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# Environment and Climate Regional Accession Network (ECRAN)

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Workshop report  
Capacity Building on  
Compliance with  
Chemical Legislation  
with emphasis on  
REACH/CLP linked to IED  
(4th Regional Workshop)

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08-10 December 2016, Istanbul

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**ENVIRONMENT AND CLIMATE REGIONAL NETWORK FOR ACCESSION - ECRAN**

**WORKSHOP REPORT**

**Activity 2.3**

**REPORT ON THE WORKSHOP ON CAPACITY BUILDING ON COMPLIANCE WITH  
CHEMICAL LEGISLATION WITH EMPHASIS ON REACH/CLEP LINKED TO IED  
(4<sup>TH</sup> REGIONAL WORKSHOP)**

**08-10 December 2016, Istanbul, Turkey**



This Project is funded by the  
European Union



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Human Dynamics Consortium

LIST OF ABBREVIATIONS	
CMR	Carcinogenic, mutagenic, reprotoxic substances
CLP	Classification, Labelling and Packaging
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
DU CSR	Downstream User Chemical Safety Report
DU	Downstream Users
EC	Effective Concentration
ECHA	European Chemicals Agency
EC	European Commission
EEA	European Environmental Agency
EU	European Union
ES	Exposure Scenarios
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HPC	Home and Personal Care
IED	Industrial Emissions Directive
IPA	Instrument for Pre-accession Assistance
IPPC	Integrated Pollution Prevention and Control
LD	Lethal Concentration
MS	Member State
PBT	Persistent Bioaccumulative and Toxic substances
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentrations
REACH	Registration, Evaluation, Authorisation and Restrictions of Chemicals
SDS	Safety Data Sheet
SVHC	Substances of Very High Concern
KEMI	Swedish Chemicals Agency
TOR	Terms of Reference
vPvB	Very Persistent and Very Bioaccumulative



## I. Contents

I. Background/Rationale.....	1
II. Objectives of the Training .....	4
General objective .....	4
Specific objectives .....	4
Results/outputs .....	4
III. EU policy and legislation covered by the training .....	5
IV. Highlights from the Training.....	7
Day 1 – Grand Oztanik Hotel, Istanbul, 8 December.....	7
Day 2 – Grand Oztanik Hotel, Istanbul, 9 December.....	12
Day 3 – Unilever HPC Gebze Factory (Istanbul) 10 December.....	15
V. Evaluation.....	16
ANNEX I – Agenda .....	20
ANNEX II – Participants.....	25
ANNEX III – Workshop materials (under separate cover) .....	28



## I. Background/Rationale

In their third meeting, the Ministers of Environment of RENA countries, expressed gratitude to the European Commission for its continued assistance and guidance towards full transposition and implementation of the EU environment and climate acquis and welcomed the intention of the EC to provide financial assistance for the continuation of RENA program, as Environment and Climate Regional Accession Network (ECRAN).

Considering that the full approximation with the EU environment and climate acquis is a priority for all enlargement countries, the Ministers indicated the need for strengthening capacity at all levels, for awareness raising, cross-border cooperation, public participation for better institutional cooperation and more efficient legislative alignment, implementation and enforcement. Following this, the Ministers reaffirmed their commitment to continue cooperation and exchange experiences and best practices in this field.

In addition, the Ministers agreed upon the following priorities to be covered in ECRAN:

- Building capacity for correct planning, transposition, implementation and enforcement of environmental/climate acquis;
- Assistance to the enlargement countries in the preparation of accession negotiations;
- Exchange of sharing experiences between candidates and /potential candidate countries and
- Support to enlargement countries in dealing with environmental and climate issues of transboundary importance.

As part of the ECRAN package of activities, also considering the health and environmental conditions in the region, the initiation of an IED/Chemicals Working Group within ECRAN is in line with the identified priorities and project TOR.

Chemicals are an essential component in our daily lives. At the same time, some chemicals can severely damage our health and ecosystems. Others could be dangerous if not properly used, treated or controlled as pollutants. Most of the ECRAN beneficiary countries are at a different level when it comes to transposition of the EC chemicals legislation and additional efforts are needed in the area of its implementation. The REACH and CLP regulations, interlinked amongst other with the Industrial Emissions Directive (IED), are covering major chapters of chemicals legislation and Industrial pollution control.

It should be noted that REACH and CLP are regulations and therefore directly applicable to citizens in the EU. As they enter into force, they will automatically form part of Member States' national laws. In order to enable REACH and CLP to operate effectively in practice, Member States are obliged to establish the necessary arrangements for their implementation. The Regulations have EEA relevance, i.e. they are binding also for Norway, Iceland and Lichtenstein. As the EEA agreement is allowing for free movement of goods, it is important that EEA countries have the same approach in enforcing REACH and CLP as Member States, thus ensuring level playing field for their industry and high level of protection for both human health and the environment.

An important synergy between REACH and IED is that information on the substance under the registration, authorization and restriction procedures may be used to support the development of BAT reference documents. The risk assessment of substances under REACH that are manufactured or

placed on the market in quantities of 10 tonnes or more per year comprises the complete life-cycle of the substance and therefore includes the use and manufacture of these substances in industrial installations covered by this Directive and options to avoid and control emissions. In this respect, Recitals (14) and (21) of REACH state that the information yielded on substances may also be used in risk management procedures under other EU legislation.

The ECRAN beneficiaries include the representatives of Ministries of Environment of Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo\*<sup>1</sup>, Montenegro, Serbia and Turkey. In addition the other ministries and other bodies and institutions will be actively engaged in so far as their work is relevant for the scope of ECRAN.

