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# Environment and Climate Regional Accession Network (ECRAN)

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Workshop report  
Activity 2.8.2  
Capacity Building on  
Compliance with  
Chemical Legislation (1<sup>st</sup>  
Regional Workshop)

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Podgorica, 13 -15 May 2014

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**WORKSHOP REPORT**  
**Activity 2.8.2**

**CAPACITY BUILDING ON COMPLIANCE WITH CHEMICAL  
LEGISLATION, WITH EMPHASIS ON REACH/CLP LINKED TO IED  
(1<sup>st</sup> Regional Workshop)**

**Podgorica, 13 -15 May 2014**

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## 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 programme, 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, authorisation 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, Croatia, 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 1 training. The Module 1 training was carried out as a three-day regional training workshop focusing on the general introduction on the main elements and procedures under REACH and CLP Regulation, the importance of chemical substances in permitting and inspection of industrial installations (IED permitting and inspection). And the relation between IED and REACH. The training was held in Montenegro, the first two days in Podgorica and the third day on site at an acetylene production factory (Progas) located in Herceg Novi, Montenegro.

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

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

<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.

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.

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation 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.

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 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 labeling 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

## IV. Highlights from the training workshop

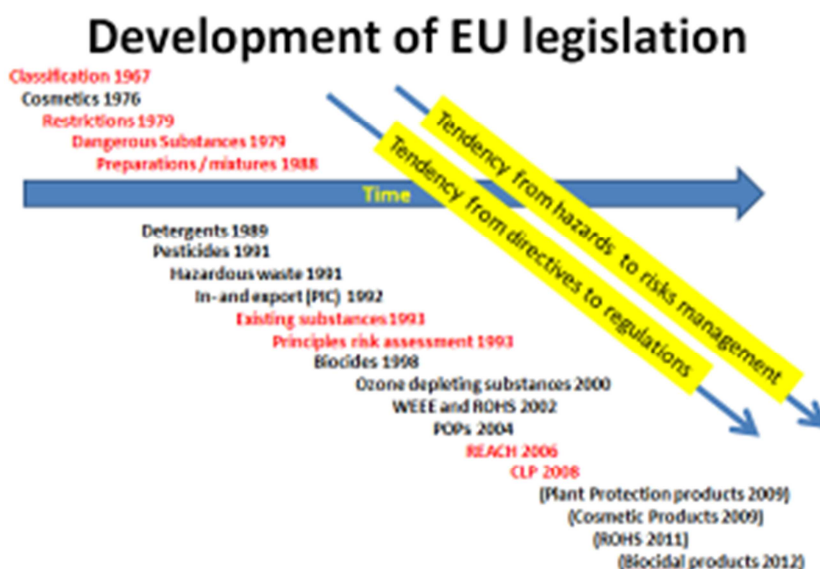
Reference is made to Annex I for the agenda and Annex III for the presentations.

### *Day 1 – Best Western Premier Hotel, Podgorica, 13 May*

1. The workshop was opened by Mr. Ike van der Putte with a short welcoming and introduction on ECRAN (Environment and Climate Regional Accession Network). The information of ECRAN has been given including project summary, results to be achieved, structures and planned activities.
2. An introductory round was held among the participants with the question on the years of experience in the field of environment, chemicals (REACH/CLP) and IPPC/IED. The results showed that most of participants have limited knowledge and experience on chemicals (REACH/CLP).

