

IED/Chemicals Working Group (Activity 2.8)

Training modules Results/Outputs/2014/2015

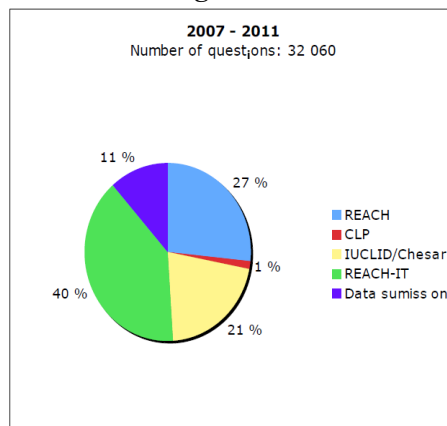


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REACH complemented by CLP is the most ambitious piece of chemicals legislation in the world



QUESTIONS RECEIVED BY THE ECHA HELPDESK BY TOPIC.

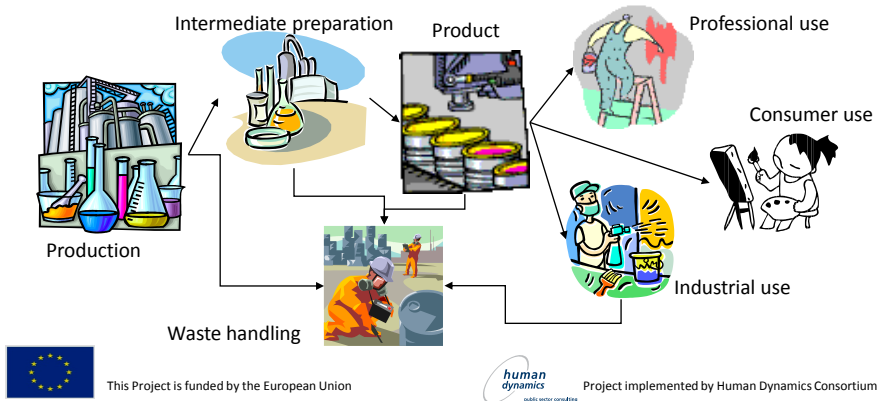


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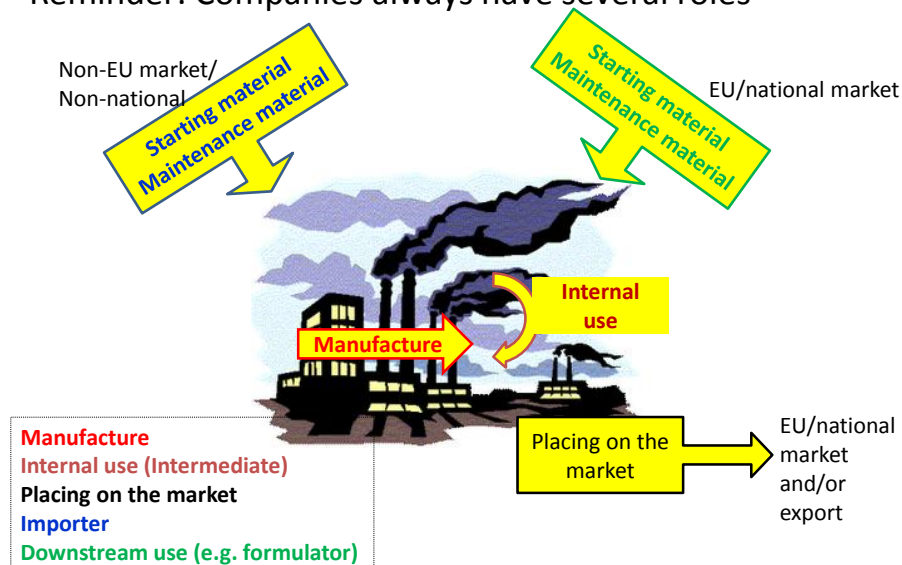


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Production & Use of chemicals