According to the work plan of WG IED/Chemicals (Activity 2.8), the following specific tasks will be implemented:

#### 2.8.1 Organisation of the Annual meetings of the national coordinators of this Working Group

#### 2.8.2 Capacity Building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED:

- Module 1 General Introduction on chemicals, procedures of REACH/CLP and interlinkage with IED;
- Module 2 REACH specifics – procedures;
- Module 3 Technical aspects of REACH/CLP and IED;
- Module 4 REACH/CLP downstream consequences, interlinkages with IED and other legislation, accession issues.

The target group for this training were government officials and experts from background institutions from ECRAN beneficiaries responsible for, or involved in environmental and (partly) chemical issues. In order to ensure the optimal results, participation from the representatives of beneficiary countries will have to be continuous for all four modules.

This report describes the results of the implementation of the Module 4 training. The Module 4 training was carried out as a three-day regional training workshop which followed the first three trainings (Module 1, 2 and 3) focusing on explaining the main elements and procedures under REACH and CLP Regulation as well as the technical aspects of REACH and CLP. This training further discussed the most important elements (roles and responsibility, exposure scenarios, restriction, downstream consequences) and methodologies (risk assessment, PBT & vPvB assessment) in REACH and CLP. Furthermore, the lessons learned during the implementation and enforcement of REACH and CLP in Croatia and the transposition process of REACH and CLP Regulations in Turkey have been shared. The training was held in Istanbul, Turkey. The first two days training was held in Grand Oztanik Hotel in Istanbul and the third day (on-site training) was at Unilever HPC Gebze Factory located in the east part of Istanbul.

The training has been organized in collaboration with the TAIEX unit of the European Commission.

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<sup>1</sup> This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ opinion on the Kosovo declaration of independence.



Chapter 2 describes the objectives of the workshop and the topics addressed. Chapter 3 provides an outline of the relevant EU Chemical legislation (REACH and CLP). Chapter 4 presents the workshop highlights and Chapter 5 presents the evaluation. Furthermore the following Annexes are attached:

- Annex I: Workshop agenda
- Annex II: List of participants
- Annex III: PowerPoint presentations under separate cover [www.ecranetwork.org](http://www.ecranetwork.org)



## II. Objectives of the Training

### General objective

The general objective is to strengthen regional cooperation between the EU candidate countries and potential candidates in the fields of environment and climate action and to assist them on their way towards the transposition and implementation of the EU environmental and climate policies and instruments which is a key precondition for EU accession.

### Specific objectives

Within the scope of regional cooperation and assistance in transposition and implementation of EU environmental legislation, the specific objective of the assignment is to provide assistance in strengthening the institutions and building capacity in complying with the EC Chemicals legislation.

### Results/outputs

The following result is expected for this activity

- improved functioning of the environmental authorities and related authorities envisaged to be responsible for implementation of the REACH/CLP regulations and IED ;
- streamlined working methods and implementation of best practice in the region moving towards EU standards.



### III. EU policy and legislation covered by the training

The two EU regulations REACH<sup>2</sup> and CLP<sup>3</sup> contain the basic rules for chemicals control at EU level. The principal components of REACH are summarised in the following way:

- **Registration:** Manufacturers and importers have to register substances handled in quantities of least 1 tonne per year. Data (test results) have to be reported in the registration, as well as a separate risk assessment for each use recommended by the registrant (chemical safety report) if the volume handled exceeds 10 tonnes. The chemical safety report contains exposure scenarios with more or less detailed conditions for the handling of hazardous substances that must be followed;
- **Information requirements:** requirements to be met by safety data sheets for professional users of chemicals, which supplement the labelling under the CLP Regulation and contain exposure scenarios. There is also a limited obligation to inform about substances of very high concern in articles;
- **Downstream users** who are not manufacturers or importers but who use a substance in their activity may, in certain cases, be obliged to produce their own chemical safety report;
- **Evaluation** of registrations must be done firstly to check that the registrations received are correct and secondly in the form of an in-depth substance evaluation of the substances on a priority list;
- **Authorisation** has to take place for substances that have particularly hazardous properties for the environment or human health. Such substances are placed on a candidate list and transferred successively to a list in Annex XIV with a timetable for authorisation;
- **Restrictions** are bans or other restrictions on particular substances and specified uses. Annex XVII contains restriction rules for 60 substances and a long list of chemicals of very high concern for health (CMR substances) that may only be sold for professional use.

In the REACH regulation, various stakeholders will have their specific roles, responsibilities and competences identified, but the main concept of REACH is that manufacturers and importers are responsible for the safe use of chemicals by themselves and by the downstream users. The know-how regarding the hazards and potential risks of chemicals lays primarily with the manufacturers and importers and in a derived manner with the national agencies/authorities. The so called “exposure scenarios” in the REACH system are the Conditions of use for specific chemicals.

REACH is complemented by the new Regulation for Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation, January 2009). This Regulation incorporates the classification criteria and labelling rules agreed at UN level, the so-called Globally Harmonised System

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<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC .

<sup>3</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directive 67/548/EEC and 1999/45/EC, and Regulation (EC) No 1907/2006.



of Classification and Labelling of Chemicals (GHS). It is based on the principle that the same hazards should be described and labelled in the same way all around the world. Using internationally agreed classification criteria and labelling elements is expected to facilitate trade and to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals.

