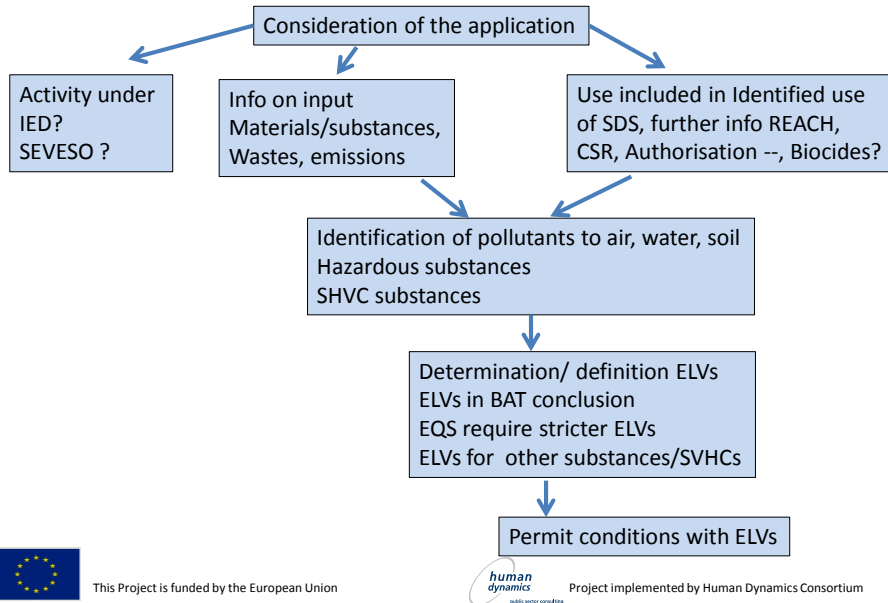


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Steps in the permit procedure with relation to substances Environment and Climate Regional Accession Network **ECRAN**
Tasks of the authority – application for new installation



Environment and Climate Regional Accession Network **ECRAN**

MODULE 2: - 3 days December 2014
REACH/CLP/IED Procedures
REACH IT IUCLID
<i>REACH/CLP authority obligations</i>
CSR/SDS detail
<i>REACH Info & Helpdesks</i>
<i>REACH Enforcement</i>
CLP requirements
REACH IED interaction (analysis and BAT)
Site visit 2 (IPPC/SEVESO installation)



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Obligations - Authorities



The authorities having obligations and rights in the REACH processes are:
the Agency (specifically set up for REACH) - ECHA,
the Member States Competent Authorities and
the European Commission.

The authorities carry out the evaluation, authorisation and restriction processes of REACH.

In addition, the Agency and Member States will provide helpdesk assistance. Member States are responsible for Enforcement under REACH.



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European Chemicals Agency
Centre of Helsinki, Finland

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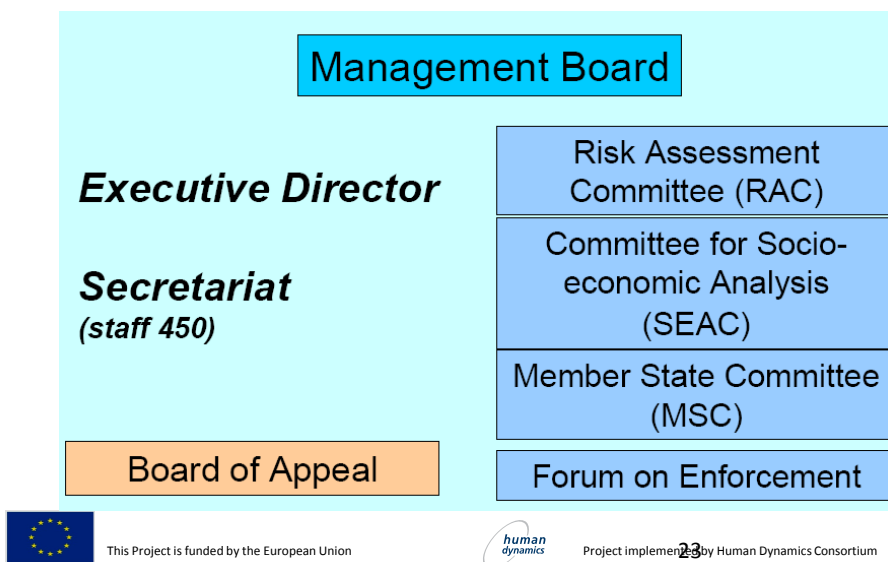


