Environment and Climate Regional Accession Network ECRAN

# Environment and Climate Regional Accession Network (ECRAN)

## Workshop report
## Activity 2.8.2
## Capacity Building on Compliance with Chemical Legislation (2nd Regional Workshop)

Tirana, 2 -4 December 2014

Enviroment and Climate Regional Accession Network ECRAN

# WORKSHOP REPORT
## Activity 2.8.2

# CAPACITY BUILDING ON COMPLIANCE WITH CHEMICAL LEGISLATION, WITH EMPHASIS ON REACH/CLP (CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES) LINKED TO INDUSTRIAL EMISSIONS DIRECTIVE (IED) - PROCEDURES
## (2nd Regional Workshop)

## Tirana, 2 - 4 December 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*[1], 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 are government officials and experts from institutions in ECRAN beneficiary countries responsible for, or involved in environmental and (partly) chemical issues . In order to ensure optimal results, participation of representatives of the beneficiary countries will have to be continuous for all four modules.

This report describes the results of the implementation of the Module 2 training. The Module 2 training was carried out as a three-day regional training workshop which followed the Module 1 training focusing on the general introduction on the main elements and procedures under REACH and CLP Regulation. This training emphasized the specific obligations for authorities, methodologies and tools in risk assessment, REACH implementation details and interlinks of the REACH with IED (IMPEL project 2013 and results 2014). The training was held in Albania, the first two days in Tirana and the third day on site at a Canadian originated onshore petroleum company (Bankers Petroleum Albania Ltd.) located in Fier, Albania.

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, IED). 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

# 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

[1] 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[2] and CLP[3] 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.

[2] 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 .

[3] 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 – Hotel Mondial, Tirana, 2 December*

1. The workshop was opened by Ms Rovena Agalliu from Ministry of Environment in Albania with a warm welcoming and a short introduction on the implementation of chemical legislation in Albania.
2. Following Ms Agalliu, Mr. Ike van der Putte 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.
3. 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).

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

() means the number of people who has experience in more than one filed.

4. Furthermore, Mr. van der Putte summarized the results from 1st workshop and the knowledge on REACH Regulation. This introduction presentation refreshed the knowledge of the participants on the main elements of REACH such as what to be registered, who has to register, when to register and how to register chemicals. The interaction between the REACH/CLP regulations and other EU Directives has been briefly discussed in one of the slides.
5. Mr. Arnold van der Wielen discussed in details of the roles and the responsibilities of industry and the authorities, after a short refreshment on the important elements of the REACH Regulation. 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 of the company under REACH. In this presentation, the definition of every roles under REACH have been discussed and corresponding examples and exercises have been given to the participants.