Enforcement of REACH and CLP means, generally, a range of actions that national authorities initiate to verify the compliance of the duty holders with REACH and CLP Regulations. For example, this includes checking whether the substance has been pre-registered or registered or verifying the presence and correctness of the Safety Data Sheets. Enforcement of REACH and CLP is a national responsibility, therefore each EU Member State, Norway, Iceland and Liechtenstein must ensure that there is an official system of controls and lay down legislation specifying penalties for non-compliance with the provisions of REACH.

The Directive on Industrial Emissions (IED) is the successor of the IPPC Directive and in essence, it is about minimising pollution from various industrial sources throughout the European Union. Operators of industrial installations operating activities covered by Annex I of the IED are required to obtain an integrated permit from the authorities in the EU countries. About 50.000 installations were covered by the IPPC Directive and the IED will cover some new activities which could mean the number of installations rising slightly.

An important synergy between REACH and the Industrial Emissions Directive is that information on the substance under the registration and authorisation procedures may be used to support the development of BAT reference documents. The risk assessment of substances under REACH that are manufactured or placed on the market in quantities of 10 tonnes or more per year comprises the complete life-cycle of the substance and therefore includes the use and manufacture of these substances in industrial installations covered by this Directive and options to avoid and control emissions. In this respect, Recitals (14) and (21) of REACH state that the information yielded on substances may also be used in risk management procedures under other EU legislation.



#### IV. Highlights from the Training

Reference is made to Annex I for the agenda and Annex III for the presentations.

##### Day 1 – Grand Oztanik Hotel, Istanbul, 8 December

1. The workshop was opened by Mr. Ike van der Putte, the ECRAN-ECENA Coordinator, with a warm welcoming. Following the welcome, he has given an introduction on ECRAN (Environment and Climate Regional Accession Network). The information of ECRAN has been given including the project summary, results to be achieved, structures and planned activities. Furthermore, Mr. van der Putte also explained the training program end logistics.
2. An introductory round was held among the participants with the question on the years of experience in the field of environment, IPPC/IED and chemicals (REACH/CLP). The results showed that most of participants have reasonable knowledge and experience on chemicals (REACH/CLP).

Field	Years of experience		
	1 – 5 year	5 – 10 years	> 10 years
Environment	1	2	5
IPPC/IED	1	3	2
Chemicals (REACH/CLP)	8	4	7
Others		1	2

Among the participants, 2 have participated in all the 4 workshops under IED/Chemicals (ECRAN), 5 participated in 3 workshops, 6 participated in 2 workshops, and 17 participated in the ECRAN IED/Chemicals training workshop for the first time.

3. Mr. Arnold van der Wielen gave a brief introduction on REACH and CLP Regulation which have been explained in details in the last three trainings. Besides refreshing the knowledge on principles, main elements, scope, legal structure, timelines and ECHA guidance documents of REACH and CLP, Mr. van der Wielen also gave an overview on EU chemicals management with REACH and CLP which shows a complete picture on EU risk management of chemicals.



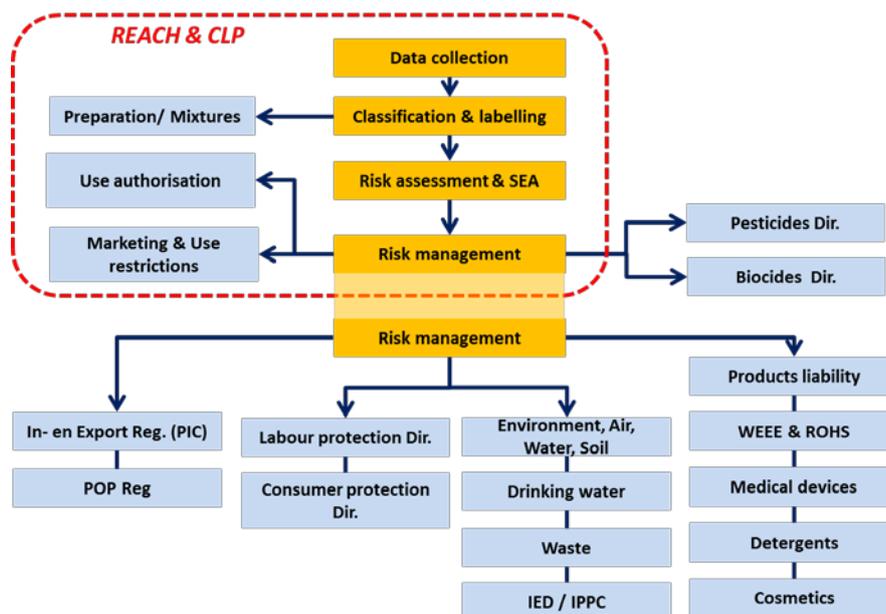
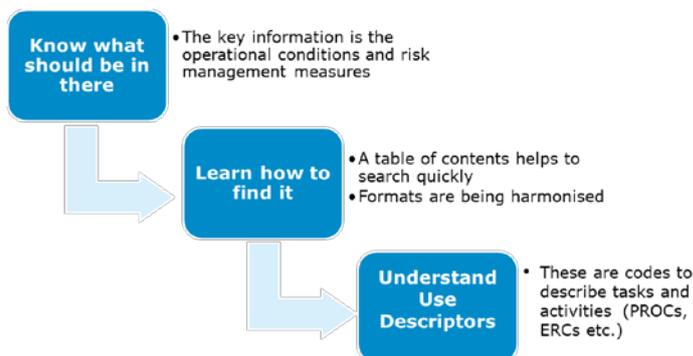