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EU chemicals Agency



Enforcement of REACH

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

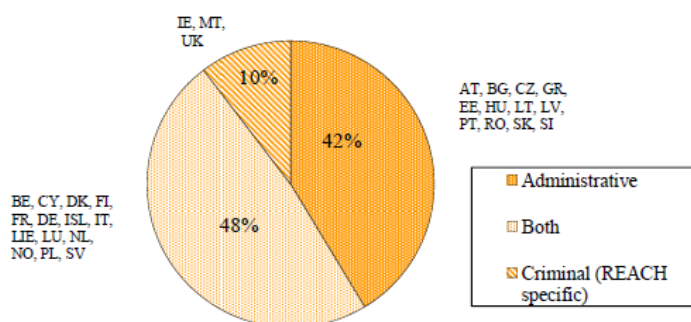


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Enforcement regimes REACH*



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



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Enforcement of REACH/CLP in the Netherlands (example)

- **Three inspections agency working together**
 - The Labour Inspection team (AI)
 - Food and Consumer Product Safety Authority (VWA)
 - Environmental Inspection (VI)
- **Together they have supervision of the compliance with REACH/CLP**
 - AI will supervise the professional users of substances, preparations and objects
 - VWA will supervise producers, importers and traders of substances, products and objects for consumers
 - VI will supervise producers, importers and traders of substances, products and objects for professional use.



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Member states

National REACH Helpdesks

ECHA is obliged to support national helpdesks (Art. 77(2)(h)), and does this via establishing:

- A network (REACH HELP-NET)
- REACH Helpdesk Correspondents' Network (REHCORN)
- REACH Helpdesk Exchange Platform (RHEP)



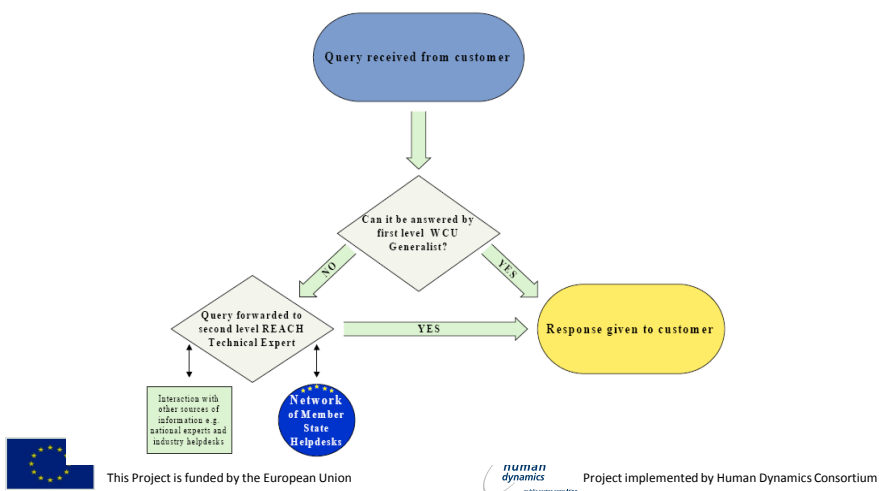
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REACH Helpdesk

Figure 1- Flow Diagram of REACH helpdesk function.

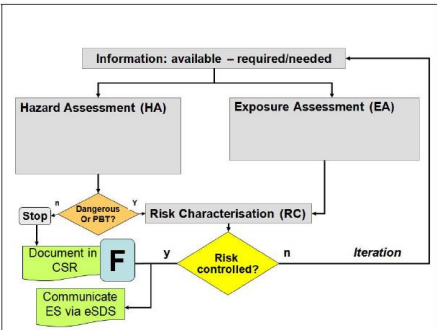
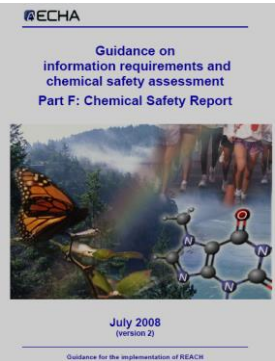