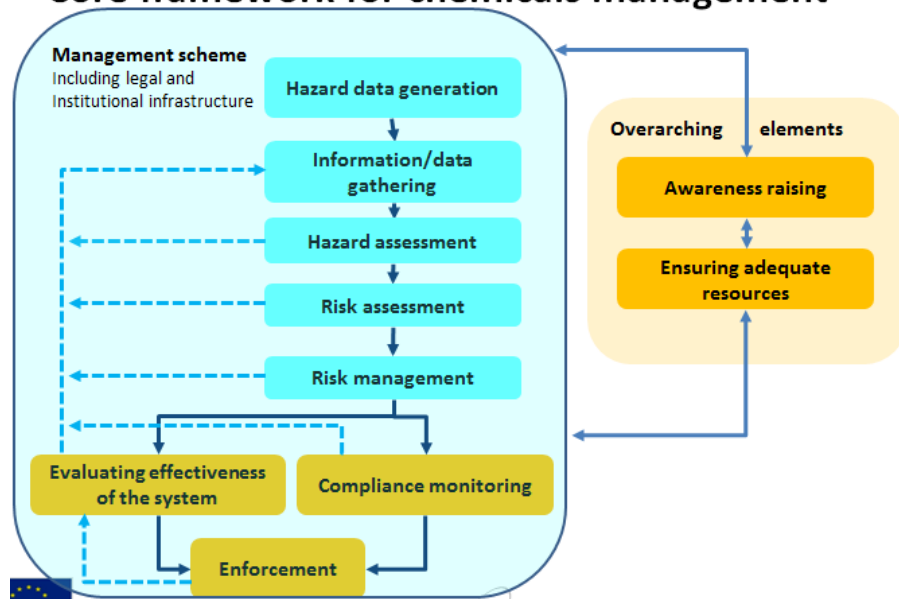
	Years of experience		
	0 – 1 year	1 – 5 years	5 – 10 years
Environment	4	9	7
Chemicals (REACH/CLP)	7	10	
IPPC/IED	11	3	4

3. Mr. Arnold van der Wielen has given an introduction on chemical management in the EU. It included the structure, development and (precautionary) principle of EU legislation with the emphasis on the chemical management before and with REACH. He has pointed out that risk management is the core for chemicals management. The management of mercury globally and in the EU has been discussed as a specific case.
4. Furthermore, Mr Arnold van der Wielen has also discussed the history and reason of REACH/ CLP, and introduced the principles, main elements, scope, core issues and legal structure of these two regulations.





## Core framework for chemicals management



5. A roundtable discussion has been held. During the discussion, each participating country has presented the approximation status of chemical management with the emphasis on REACH/CLP/IED. The main discussion has been summarized below:

### Montenegro

The main problem is that there is no inventory/register on chemicals at national level.

- REACH has been adopted in the national chemical law and restrictions have been translated;
- Screening report of the acquis was sent to the Commission;
- A inventory/register of chemicals will be developed under the IPA project for the substances that are imported in quantities of more than 100 kg per year;
- No poisoning center in place;
- No chemical production and only chemical import;
- No Helpdesk yet and AARHUS center is used;
- Chemicals are under Ministry of Spatial Planning and Environment;
- No formal cooperation between the ministries;
- Penalties are included in the national law.

### Turkey

The main difficulty is the Safety Data Sheet (SDS) and related communication.

- Legislation aiming at alignment with REACH and CLP has been drafted in 2013;
- Chemicals inventory is in place but there are difficulties with data processing due to lack of staff;
- Competent authority has been set up;
- Ministry of Environment and Urbanisation (MoEU)-Ministry of Transport, Maritime Affairs and communications (MoTMC)-Ministry of Health (MoH) set up a website;
- Helpdesk is taken over by the Ministry from IMMIB;
- No poisoning center established;
- Penalties are included in the national law;
- IPPC legislation in place, companies under control.

### Albania

No chemical inventory/register is available and there are difficulties on inter-ministerial cooperation.

- There is a law on chemicals dating from 2003;
- Ministry of Environment (MoE) has been drafting new law to implement REACH and CLP. It is expected to be approved in 2014;
- No inventory/register for chemicals;
- Penalties and helpdesk will be included in the new law;
- The responsibility of each ministry will be defined in the new law.

#### *Macedonia*

Lacking of human resource is one of the problems.