Figure 1 EU chemicals management with REACH/CLP

4. In the next presentation, Mr. van der Wielen discussed in details of the roles and the responsibilities of industry. The role of industry under REACH is a complicated issue. One company can have several roles. The role of a company defines the responsibilities and obligations. In this presentation, the definition of each role under REACH has been discussed and corresponding examples and exercises have been given to the participants.
5. After the coffee break, Mr. Martin Murin introduced the risk assessment methodology and tools used in US and in EU. Furthermore, the basic terms and methodology in risk assessment including hazard assessment and effect assessment/exposure assessment have been given. The important terms in (eco) toxicology such as LC50 (Lethal Concentration 50%)/LD50 (Lethal Dose 50%)/, DNEL (Derived No Effect Level), DMEL (Derived Minimal Effect Level), EC50 (Effective Concentration 50%), PEC (Predicted Environmental Concentration) and PNEC (Predicted No Effect Concentrations) were explained in theory and with given examples.
6. Mr. Murin has further given an introductory presentation on PBT and vPvB assessment. This presentation covers the topics such as the objective, criteria, testing strategies, steps of PBT and vPvB assessment. How to interpret the outcomes of the assessment has also been discussed.
7. The next presentation was given by Mr. van der Wielen on Exposure Scenarios (ESs). This presentation included the general topics such as format and content of ES, major terms used in ESs and how should Downstream Users (DUs) understand ESs. When the uses/conditions are not covered in the ESs delivered by supplier, the DU should take actions:
  - Contact supplier to have the ES updated with use covered ;
  - Change process to implement the ES;
  - Substitute with another substance or process, or stop the activity;
  - Find a supplier providing ES that covers company's conditions;

- Prepare a downstream user chemical safety report (DU CSR) to establish safe conditions for the use not covered in ES and reported unsupported use to ECHA.



**Figure 2** How to read Exposure Scenarios (ESs)

- Mr. van der Wielen also discussed restriction under REACH including the topics of history and structure of REACH Annex XVII, overlap by other legislation, and challenges in enforcement. An example has been given in the presentation.



**Figure 3** Consumer product for repairing bicycles

- Ms. Ahu ÇEKİM, an expert in the Ministry of Environment and Urbanization in Turkey, has given an overview of current Turkish legal framework for chemical management legislation and shared the progress of Turkey on the implementation of the EU REACH Regulation. Turkey has transposed the most important EU legislation on chemical management (see the overview table below). Awareness of major groups (manufacturers, importers, downstream users of chemicals) and decision makers has been raised. Chemicals Helpdesk & Chemicals Registering System have been established. Furthermore, draft legislation (KKDİK By-Law) and guidelines on REACH have been prepared.

**Table 1** Transposition of EU chemical legislation to Turkish by-law

EU-DIR./REGULATION	TURKISH REGULATION
67/548/EC Dir.	By-law On Classification, Packaging And Labelling Of Dangerous Substances And Preparations (26.12.2008/27092) (CPL By-law)
99/45/EC .Dir.	
1272/2008/EC CLP Reg.	By-law On Classification, Packaging And Labelling Of Dangerous Substances And Preparations (26.12.2008/27092) (CPL By-law)
91/155/EC Dir.-REACH Annex II	By-law On The Preparation And Distribution Of Safety Data Sheets (26.12.2008/27092)
In parallel to REACH Annex II	By-law on the Safety Data Sheets of Hazardous Substances and Mixtures (13.12.2014/29204)
In parallel to REACH Annex XVII	By-law On Restrictions And Prohibitions Of Hazardous Substances And Mixtures (26.12.2008/27092; last rev. 27.11.2014/29182)
440/2008/EC Dir.	By-law On Test Methods Applied For Determining The Physicochemical Toxicological And Ecotoxicological Properties Of The Substances And Mixtures (11.12.2013/28848)
(in parallel to 793/93/EEC) NATIONAL NEEDS	By Law on Inventory and Control of Chemicals (26.12.2008/27092)

10. Furthermore, all the participating countries shared the implementation status of the EU chemical legislation in their own countries. The discussion is summarized below.

### Albania

During the period November 2014 – March 2015 Ministry of Environment, in collaboration with the ECRAN Project, European Commission TAIEX unit and the Swedish Chemicals Agency (KEMI), has organized 5 TAIEX Expert Mission for being assessed on approximation of the legislation on chemical management field, based on the relevant EU Regulations.

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

In the 5 TAIEX Expert Missions representatives participated from the Ministry of Health, Public Health Institute, Ministry of Economy, Trade and Enterprises, Ministry of Energy and Industry, Ministry of Agriculture, Rural Development and Water Administration, National Environment Agency, General Directorate of Customs and the National Licensing Center.

During this TAIEX assistance period the following legislation has been prepared:



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- a) The draft law on “Chemicals management”, which has partially transposed REACH Regulation no. 1907/2006 and CLP Regulation (EC) Nr.1272/2008. The draft law is approved by Council of Ministers with DCM no. 927, dated 18.11.2015. Actually, the draft law is expected to be discussed in Parliamentary Commissions. Its approval is foreseen within December 2015;
- b) Draft Decision “On the classification, packaging and labeling of chemicals”, that partially transpose CLP Regulation Nr. 1272/2008 “On the classification, labeling and packaging of substances and mixtures”;
- c) Draft Decision “On import and export of dangerous substances”, which aims to transpose in Albanian legislation EC Regulation 649/2012 on export and import of dangerous chemicals;
- d) Draft Decision “On restriction of production, placing into the market and use of several chemicals and dangerous articles”, which partly transposes the Annex XVII of REACH Regulation;
- e) Draft Decision “On the list of Substances of Very High Concern (SVHC), criteria for including substances in the list of SVHC and issuing of a conditional authorization for the continuing use of SVHC”, which partly transposes the Annex XIII, Annex XIV and XVI of REACH Regulation.