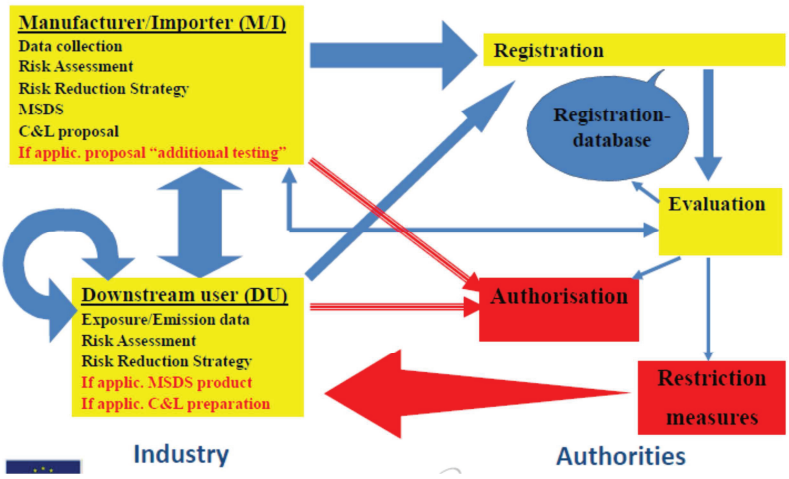



**Figure 1** REACH system running in practise – simplified: responsibility to industry

6. The next presentation was given by Mrs. Shufan Keetlaer-Qi focusing on REACH and CLP National Helpdesk (NHD). The responsibilities and activities of NHD, ECHA Helpdesk, network of NHD (Helpnet) and tools used have been presented. The approach and the experience of Dutch REACH and CLP NHD have been shared as a practical example.
7. Enforcement is essential for a successful implementation of a legislation. Mr. Ike van der Putte has shared the practical consequences of REACH enforcement with the participants. The emphasis has been given to classification and labelling of chemicals, Safety Data Sheet (SDS) and the communication along the supply chain. Moreover, the checklist for the inspection on chemical legislation was discussed and shared with the participants.

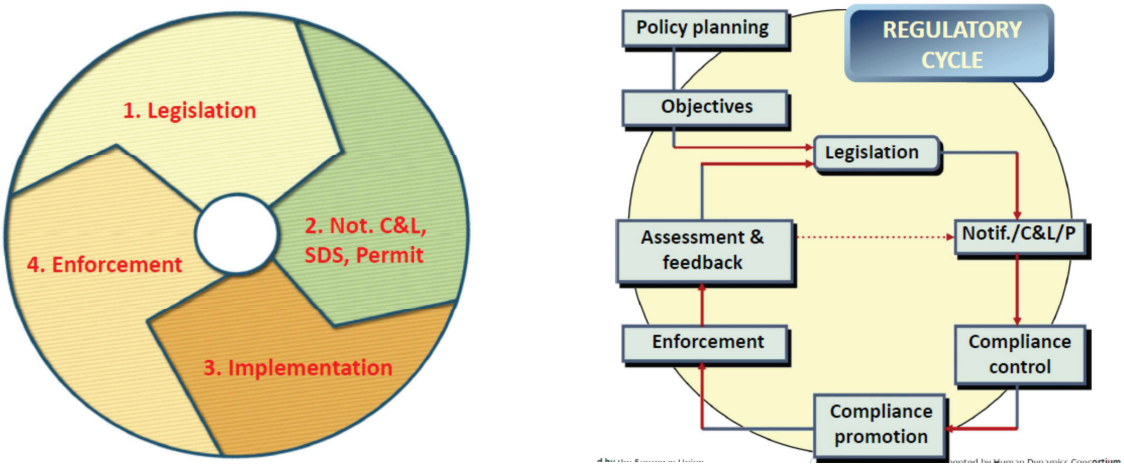



**Figure 2** Regulatory cycle

8. After lunch, Mr. Martin Murin has introduced the inventory (register) for chemicals. An inventory is a database created from information submitted to government authorities by manufactures, processors, users and/or importers. In general, existing substances are listed in EINECS (European Inventory of Existing Commercial chemical Substances) and new substances are listed in ELINCS (European List of Notified Chemical Substances).

   Furthermore, all the participating countries shared information on the status regarding the inventory (register) for chemicals in their own countries. The presentations from the participating countries are attached in the report as Annex IV (Presentations from the participating countries on current status of chemical inventory)

   *Albania*

   There is no register for chemicals. There is a law on chemicals from 2003. There is a plan to develop an inventory/register for chemicals with the assistance of TAIEX.

   *Bosnia and Herzegovina*

   There is a register for chemicals including data from Safety Data Sheets (SDSs).

   *Kosovo*

   There is no inventory/register for chemicals currently. However, this subject is included in the planning process.

*FYR of Macedonia*

Macedonia has an inventory for licensed chemicals companies.

*Montenegro*

Currently there is no register for chemicals. There is a plan to have a register.

*Serbia*

Serbia has an integrated register for chemicals, biocides and plant protection products.