- No production of chemicals, only import;
- New law on chemicals from November 2010;
- Preparing rulebooks and list of chemicals;
- Has intersectoral body consisting of 11 institutes and industry;
- Helpdesk was set up in 2011 and it is now out of order;
- National poisoning center needs to be established according to the new chemical law;
- Has a system to control transportation and import of chemicals (custom administration).

#### *Serbia*

Lacking of capacity to process and evaluate the information/data from industry is the main problem.

- The new law on chemicals translating REACH and CLP from 2009 which accepts the definition of REACH and CLP;
- National chemical register has been established for the chemicals over 100 kg per year. Companies are sending the information every year. Register built based on Swedish model with help of SIDA;
- Has Helpdesk and national poisoning center;
- Information on chemicals is used and partly shared with the poisoning center (non-confidential information).

#### *Kosovo*

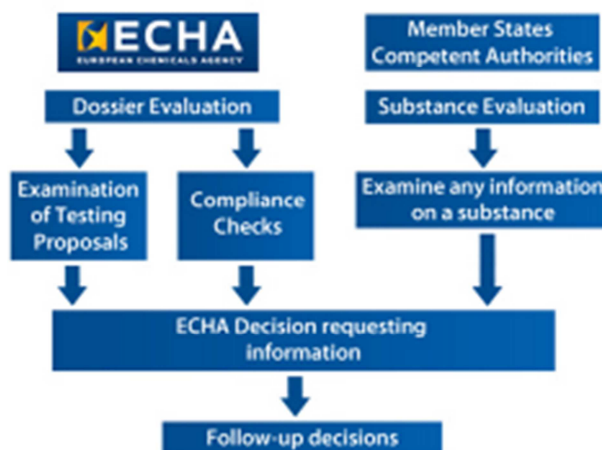
Kosovo is facing the problems of having no chemical inventory/register and lacking human resource.

- No chemical production and only import;
- Has chemicals law from 2007 and new chemical law in 2014;
- Adopted an administrative instruction on risk assessment (Ministry of Health);
- Ministry of Environment is the coordinatory body;
- No chemical register and national poisoning center;
- A new law which transposing PIC is planned in 2014.

6. Mr. Martin Murin introduced the registration under REACH from the procedural point of view. The topics covered include REACH registration deadline, registration scope, the results for the first two registration deadlines, the content of registration dossier, Chemical Safety Report (CSR), communication in the supply chain, Safety Data Sheet (SDS), as well as late pre-registration.

7. The other main elements, of REACH, evaluation, authorisation and restriction, were also presented by Mr. Murin. The procedures of evaluation of dossiers and substances by ECHA and EU Member States were showed. Furthermore, the principle and procedure of REACH authorisation and restriction have been discussed. Following the presentations, two case studies were presented to the participants. One case study is regarding the role and responsibilities under REACH and

#### **Evaluation: Overview**



the other case study is on the definition of substance, mixture and articles, and the relevant obligations.

8. At the end, Mrs Shufan Keetlaer-Qi presented the IT organisation under REACH. In this section the development, function, difference and example of REACH IT and IUCLID 5 were given.

### *Day 2 – Best Western Premier Hotel, Podgorica, 14 May*

1. In opening the second day, Mr van der Putte summarized the outcomes of the workshop on the first day. The subjects such as main elements of REACH and the registration process (who, what, when and how) were presented again in a summarized manner to the participants.

2. Mr. Murin has provided the knowledge on how the information under REACH is being shared in the consortium and (pre-)Substance Information Exchange Forum (SIEF). This includes the information on the consortium, pre-SIEF and SIEF, the legal context, formation and functions of SIEF, as well as SIEF activities.