Approval of the above four draft decisions is foreseen after the approval of the law on chemicals management (March 2016).

### **Bosnia and Herzegovina**

The environmental legislation in the district and two entities is generally in line with the EU. Chemicals legislation is however different. The law on chemicals in the Federation has yet to be adopted. A national plan for implementing the Stockholm Convention on Persistent Organic Pollutants has been drafted but has yet to be adopted. An inventory of chemicals has been made in the Republika Srpska and there is legislation on SDS. A helpdesk is however not available yet.

### **Kosovo\***

- a) There is no inventory/register for chemicals currently. However, it is on the plan.
- b) There is a new law which transposes the CLP Regulation.
- c) There is a new draft on the PIC regulation.
- d) There is a new regulation on detergents.
- e) There is a plan for a regulation on SDS. The new version is being prepared due to the update of CLP.
- f) The law on IPPC is in place.
- g) SEVESO III will be transposed in 2016. There are 22 SEVESO II installations in Kosovo.
- h) There are 25 IPPC installations in operation. Two IPPC permits have been issued (one for a cement plant and another one for a ferro-nickel plant).



### Former Yugoslav Republic of Macedonia

Macedonia has an inventory for licensed chemicals companies. There is an operational helpdesk.

### Montenegro

- a) Montenegro has transposed REACH Annex XIV and Annex XVII.
- b) National laws transposing IPPC and IED Directives are in place.
- c) In 2016 new laws on IED and SEVESO III are expected.
- d) The new law on biocides has been drafted in 2015 which has been sent to parliament for approval.
- e) Currently there is no register for chemicals. There is a plan to have a register.

### Serbia

- a) Since 2000 there was a national law on biocides referring the old EU Biocides Regulation. Within the framework of a current IPA project, this national law will be revised based on the new EU Biocides Regulation and is expected at the end of 2016.
- b) Since 2004 there is a new law on IPPC. There is a plan to issue all the IPPC permits before 2020. Until now 17 IPPC permits have been issued. Due to the difficulties to accomplish the 2020 target, Serbia is negotiating for a transitional period.
- c) IED will be adopted in the national law in 2018.

### Turkey

- a) Chemical inventory is replaced by registration.
- b) The national helpdesk for REACH and CLP has been transferred to the Ministries. IMMIB (Industry Association) has still a helpdesk for the industry.
- c) There is a poisoning center. .
- d) For the transposition of EU chemical legislation, please see the overview in Table 1.

### Day 2 – Grand Oztanik Hotel, Istanbul, 9 December

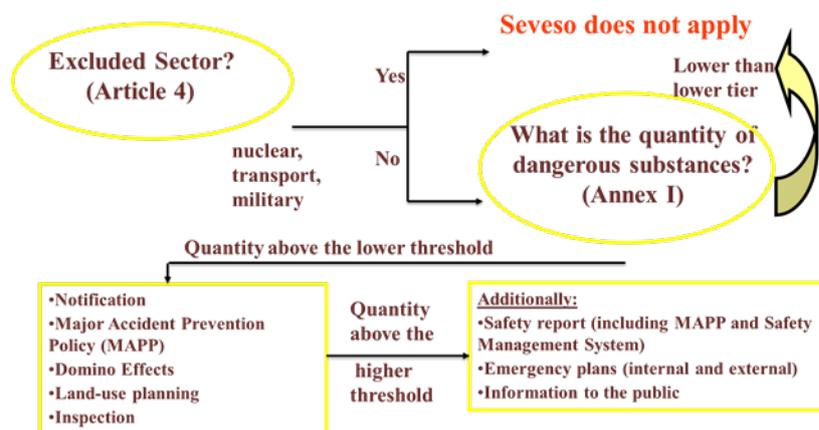
1. Ms. Sandra Pezelj Meštrić has shared Croatian experience on the accession issues regarding REACH and CLP Regulations. Ms. Meštrić showed a short overview on REACH and CLP timelines, and the relevant accession timelines for Croatia. On the road of Croatia to EU membership, within one night (June 30 2013), the obligations of Croatia have changed from non-EU country to the 28th EU Member State. Based on the lessons learnt, Ms. Meštrić has given recommendations to the EU candidate countries. These not only included a transparent communication between the negotiation team and various stakeholders and experts but also a number of practical recommendations with reference to the allocation of responsibilities from the Only Representative (OR) to the manufacturer, and a well informed negotiation team on the various bottlenecks.





**Figure 4** Transparent communication within the candidate country

2. Ms Miljenka Kliček, a senior environmental inspector of the Ministry of Environment and Nature in Croatia, talked about the implementation of chemical legislation in Croatia from the environmental perspective. She shared her experiences on the enforcement aspects of chemical legislation in Croatia. The topics included legal framework, enforcement strategies, relation to other legislation-Seveso III, cooperation and coordination between enforcement authorities and minimum criteria for inspection. The REACH and CLP Regulations have a considerable impact on the Seveso Directive.
3. Mr Ike van der Putte has given an introductory explanation on Seveso Directive including the aim, the scope and main obligations, methods and definition. He further discussed the definition and criteria of upper and lower tier Seveso installations and the obligations of the Seveso installations. Moreover, the correlation of Seveso with other legislation such as CLP, REACH, GHS, IPPC and Labour safety was also discussed.