9. Safety Data Sheets (SDSs) are discussed as communication instrument by Mr. Arnold van der Wielen. This was a general introduction on the changes in the new format of SDS introduced by REACH. The presentation covered the requirements for the SDS, the SDS control steps such as the consistency check of the information in the different sections of SDS.
10. Mr. van der Wielen further shared the results of the SDS compliance check project in 2013 in the Netherlands. This compliance analysis focused on distributors and was accomplished in 2 phases. It was found that the most striking short-comings included:

    - wrong format of SDS;
    - information concerning the Dutch National Poisoning Centre was incorrect, incomplete or missing in section 1;
    - confusion on CLP (H- and S-statement) and DPD/DSD (R- and S-sentences) in section 2;
    - wrong classification in section 3;
    - applying wrong terminology and/or missing information in section 8;
    - missing information on Chemical Safety Assessment or having label in section 15;
    - missing version number or glossary and list of abbreviations in section 16.

## *Day 2 – Hotel Mondial, Tirana, 3 December*

1. Following the first training day, Mr. Martin Murin started the second day with explaining the basics in toxicology and ecotoxicology. The fundamentals of risk assessment including hazard assessment and effect assessment/exposure assessment have been given. The important terminology and definitions 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 Envitonmental Concentration) and PNEC (Predicted No Effect Concentrtions) were explained in theory and with examples.

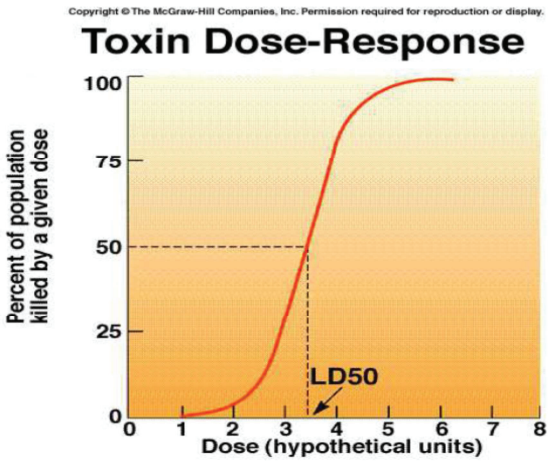



**Figure 3** Dose-Response of chemical toxicity

2. Following the explaination on risk assesmment of chemicals, a case study on environmental hazard/risk assessment has been given by Mr Murin. During the excercise, the participants were required to classify chemical substances for environmental hazard based on the available information, and calculate PNEC and PEC of chemical substances (caprolactame, diphenylamine, dioctylphthalate).
3. Mr. van der Putte has given another hypothetical case study on environmental risk calculation of dibuthylphthalate, xylene and diazinon. The ecotoxicological data of these chemicals and data sources were given in the case study. The purpose of this case study is to learn how to calculate environmental concentrations in a river; how to select toxicity data for risk assessment and how to calculate a PNEC.
4. Ms Gisela Holzgraefe from Ministry for Energy, Agriculture, the Envitonment and Rural Areas of Land Schleswig-Hostain in Germany has talked about the obligations of mixture and article under REACH. It included the definitions of mixture and article, and the obligations under REACH for mixtures and articles. Moreover, some examples such as bicycle, laptop, computer components, and nicotine in e-cigarettes were given and explained.