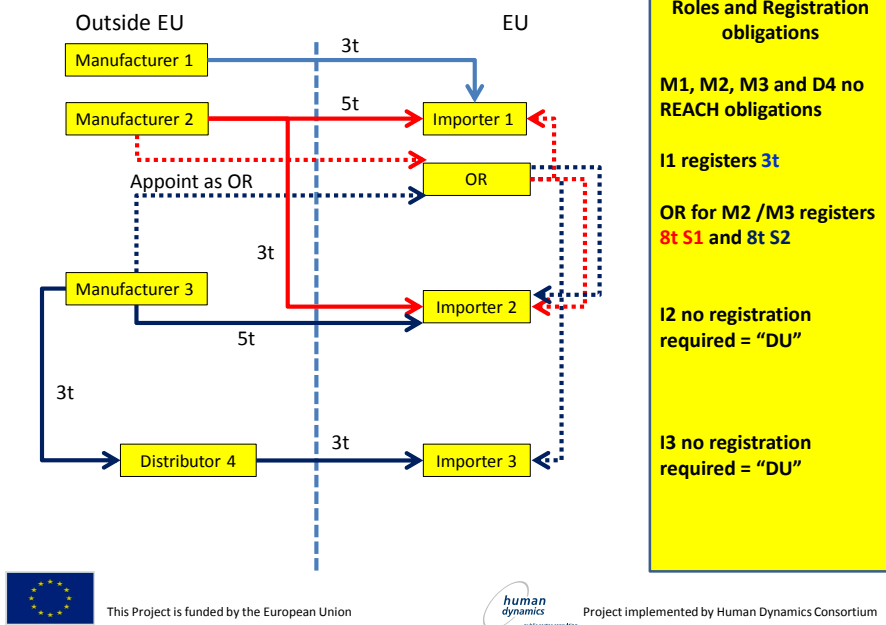


Reminder: Companies always have several roles



Explaining roles

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Regional Accession Network **ECRAN**



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

MODULE 1: 13-15 May 2014, Podgorica, Montenegro
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) ,PROGAS in Hercec Novi, plant (IPPC/SEVESO lower tier) produces Acetylene based on the calcium carbide process



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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 11years)
 - 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

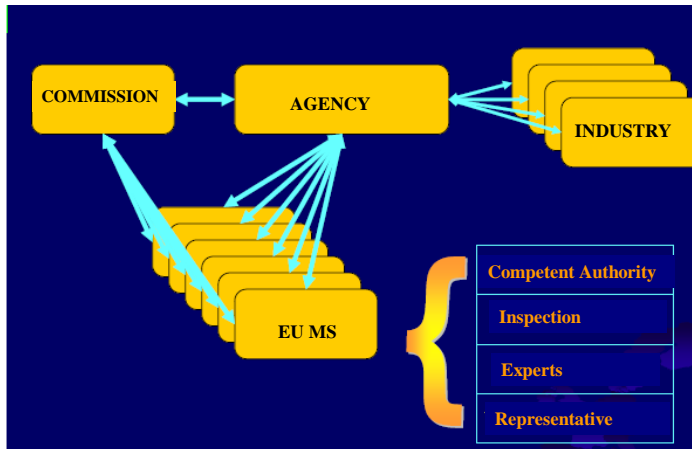


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REACH ORGANISATION



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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?



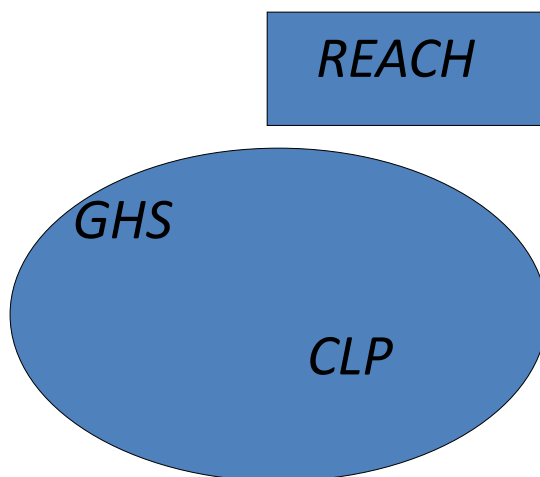
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INTERCONNECTIONS

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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?

Substance - oral toxicity $LD_{50} = 257 \text{ mg/kg}$

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



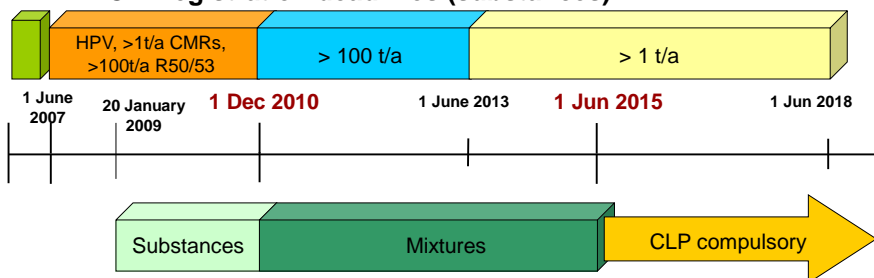
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CLP & REACH Timelines Compared

REACH: registration deadlines (substances)