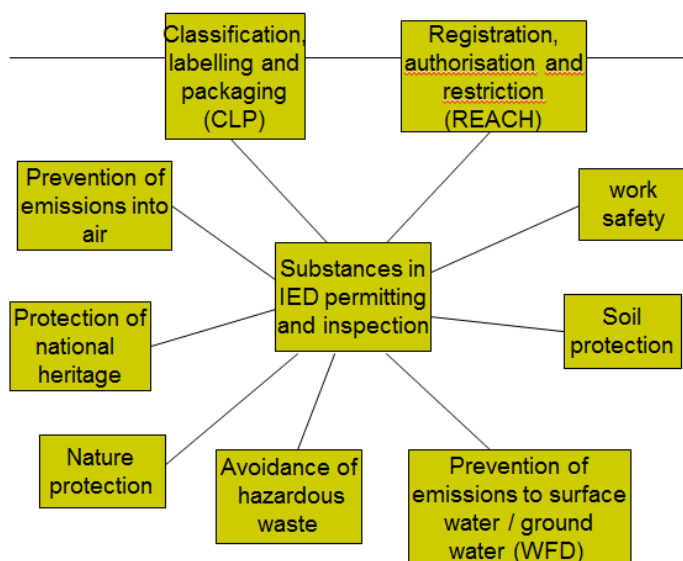
3. The basic knowledge on toxicology and risk assessment has been given by Mr van der Putte. He presented the principle in toxicology and risk assessment, discussed the approaches used for chemical risk assessment under REACH, the computer models which can be used and the ECHA guidance documents.

4. Mrs Keetlaer-Qi presented the CLP Regulation which includes the content of the regulation, the timelines and the changes of the new classification and labelling system compared to the old system. Subsequently, the implementation of CLP was demonstrated with a few examples, and hazard and safety communication were discussed.

5. Mr. van der Wielen further discussed Chemical Safety Assessment and SDS. The procedure of the risk assessment has been explained to the participants with the format and structure of SDS.

6. Enforcement of a regulation is the crucial step of the regulatory cycle. Mr. Van der Putte presented the enforcement of REACH and CLP in the EU Member States. The topics include the requirements for enforcement, and the function and activities of the FORUM.

7. Ms Gisela Holzgraefe as an IMPEL expert presented the importance of substances in permitting and inspection of industrial installations. This presentation gives overview on the regulatory cycle of IED permitting and inspection, relevant procedures on substances in IED/REACH, and the relation between IED and REACH.



8. In another presentation of Ms Holzgaefe, she discussed the relevance of interaction between IED and REACH, analyzed the interlink between REACH and IED, and demonstrated the importance of substances in IED-inspection tasks.

### *Day 3 – Progas d.o.o., Herceg Novi, Montenegro, 15 May*



For the site visit the Progas (Messer Group) located in Herceg Novi, Montenegro was selected. The plant (IPPC/SEVESO lower tier) produces Acetylene based on the calcium carbide process.

The participants have been divided into four groups that focused on different part of the factory.

The findings of each group are summarized below.

#### ***Group 1 (supply of raw material)***

The label for calcium carbide was noted not to be in the national language of Montenegro. However, it might be the case that it is not required by the national law. The SDS of acetylene is not on site and can be faxed from the head office to the factory on request. The quality certificates of product are available. The IPPC permit has been issued to the company Progas and not to the German mother company (Messer Group).

#### ***Group 2 (production process and air emission)***

The working procedures followed in Progas are according to those required by EU legislation as the mother company is of German origin. For example, the color of gas bottles are standardized according to the EU requirements. Progas monitors the concentration of the acetylene gas in the air and control the production system (closed system) regularly. A report including operational section, financial section and shortcomings is being submitted to the mother company on a yearly basis.



#### ***Group 3 (production process and water emission)***

Regarding occupational health and safety, it was mentioned that Personal Protection Equipment (PPEs) are always used during production. The water from the production contains 5% lime. The water is directly (no treatment) reused in the production process and the residual lime is taken to the city landfilling. The waste

has been classified as non-hazardous waste and a permit for this waste was issued to the factory. The waste water is being treated before being discharged.



***Group 4 (waste)***

There is a written plan for waste management which is integrated in the permit. The waste in the factory is classified as non-hazardous waste. The waste oil is handled by a certified company.