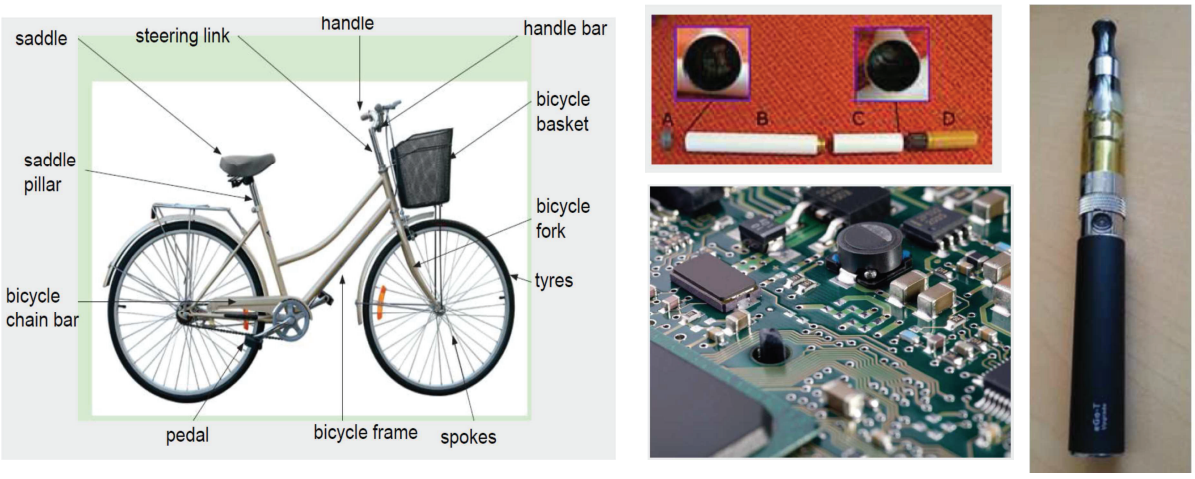
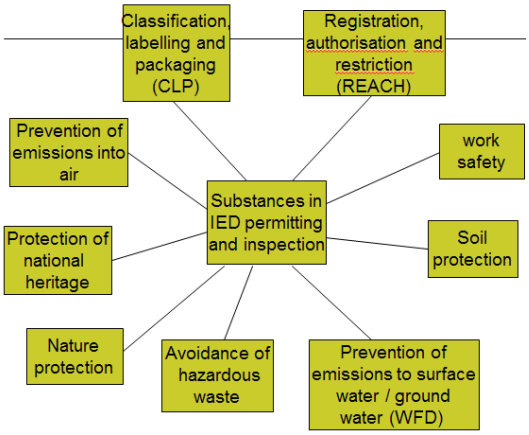



**Figure 4** Examples of articles

5. Ms. Holzgraefe further discussed with all the participants the linterlinks of the REACH Regulation with IED. This presentation focused on the results of IMPEL projects in 2013 and 2014.
   The topics included in this presentations were:

   - Different aims of REACH and IED
   - Interlinkage analyses of REACH and IED
   - REACH and IED synergies (operators/downstream user (DU))
   - Work in practice: permitting and inspection
   - Obligations/duties of operators
   - Cooperation of authorities
   - Supporting tools for authorities




## *Day 3 – Bankers Petroleum Company, Fier, Albania, 4 December*

For the site visit Bankers Petroleum Albania Ltd. (http://www.bankerspetroleum.com/) in Fier, Albania has been selected. Bankers Petroleum Albania Ltd. was established in 2004 and has the full rights to develop the Patos-Marinza and Kuçova heavy oilfields pursuant to a 25 year license agreement with the Albanian National Agency for Natural Resources (AKBN) and a Petroleum Agreement with Albpetrol Sh. A. (Albpetrol), the state owned oil and gas corporation. Bankers has approximately 500 direct local employees, and another 1,600 indirect local employees who work for service providers and subcontractors. Bankers possess 27 environmental permits and has annual compliance audits. It follows IFC EBRD guidelines (bank loan).

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 (Liquid soil waste treatment, separation and monitoring)***
Water for drilling is filtered and re-injected. Solid waste is recycled and incinerated by credited contractor. The waste is incinerated at 1200 °C to prevent the generation of dioxin. (Biological) waste water treatment system is applied. Oil sludge (1500 $m^3$) can be treated with this water treatment system with recovery of oil. There are only 4 or 5 such water treatment system in Albania. Surface and ground water monitoring data show that these comply withr Albanian standards. Air monitoring data however comply with Albanian standards but are somewhat higher than EU standards e.g. SOx.

***Group 2 (Chemicals classified as dangerous for environment and existing measures)***

SDSs of dangerous chemicals are available on site and are translated to local language. Hazardous material procedures are available which are drafted according to PPC (Pollution Prevention and Control (Scotland)) and PPE (Personal Protective Equipment) Regulations. Worker instruction cards are available on site. Banker is also a SEVESO site and comply with SEVESO requirements including the training of workers.

***Group 3 (Chemical storage)***

Bankers has a newly built area for chemical storage and adopt BAT for storage, handling and management of materials. 58,000 $m^2$ of storage facility and site design allows separation of different equipment and materials. HAZMAT procedures/policy in place. The Site environment management plan is under development.