CLP Regulation



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LINK IED and REACH

SUBSTANCES

REACH/CLP

IED

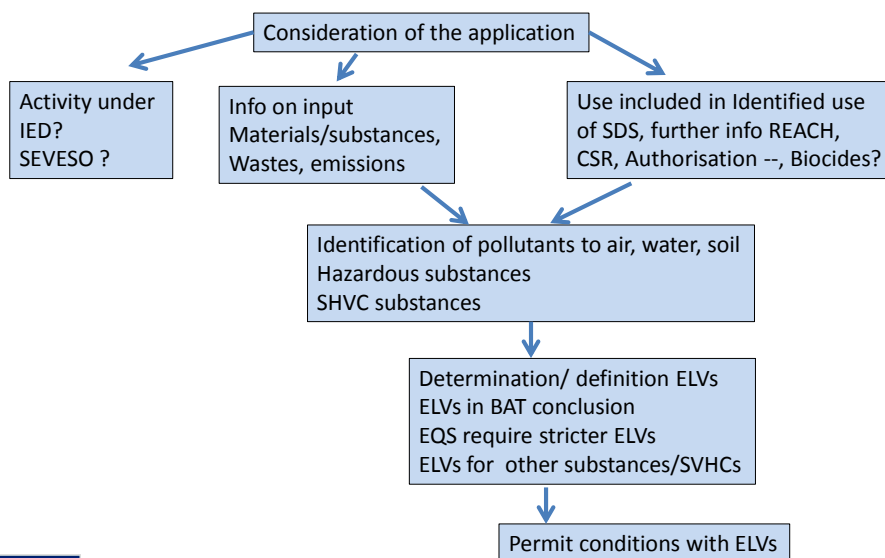


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Steps in the permit procedure with relation to substances Tasks of the authority – application for new installation



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MODULE 2: 2- 4, December 2014, Tirana, Albania
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) to Bankers Petroleum Albania Ltd.(IPPC/SEVESO plant) oil extraction in Fier



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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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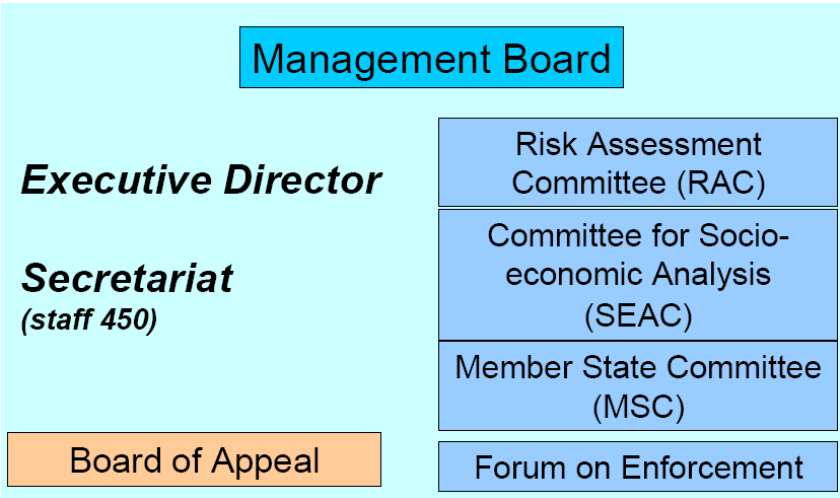
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EU chemicals Agency

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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

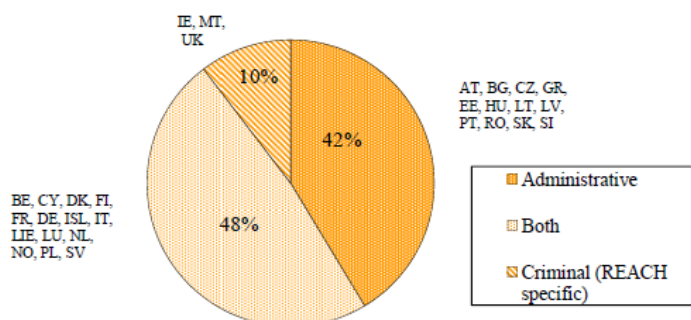


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Enforcement regimes REACH*



*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)