**Figure 5** Seveso Directive – Scope & main obligations

4. The recent developments on the interlinkage of REACH and IED were presented by Ms Gisela Holzgraefe, a senior expert of Ministry for Energy, Agriculture, the Environment and Rural Areas of Land Schleswig-Holstein in Germany. In her presentation, Ms Hozgraefe used three examples, namely baseline report – waste, new classification of formaldehyde and consequences, and use of trace element mixtures for biogas plants to explain the interactions of REACH/CLP and IED.

Furthermore, the development of BREF documents and the recommendations of IMPEL project in 2014 were discussed.

5. Ms Holzgraefe further showed and explained the guidance for REACH inspection, including:
  - Sources for information on inspections
  - Role and responsibilities of FORUM
  - Guidance on REACH/CLP inspections
  - Minimum criteria for REACH/CLP inspections
  - Guidance in the EU MSs
  - Results of FORM enforcement projects
  - Development of Guidance Document by FORM

Furthermore, Ms Holzgraefe also shared the approach in Schleswig-Holstein on inspection of REACH and CLP.

6. At the end, Mrs Shufan Keetlaer-Qi has talked about the hazard communication – Safety Data Sheets (SDSs). The presentation included the legal text of SDS and the general requirements for the 16 sections in SDS. As an exercise, two example SDSs were evaluated by the participants against the requirements.



## Day 3 – Unilever HPC Gebze Factory (Istanbul) 10 December



For the site visit Unilever HPC Gebze Factory in Turkey was selected. Unilever Turkey is leading the “NAMET & RUB” (North Africa, Middle East, Turkey and Russia) Cluster. Product Categories are Home Care, Personal Care, Refreshment and Food. Unilever Turkey has tripled its turnover in the last ten years and became one of the top ten countries of Unilever with 29 brands, 5000 employees, 8 factories.

Gebze is located 70 km east of Istanbul and 50 km west of Kocaeli. Gebze Factory initiated its production in 1975 as a Home Care production Site. It became a Home and Personal Care (HPC) production Site when Elida Cosmetics joined in 1996. All HPC brands, except soaps & deodorants, are produced at the Gebze Factory for Unilever Turkey.

The participants have been divided into three groups that focused on different parts of the industry.

The findings of each group are summarized below.

### Group 1 Chemical management

- Unilever EU global team takes care of REACH registration of the substances used in the products. The team is also responsible for the compliance of the products exported to Italy (the EU).
- The quality of raw material is checked and a certifying system is in place.
- Enzymes are registered under REACH.

### Group 2 Safety measures

- HPC Gebze Factory is a high tier Seveso installation. All the safety measures are in-line with Seveso II requirements. The safety report will be ready in January 2016.
- SDSs are compliant with the relevant Turkish by-law and are available at the workplace.
- Workers are trained regularly on understanding of the SDSs.

### Group 3 Waste

- The waste is handled by licensed waste companies.
- Most of the waste is recycled.
- A plan has been drafted to clean up the waste after moving the present plant to another location.

## V. Evaluation

The following summary of the training evaluation report, developed on the basis of analysis of the training questionnaires can be given. A number of 25 participants filled the evaluation form. It shows that the expectations of the workshop were met. The participating countries expressed their appreciation to this training and the know-how 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.

All trainees indicated that their expectations for the workshop were met. Most of the trainees indicated that the training was of a high quality and useful. The well preparation and knowledge of the trainers were appreciated.



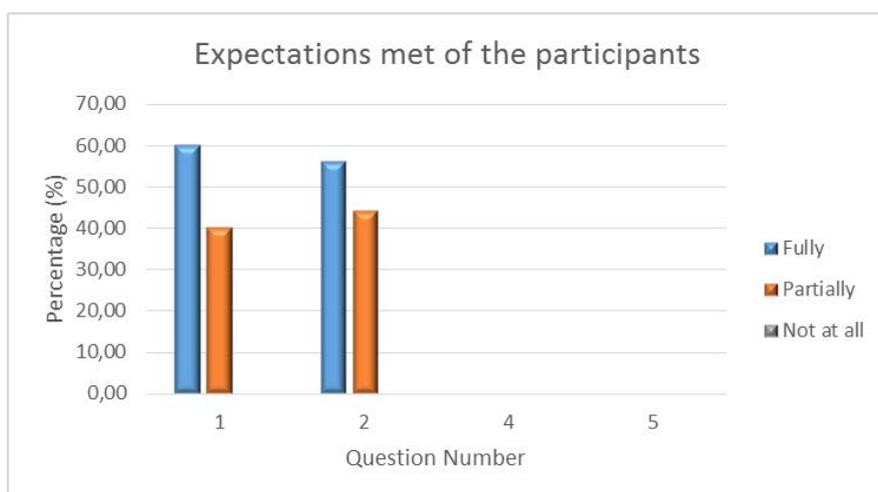
### Statistical information

1.1	Workshop Session	Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – Technical aspects, downstream consequences and accession issues
1.2	Facilitators name	Ike van der Putte/ Arnold van der Wielen/Gisela Holzgraefe/ Martin Murin/Shufan Keetlaer-Qi
1.3	Name and Surname of Participants (evaluators) optional	As per participants' list

### Your Expectations

Please indicate to what extent specific expectations were met, or not met:

My Expectations	My expectations were met		
	Fully	Partially	Not at all
1. Filling gaps in knowledge (several REACH/CLP IED), general and specific	(60%)	(40%)	
2. Practical experience of the new Member States and Candidate Countries	(56%)	(44%)	

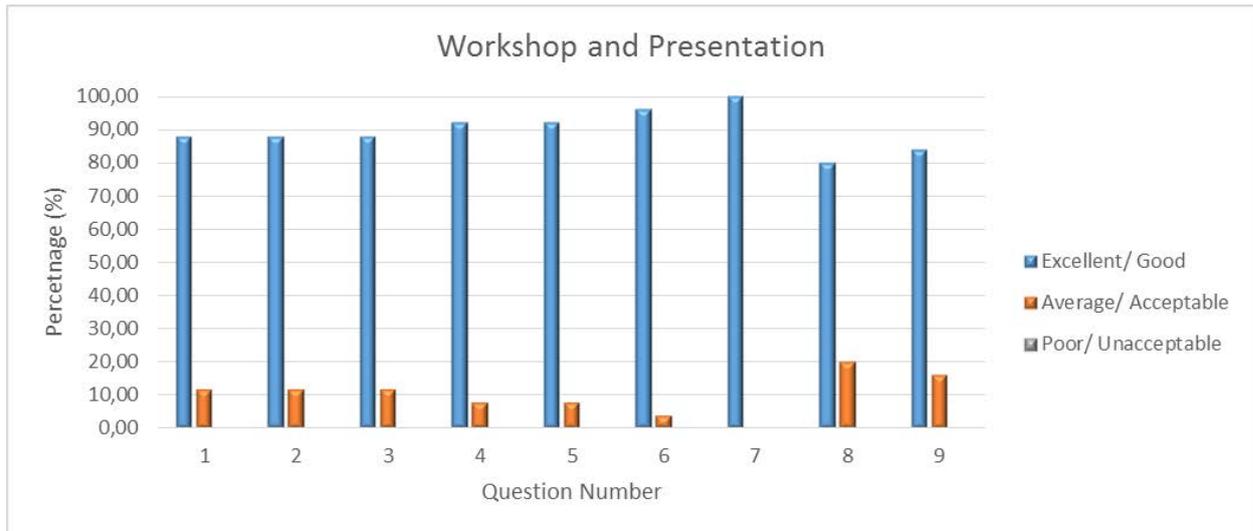


### Workshop and Presentation

Please rate the following statements in respect of this training module:

Aspect of Workshop	Excellent	Good	Average	Acceptable	Poor	Unacceptable
1. The workshop achieved the objectives set	 (48%)	 (40%)	 (12%)			
2. The quality of the workshop was of a high standard	 (44%)	 (44%)	 (12%)			
3. The content of the workshop was well suited to my level of understanding and experience	 (44%)	 (44%)	 (12%)			
4. The practical work was relevant and informative	 (56%)	 (36%)	 (8%)			
5. The workshop was interactive	 (56%)	 (36%)	 (8%)			
6. Facilitators were well prepared and knowledgeable on the subject matter	 (60%)	 (36%)	 (4%)			
7. The duration of this workshop was neither too long nor too short	 (52%)	 (48%)				
8. The logistical arrangements (venue, refreshments, equipment) were satisfactory	 (56%)	 (24%)	 (16%)	 (4%)		
9. Attending this workshop was time well spent	 (56%)	 (28%)	 (16%)			





### ***Comments and suggestions***

I have the following comment and/or suggestions in addition to questions already answered:

#### **Workshop Sessions:**

- Well prepared
- Appropriate level for the participants
- Answers given to a large number of questions

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#### **Facilitators:**

- No comments

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#### **Workshop level and content:**

- In future, more information on interlinkage between environmental topics and REACH&CLP are required.
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## ANNEX I – Agenda

### Day 1 : December 8, 2015

**Topic: Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – Technical aspects, downstream consequences and accession issues**

**Chair and Co-Chairs: Ike van der Putte/Ahu Cekim**

Start	Finish	Topic	Speaker	Sub topic/Content
<b>08:30</b>	<b>08:45</b>	<b>Registration</b>		
08:45	09:00	Opening	Mr. Kemal DAĞ Deputy General Director, Ministry of Environment and Urbanisation  Ike van der Putte (ECRAN –ECENA Coördinator)	<ul style="list-style-type: none"> <li>- Welcome</li> <li>- Introduction of trainers</li> <li>- Introduction of participants</li> </ul>
09:00	09:15	Introduction	Ike van der Putte (ECRAN –ECENA Coördinator)	<ul style="list-style-type: none"> <li>- Explanation of the training programme</li> <li>- Information on ECRAN</li> <li>- Defined ECENA activities</li> </ul>
09:15	10:00	General introduction on REACH and CLP Regulations	Arnold van der Wielen (ECRAN expert)	<ul style="list-style-type: none"> <li>- Introduction and recapitulation on the main elements of REACH and CLP Regulations (such as What, Who, When and How)</li> </ul>
10:00	10:45	REACH Specifics – Roles & Responsibility case study	Arnold van der Wielen, ECRAN	<ul style="list-style-type: none"> <li>- Identifying the roles of organization</li> <li>- Defining the responsibility for specific role</li> </ul>
10:45	11:00	<b>Coffee Break</b>		
11:00	11:45	Risk assessment	Martin Murin	<ul style="list-style-type: none"> <li>- Summary for the participants with the purpose of understanding how the</li> </ul>