## 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 17 out of 20 participants filled the evaluation form. It shows that the expectations of the workshop were met. Furthermore, more practical work/case studies 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. The trainees also expressed their wish to have more practical work/case studies in the following trainings. Some trainees raised the problem that there is no inventory/register for chemicals in their country. This discussion results in that the development and implementation of inventory/register for chemicals will be included in next training in December 2014.

### Statistical information

1.1	Workshop Session	Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – General introductory module/procedures
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	IIII IIIII IIIII I (94%)	I (6%)	
2. Practical experience of the new Member States and Candidate Countries	IIII III (47%)	IIII IIIII (53%)	

## 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	IIII IIII (60%)	IIII II (40%)				
2 The quality of the workshop was of a high standard	IIII IIII (60%)	IIII II (40%)				
3 The content of the workshop was well suited to my level of understanding and experience	IIII IIII (53%)	IIII II (41%)	I (6%)			
4 The practical work was relevant and informative	IIII IIII III (76%)	IIII (24%)				
5 The workshop was interactive	IIII IIII II (71%)	IIII (29%)				
6 Facilitators were well prepared and knowledgeable on the subject matter	IIII IIII IIII (82%)	I (6%)	II (12%)			
7 The duration of this workshop was neither too long nor too short	IIII III (47%)	IIII I (35%)	III (18%)			
8 The logistical arrangements (venue, refreshments, equipment) were satisfactory	IIII IIII I (65%)	IIII I (35%)				
9 Attending this workshop was time well spent	IIII IIII II (71%)	IIII (29%)				

## Comments and suggestions

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

### Workshop Sessions:

- Workshop was interesting and was a good experience.
- All the information delivered and the workshop is very useful.
- The workshop is very comprehensive and well organized.
- In future, more attention should be paid to practical work.
- Good.

### Facilitators:

- Well prepared.
- Everything was at a satisfactorial level.
- If a presentation about factory can be prepared before the site visit, it could be more understandable.
- Good.

### Workshop level and content:

- Excellent.
- Good.

## **Annex I Workshop Agenda**







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

## **General Introductory Module/procedures**

ECRAN - 56358

**Financed by the TAIEX Instrument  
in the Framework of the implementation of the  
Environment and Climate Regional Accession Network**

**Venue : TBD**

**Podgorica, Montenegro**

**13-15 May 2014**

**For more information on TAIEX assistance and to download presentations of  
this event, please go to : [http://ec.europa.eu/enlargement/taieux/dyn/taieux-  
events/library/index\\_en.jsp?LibEvents=56358&submit1=Submit](http://ec.europa.eu/enlargement/taieux/dyn/taieux-events/library/index_en.jsp?LibEvents=56358&submit1=Submit)**

## **Aim of the meeting :**

### **Background**

In the REACH regulation, various stakeholders will have their specific roles, responsibilities and competences identified. The know-how regarding the hazards and potential risks of chemicals lays with the manufacturers and importers and 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 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 labeling elements is expected to facilitate trade and to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals.

It should be noted that REACH and CLP are regulations and therefore directly applicable. 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 man and environment.

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 registered or pre-registered or verifying the presence and correctness of the Safety Data Sheets.

The 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

\* 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

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.

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.

#### **Objectives of the Workshop:**

##### Overall objective

The overall 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 of the assignment

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.

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

#### **Expected results**

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.

#### **Beneficiaries:**

Ministries of Environment of Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo\*, Montenegro, Serbia and Turkey.