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The Chemical Safety Report



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MODULE 3: - May-June 2015
REACH/CLP/IED Technical aspects
Exposure scenarios
PBT & vPvB assessments
Environmental Risk Assessment
Human Health Risk Assessment
Classification of chemicals: Endpoints and testing
REACH IT IUCLID - application
REACH IED practical cases
Site visit 3 (IPPC/SEVESO installation)



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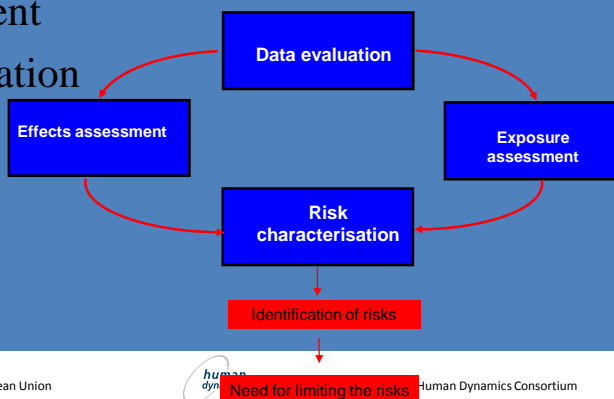


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Principles of Chemicals Risk and Safety assessment

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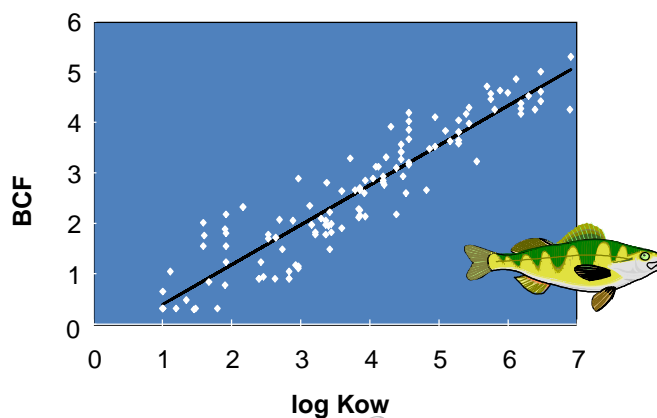
- Data evaluation: hazard identification
- Exposure assessment
- Effects assessment
- Risk characterisation



Basic properties

Quantitative Structure-Activity Relationship: QSAR

Relating a “cheap” parameter to an “expensive” one



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MODULE 4: - December 2015
REACH/CLP EU accession elements, downstream consequences and interlinkages
Sharing practical experience in accession, tools and guidance
Downstream consequences (SEVESO, Waste etc)
Interlinkages (WFD, IED, Biocides, Cosmetics, Detergents etc)
Site visit 3 (IPPC/SEVESO installation)



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Downstream consequences REACH/CLP

- ✓ **Cosmetics**
 - *Raw material for cosmetics needs to be correctly classified, labelled and packaged*
- ✓ **Handling chemicals for particular uses (biocides/pesticides)**
 - *Classification and labelling of biocides/pesticides*
 - *Registration of co-fomulants under REACH*
- ✓ **Control of dangerous / hazardous chemicals (SEVESO/VOC etc)**
 - *Classification - Tier system*
- ✓ **Occupational health and safety**
 - *Classification/control/measures*
- ✓ **Waste/end-of-waste**
 - *Authorisation and registration of substances with end-of-waste status*
- ✓ **Others (Toy safety, Detergents, Waste electrical and electronic equipment (WEEE) and Batteries and accumulators)**



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ECHA > Support > Croatian accession to the European Union

Croatian accession to the European Union



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

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

Related links

- > [ECHA's Q&A for Croatian companies pre-registering and registering under REACH](#)
- > [List of CLP and REACH national helpdesks](#)
- > [The ECHA Helpdesk](#)

See also

- > [EUR-LEX - legislation in Croatian](#)
- > [Text of the Accession Treaty](#)
- > [ECHA-Term](#)
- > [ECHA-Term Leaflet and Quick Guide](#)

Key material in Croatian

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

Original Planning

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



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Outputs under Task 2.8.2 for 2013 - 2014