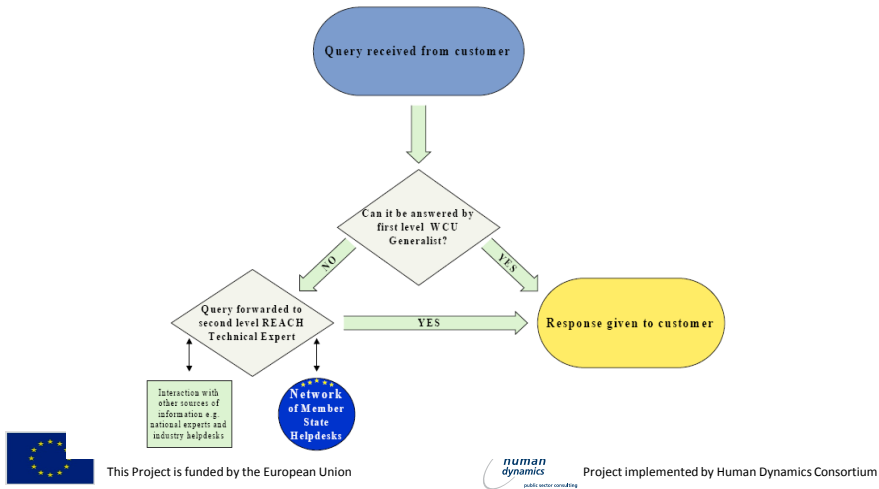
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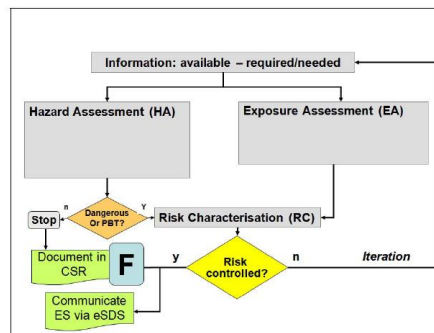
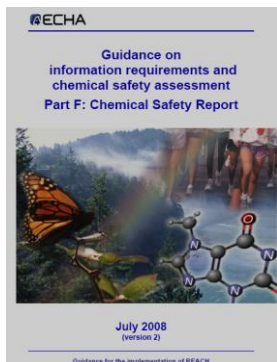
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REACH Helpdesk

Figure 1- Flow Diagram of REACH helpdesk function.



The Chemical Safety Report



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MODULE 3: - 1-3 September 2015, Skopje FYR of Macedonia

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) MAKPETROL, pilot biodiesel factory.



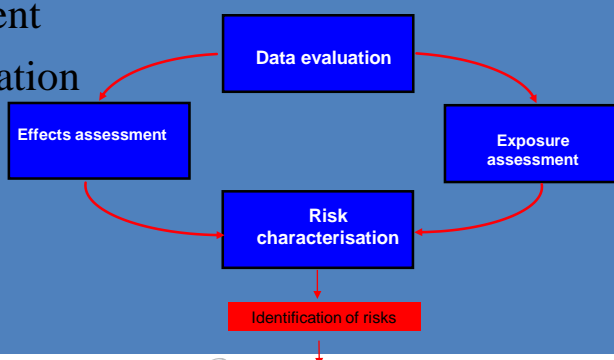
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Principles of Chemicals Risk and Safety assessment

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



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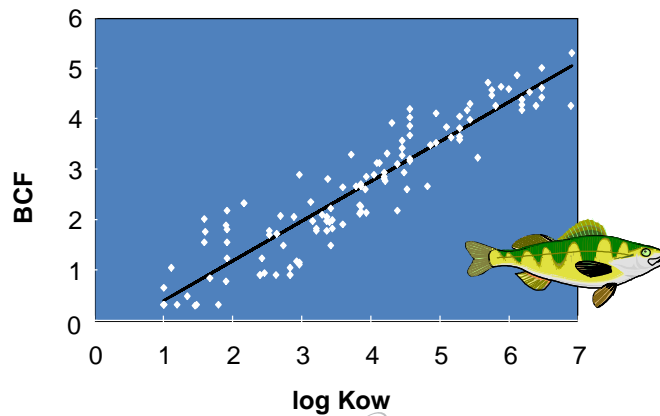


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Basic properties

Quantitative Structure-Activity Relationship: QSAR

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



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MODULE 4: 8 - 10 December 2015, Istanbul, Turkey

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 4 (IPPC/SEVESO installation) UNILEVER HPC Gebze Factory



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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-formulants 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)**



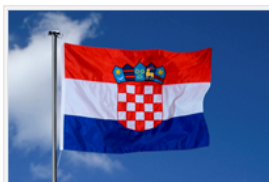
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[ECHA](#) > [Support](#) > [Croatian accession to the European Union](#)

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 updates can be accessed through the Publication link in the Support section.

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ASSISTANCE AT NATIONAL SCALE – Albania (1)

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 missions provided 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).

1) (1)* Is now approved by the Albanian Parliament on 17th March 2016.