				environmental risk is assessed.
11:45	12:30	PBT & vPvB assessment	Martin Murin	<ul style="list-style-type: none"> <li>- Definitions of PBT and vPvB chemicals</li> <li>- Determination of PBT and vPvB chemicals</li> </ul>
12:30	13:30	<b>Lunch Break</b>		
13:30	14:15	Exposure scenarios in general	Arnold van der Wielen	<ul style="list-style-type: none"> <li>- The format and content of exposure scenarios</li> <li>- Major terms used in exposure scenarios</li> <li>- Understanding of exposure scenarios</li> </ul>
14:15	15:00	Restriction under REACH	Arnold van der Wielen	<ul style="list-style-type: none"> <li>- How the EU MSs deal with Annex XVII to REACH (restricted chemicals under REACH) as one of the outcomes of REACH</li> </ul>
15:00	15:15	<b>Coffee Break</b>		
15:15	16:00	Implementation in Turkey	Ahu Cekim (Turkey)	<ul style="list-style-type: none"> <li>- Overview of the implementation in Turkey</li> </ul>
16:00	17:00	Round table discussion of the participating countries with presentations	Ike van der Putte Participants and trainers	<ul style="list-style-type: none"> <li>- Existing organisation structures for implementation of REACH in the participating countries.</li> </ul>



## Day 2 : December 9, 2015

**Topic: Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – Technical aspects, downstream consequences and accession issues**

**Chair and Co-Chairs: Ike van der Putte/Ahu Cekim**

Start	Finish	Topic	Speaker	Sub topic/Content
9:00	9:15	Welcome coffee and summary of day 1	Ike van der Putte	
9:15	10:15	REACH/CLP implementation and enforcement in Croatia	Sandra Pezelj Meštrić Miljenka Kliček Directorate for Inspection Ministry of Environmental and Nature Protection	- Experience in Croatia on approximation/implementation of chemicals legislation in particular enforcement aspects in REACH and CLP
10:15	10:45	Downstream consequences	Ike van der Putte	- SEVESO as a case
10:45	11:00	<b>Coffee Break</b>		
11:00	11:45	Downstream consequences	Ike van der Putte	- Case exercise SEVESO
11:45	12:30	Interlinkage REACH with IED	Gisela Holzgraefe (TAIEX expert)	- The IMPEL work is summarised on this the IED/REACH interlinkages
12:30	13:30	<b>Lunch Break</b>		
13:30	14:15	Manual for REACH inspection	Gisela Holzgraefe (TAIEX Expert)	- General explanation of the Manual for REACH inspection - Recent relevant developments in IMPEL
14:15	15:00	SDS and cases	Shufan Keetlaer-Qi	- Contents of SDS and case evaluation



15:00	15:15	<b>Coffee Break</b>		
15:15	16:15	SDS and cases	Shufan Keetlaer-Qi	- Contents of SDS and case evaluation (part 2)
16:15	17:00	Preparation visit Factory	Gisela Holzgraefe Participants and trainers	

## Day 3 : December 10, 2015

<b>Topic: Visit to PILOT FACTORY</b>				
<b>Venue: Unilever Türkiye (<a href="http://www.unilever.com.tr/">http://www.unilever.com.tr/</a>)</b>				
<b>Saray Mahallesi Dr. Adnan Büyükdeniz Caddesi No:13 34768</b>				
<b>Ümraniye/İstanbul, Turkey</b>				
Start	Finish	Topic	Speaker	Sub topic/Content
8.00	9.30	Transport of workshop participants to the pilot factory from the hotel		
9:30	12.00	Visit to FACTORY	All participants	
		Preliminary discussion in the factory office		- Review documentation (chemicals information (such as SDS, labels) monitoring data, quality checks, site plans and permits. Is necessary documentation in place. Comments and questions
		Divide into groups with chairman and reporter each. Chairman has allocated specific responsibilities to each member of the group		



		Site visit		<ul style="list-style-type: none"> <li>- Request site staff to provide guides: groups to see the entire site, but focus on areas: like labels of chemicals, SDS, handling storage, dust abatement, waste handling and filling stations, cleanliness of factory, evaluate surrounding area, maintaining and sampling.</li> <li>- Each member of the group will make their own inspection and make notes and compare results later in the group</li> </ul>
		Return to Meeting room at the factory		<ul style="list-style-type: none"> <li>- General comments on visit site and any further questions</li> </ul>
12.30	13.30	<b>Lunch Break</b>		
13.30	14.15	Visit report preparation in groups		
14.15	14.45	Presentation of reports by members of the group		<ul style="list-style-type: none"> <li>- Conclusions of site visit</li> <li>- Suggested follow-up actions</li> </ul>
14.45	15.00	<b>Coffee Break</b>		
15:00	15:30	Round table discussion of the participating countries	Ike van der Putte Participants and trainers	<ul style="list-style-type: none"> <li>- Evaluation and follow-up programme</li> </ul>
15:30	17:00	<b>Return to the hotel</b>		
17:00		<b>Closure</b>		



## ANNEX II – Participants

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### **ANNEX III – Workshop materials (under separate cover)**

Workshop materials including presentations and exercises, can be downloaded from:

[http://www.ecranetwork.org/Files/ECRAN\\_IED\\_Chemicals\\_WG\\_Workshop\\_4\\_presentations.pdf](http://www.ecranetwork.org/Files/ECRAN_IED_Chemicals_WG_Workshop_4_presentations.pdf)



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