\* 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



**DAY 1 Tuesday 13 May 2014**

**Topic: Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED - General Introductory Module/Procedures**

**Chairs: Ike van der Putte**

Start	Finish	Topic	Speaker	Sub topic/Content
08:30	08:45	<b>Registration</b>		
08.45	09.00	Opening	Host country representative – tbd Ike van der Putte (ECRAN –ECENA Coordinator)	<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>
9.15	10.00	Introduction on general EU chemical legislation	Arnold van der Wielen (ECRAN SSTE)	<ul style="list-style-type: none"> <li>- Overview and introduction on general EU chemical legislation including PIC, POPs, PPP, Biocides and mercury regulations</li> <li>- The relationship between these legislation</li> </ul>
10.00	10.45	Introduction on the REACH and	Arnold van der Wielen (ECRAN SSTE)	<ul style="list-style-type: none"> <li>- Historical background of chemicals legislation, REACH and CLP in particular</li> </ul>

		CLP Regulations		<ul style="list-style-type: none"> <li>- General approach of REACH and CLP</li> <li>- Relationship between REACH, CLP and other EU legislations</li> </ul>
10.45	11.00	<b>Coffee Break</b>		
11.00	12.30	Roundtable discussion – approximation status of REACH/CLP/IED	Ike van der Putte (ECRAN –ECENA Coordinator) Arnold van der Wielen (ECRAN SSTE)	<ul style="list-style-type: none"> <li>- Every participating country has 10 min to introduce the status of approximation of chemicals legislation in particular REACH and IED</li> </ul>
12.30	13.30	<b>Lunch</b>		
13.30	14.30	REACH specific: Registration	Martin Murin, Ekotoxikologické centrum Bratislava s.r.o.	<ul style="list-style-type: none"> <li>- Scope and timelines of REACH (including case study)</li> <li>- Procedure of REACH registration</li> <li>- Roles and responsibilities (Example and case study)</li> </ul>
14.30	15.30	REACH specific: Evaluation, Authorisation and Restriction	Martin Murin, Ekotoxikologické centrum Bratislava s.r.o. Shufan Qi (ECRAN SSTE)	<ul style="list-style-type: none"> <li>- Evaluation, authorisation and restriction under REACH from organisational and procedural aspects</li> <li>- Obligations of authorities and industries in authorisation and restriction</li> <li>- Communication</li> </ul>
15.30	15.45	<b>Coffee Break</b>		
15.45	16.15	IT organization under REACH	Shufan Qi (ECRAN SSTE)	<ul style="list-style-type: none"> <li>- Development of REACH IT and IUCLID 5</li> <li>- Function of REACH IT and IUCLID 5</li> <li>- Example of IUCLID 5</li> </ul>
16.15	17.00	Consortium and (pre-) Substance Information Exchange Forum (SIEF) under REACH	Martin Murin, Ekotoxikologické centrum Bratislava s.r.o.	<ul style="list-style-type: none"> <li>- Information on consortium and pre-SIEF and SIEF</li> <li>- Legal context, formation and functions of SIEF</li> <li>- SIEF activities</li> <li>- Formation of consortium for REACH registration</li> </ul>

**DAY 2: Wednesday 14 May 2014**

**Topic: Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED - General Introductory Module/Procedures**

**Chair: Ike van der Putte**

Start	Finish	Topic	Speaker	Sub topic/Content
9.00	9.15	Welcome coffee and summary of day 1	Ike van der Putte (ECRAN –ECENA Coordinator)	
9.15	10.15	Basic toxicology and risk assessment under REACH (60 min)	Ike van der Putte (ECRAN –ECENA Coordinator) Shufan Qi (ECRAN SSTE)	<ul style="list-style-type: none"><li>- Basics toxicology</li><li>- Principle of risk assessment</li><li>- Chemical risk assessment under REACH</li><li>- Approaches</li><li>- Computer models</li><li>- Guidance</li></ul>
10.15	10.45	CLP specific – Regulation	Shufan Qi (ECRAN SSTE)	<ul style="list-style-type: none"><li>- Content of the Regulation</li><li>- CLP Timelines</li><li>- Changes compared to the old EU system</li></ul>
10.45	11.00	<b>Coffee Break</b>		
11.00	12.30	CLP specific – Implementation	Shufan Qi (ECRAN SSTE)	<ul style="list-style-type: none"><li>- Implementation of the Regulation</li><li>- Hazard and safety communication</li><li>- Safety Data Sheet</li></ul>