2) (2-5) Is in process of approval as four draft Decisions of the Council of Ministers, also prepared in the framework of TAIEX Expert Missions



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ASSISTANCE AT NATIONAL SCALE – Albania (2)

Based on the new law requirements, a new Chemicals Office, dealing with Chemicals and Industrial Accidents is established in the Ministry of Environment.

An important tool to ensure implementation of the new chemicals legislation in place, is creation of an electronic National Chemicals Register. Chemicals produced, placed on the market or imported must be registered in this Register, which will be maintained by the Chemicals Office.

For that reason a request has been made in the framework of the ECRAN Project to have again TAIEX Expert Mission(s) on procedures needed, with creation and maintaining of such a register.



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As indicated, the results showed that most of the participants have **limited knowledge** and experience on chemicals (REACH/CLP) and that the level of experience in the group was very different. It should also be noted that the enforcement of the requirements of the REACH and CLP Regulations involves **many different enforcement authorities and other bodies**. Each country has its own system. Increasing the level of know-how with exchange of experience within the ECRAN beneficiary countries and especially with that in EU member states are important outputs. **Increased level of know-how also includes the required activities needed for accession (e.g. national inventory of chemicals).**

The outcomes of the two trainings that have been given in 2014 have been taken into consideration in developing the programmes of the courses in 2015. The provision of more basic background and exercises proved to be an appropriate approach in this respect. The participating countries expressed their appreciation to these trainings and the know-how provided on REACH and CLP Regulations. Some countries indicated that the workshops like this are extremely needed. Furthermore, **more information on interlinkage between environmental topics and REACH&CLP are requested by the participants.**



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Observations and challenges

- Compared with earlier activities under RENA, the chemicals legislation is receiving now more attention and has been included in ECRAN as a subject in combination with the IED.
- The importance of the subject is also reflected in the work programme of IMPEL, the network for environmental inspectors in EU member states. Within IMPEL the interlinkages between REACH and IED are being analysed.
- IMPEL has been one of networks we have cooperated with.
- By inviting experts involved in IMPEL and also those involved in ECHA (European Chemicals Agency) in our trainings it was possible to share, explain and train in the various new tools and guidance products provided by these organisations



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- The experience of Croatia as a new member country was very useful, especially the changes required during the transition periods from non-member to member country
- The exchange of experience between the beneficiary countries was also relevant with examples of very highly developed systems in this field in for example Turkey and Serbia
- To keep the link with practices in the field we have followed the approach to combine our activities with site visits. For this purpose the contribution of the WG national coordinators was most valuable as contacting and organizing site visits required an active involvement and approach.
- The combination of ECRAN with the TAIEX facility opened up additional opportunities, i.e. to organize trainings/assistance in specific areas on a national scale. Although use has already been made of this possibility (ref. Albania), more initiatives might be taken in this respect.



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A considerable amount of work is still to be done-----

Country	KS	SR	MN	MD	TK	AL	BiH
Inventory of chemicals	-	+	-+	-	+	-	+
Helpdesk available	-	+	-	- (+)	+	-	-
Legislation (transposable elements)							
CLP	+	+	+	-	+	-(+)	-
SDS	+	+	+	-	+	-(+)	-(+)
Capacity for implementation	limited	limited	limited	limited	limited	limited	limited

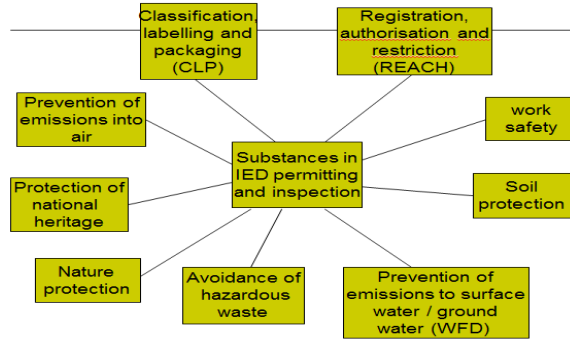


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Analyzing Interlinking and cross-cutting issues: Not an easy task!



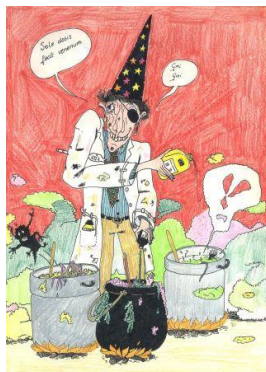
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Thank you for your attention

Paracelsus: "Dosis Sola Facit Venenum" -1538
(it is the dose which makes the poison)



Dynamic to the future....



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