No.	Date	Key outputs
1	January 2014	Training Needs Questionnaire and Training Needs Assessment. Proposals for pilot industries to be visited. TNA report
2	February 2014	Training Methodology, Training Programme and Training Materials
3	Training Workshop no. 1. Montenegro May, 13-15, 2014	Training (1) ; General introduction chemicals and procedures REACH/CLP, IED (1) with a site visit to PROGAS in Hercec Novi, plant (IPPC/SEVESO lower tier) produces Acetylene based on the calcium carbide process Training report
4	Training Workshop no.2. Albania 2-4 December, 2014	Training (2). Procedures REACH/CLP (2), with a site visit to Bankers Petroleum Albania Ltd.(IPPC/SEVESO plant) oil extraction in Fier, Training Report

In the 3-day courses use was made of **presentations** and **practical exercises**. Materials that have been produced in IMPEL projects analysing the link between **REACH and IED** have been presented by the respective **IMPEL expert**. Next to explanatory presentations also round table discussions were held on the **progress made in the field in the various Beneficiary countries**. A summary based on the discussions in the first two training courses is given in the Annual Report.

For the **site visits** the group of participants were divided into 3-4 groups with defined tasks to analyse the processes on the chemical and industrial pollution control aspects. Results have been presented in the training reports.



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PARTICIPANTS AND EXPERIENCE LEVEL

	Years of experience					
	0 – 1 year		1 – 5 years		5 – 10 years	
	C1.Mont.	C2.Alb.	C1.Mont.	C2.Alb.	C.1Mont.	C2.Alb.
Environment	4	4	9	3	7	4
Chemicals (REACH/CLP)	7	7	10	2	1	
IPPC/IED	11		3		4	1
Others						1

Most of the participants have **limited knowledge** and experience on chemicals (REACH/CLP). The level of experience in the group was very different. This is a challenge for trainers and participants as well.

Most of the trainees indicated that the training was of a high quality and useful. The trainees also expressed their wish to have more concrete knowledge on (eco)toxicology in the following trainings.



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ASSISTANCE AT NATIONAL SCALE

The trainers promoted the participating countries to use the TAIEX facility in case further assistance is needed on a national scale. This can be facilitated via the ECRAN secretariat. A good example was that via ECRAN **Albania** has asked TAIEX's assistance for REACH and CLP related issues, and subsequently could implement it on a national scale. The TAIEX expert mission now will provide assistance to the Albanian Ministry of Environment on the compliance checking of the following draft legislation prepared:

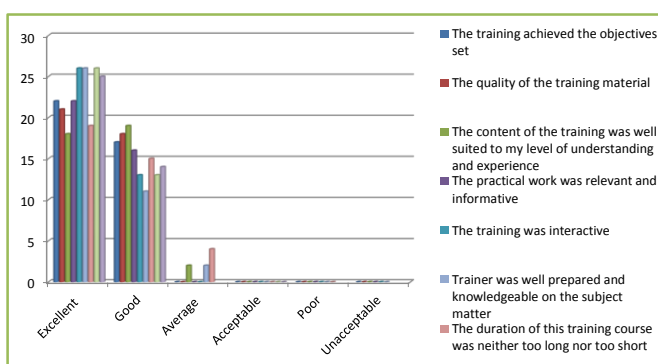
1. Framework law on chemicals legislation
2. Classification, packaging and labeling of substances and chemical mixtures (CLP);
3. Import and export of hazardous substances;
4. Approval of substances and chemicals, manufacture, placing on the market and use of which is restricted or prohibited (Annex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



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EVALUATION OF THE COURSES (2)

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Outlook and Challenges for 2015

No.	Date	Key outputs
5	Training Workshop no 3: 9, 10 and 11 June 2015	Training(3). Technical aspects REACH /CLP, IED. Training Report Skopje, FYR of Macedonia
6	Training Workshop no.4. 2-4 December 2015	Training (4). REACH/CLP downstream consequences, interlinkages with IED and other legislation; accession issues. Training Report Country to be decided (Turkey?)

Considering the positive evaluation of the training courses up to now, the courses will be continued with the present set-up covering the elements of the package that have been decided upon. Taking into consideration that some of the subjects are handled in a consecutive way in the series of training courses, it is of importance to select as much as possible the same persons to participate in the training courses.



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Thank you for your attention



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