12.30	13.30	<b>Lunch</b>		
13.30	14.00	Chemical Safety report and SDS	Arnold van der Wielen (ECRAN SSTE)	<ul style="list-style-type: none"> <li>- Structure and content of Chemical Safety Report</li> <li>- ECHA guidance for Chemical Safety Report</li> </ul>
14.00	14.30	Enforcement of the REACH and CLP Regulations in EU member states	Ike van der Putte (ECRAN –ECENA Coordinator)	<ul style="list-style-type: none"> <li>- Requirements for enforcement</li> <li>- The function and activities of Forum</li> <li>- Example: enforcement in the Netherlands</li> </ul>
14.30	15.00	REACH/IED intro	Gisela Holzgraefe, Ministry of Energy Transition, Agriculture, Environment and Rural Areas, Germany	<ul style="list-style-type: none"> <li>- Substances in permitting and inspection.</li> <li>- the regulatory cycle of IED</li> <li>- relevant procedures on substances in IED/REACH</li> </ul>
15.00	15.15	<b>Coffee Break</b>		
15.15	16.15	REACH /IED	Gisela Holzgraefe, Ministry of Energy Transition, Agriculture, Environment and Rural Areas, Germany	<ul style="list-style-type: none"> <li>- Substances in IED inspection tasks</li> <li>- Relevance of interactions between IED and REACH</li> <li>- Interlink analysis REACH /IED</li> </ul>
16.15	17.00	Preparation visit Factory (acetylene production)	Gisela Holzgraefe, Ministry of Energy Transition, Agriculture, Environment and Rural Areas, Germany  Participants and trainers	<ul style="list-style-type: none"> <li>- Mixture or article? - Obligation for registration.</li> <li>- BREF/BAT- emission control</li> <li>- Checklist for SDS</li> <li>- Checklist Personal Protection Equipment (PPE)</li> </ul>
17.00	17.30	Case study 1 on classification and labelling  Or Case study 2 discharge of chemicals and ecotox effects	Martin Murin Ekotoxikologické centrum Bratislava s.r.o.  Ike van der Putte (ECRAN –ECENA Coordinator)	<ul style="list-style-type: none"> <li>- Goal of the case study 1 is a brief practical introduction into classification and labelling for environmental and eco-toxicological properties</li> <li>- Goal of case study 2 is to learn how to calculate environmental concentrations in a river; how to select toxicity data for risk assessment, how to calculate a PNEC and assess the risk for aquatic</li> </ul>



				organisms downstream of a discharge point
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<b>DAY 3: Thursday 15 May 2014</b>  <b>Topic: Visit to PILOT FACTORY</b>  <b>Venue: PROGAS Bijela bb, Herceg Novi, Montenegro</b>				
7.00	9.30	Transport from Podgorica to Bijela		
Start	Finish	Topic	Speaker	Subtopic
9.30	15.00	Visit to PILOT FACTORY	All participants	
		Preliminary discussion in the factory office		- Review documentation (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 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>
<b>12.30</b>	<b>13.30</b>	<b>Lunch Break</b>		-

				-
15.00	17.00	<b><i>Return to meeting room in the hotel</i></b>		
17.00	17.30	Visit report preparation in groups		General comments on visit site and any further questions
17.30	18.15	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>
18.15		<b><i>Closure</i></b>		

**This meeting is being organised by the  
Technical Assistance Information Exchange Instrument of the European Commission**



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## **Annex II List of participants**



Event ID ECRAN 56358

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**Name** ECRAN Multicountry Workshop - Capacity building on compliance with chemicals legislation  
**Subject** 27 Environment [15] (Complete)

### List of participants and speakers

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<sup>2</sup>KS=Kosovo\*; 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.

<sup>3</sup>former Yugoslav Republic of Macedonia: Provisional code that does not prejudice in any way the definitive nomenclature for this country, which will be agreed following the conclusion of negotiations currently taking place under the auspices of the United Nations.