## 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 22 participants filled the evaluation form. It shows that the expectations of the workshop were met. The participating countries expressed their appreciation for this training and the know-how provided on REACH and CLP Regulations. Some countries indicated that the workshops like this are extremely needed. Furthermore, the provision of more knowledge and information on (eco)toxicology are asked for 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 preparation and knowledge of the trainers were appreciated. The trainees also expressed their wish to have more concrete knowledge on (eco)toxicology in the following trainings. Some participating countries raised the problems that they have such as lacking of knowledge and low capacity regarding implementation of REACH and CLP Regulations. 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. Via ECRAN Albania has asked TAIEX's assistance for REACH and CLP related issues..

The TAIEX expert mission now will provide assistance to the Albanian Ministry of Environment on the compliance checking of the following draft legislation prepared:

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

### Statistical information

| | | |
|---|---|---|
| 1.1 | Workshop Session | Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – 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 | IIIII IIIII IIIII I (73%) | IIIII I (27%) | |
| 2. Practical experience of the new Member States and Candidate Countries | IIIII IIIII IIIII (71%) | IIIII I (29%) | |

**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 | IIIII IIIII II (55%) | IIIII IIIII (45%) | | | | |
| 2 The quality of the workshop was of a high standard | IIIII IIIII I (50%) | IIIII IIIII I (50%) | | | | |
| 3 The content of the workshop was well suited to my level of understanding and experience | IIIII IIII (43%) | IIIII IIIII II (57%) | I | | | |
| 4 The practical work was relevant and informative | IIIII IIII (43%) | IIIII IIIII II (57%) | | | | |
| 5 The workshop was interactive | IIIII IIIII IIII (64%) | IIIII III (36%) | | | | |
| 6 Facilitators were well prepared and knowledgeable on the subject matter | IIIII IIIII II (55%) | IIIII IIIII (45%) | | | | |
| 7 The duration of this workshop was neither too long nor too short | IIIII IIIII I (50%) | IIIII IIIII (45%) | I (5%) | | | |
| 8 The logistical arrangements (venue, refreshments, equipment) were satisfactory | IIIII IIIII IIIII (68%) | IIIII II (32%) | | | | |
| 9 Attending this workshop was time well spent | IIIII IIIII III (60%) | IIIII IIII (40%) | | | | |

***Comments and suggestions***

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

**Workshop Sessions:**

- Study/field visit was very good and informative.
- All the sesstions were well organized.
- I am very happy, I hope to have other workshop.Thank you (TAIEX evaluation)
- Workshops with this thematic are extremely needed for my country as we have a very low capacity. Workshop at national level would be very useful as well. (TAIEX evaluation)
- Everything went according to plan, we are pleased by the speakers and hope that in the future will be realized in future workshops that will help us in our work. (TAIEX evaluation)
- I propose more study visits in power plant. (TAIEX evaluation)

**Facilitators:**

- The facilitators are of a very high level.
- Staff is very well organized.
-
- The level of experience in the group was very different. This is a challenge for trainers and paricipants as well. (TAIEX evaluation)
- Following the first training in the series, Albania asked for TAIEX assistance in

preparing their chemicals legislation. In this second training, countries learned from each other and for example on inventory and registers of chemicals in the accession countries, it is expected that addtional TAIEX assistance will be needed and requested. (TAIEX evaluation)

**Workshop level and content:**

- In future it will be good to be more concrete regarding toxicological topics.

# Annex I: Workshop agenda

# Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP (Classification, Labelling and Packaging of Substances and Mixtures) linked to Industrial Emissions Directive (IED) - Procedures

ECRAN - 58142

**Financed by the TAIEX Instrument**

**in the Framework of the implementation of the**

**Environment and Climate Regional Accession Network**

**Venue :**

Hotel Mondial ****, Rr. Muhamet Gjollesha

Tirana, Albania

**2 – 4 December 2014**

**For more information on TAIEX assistance and to download presentations of this event, please go to : http://ec.europa.eu/enlargement/taiex.**

## 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 minimizing 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 authorization 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 tons 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.

This workshop is the following up of the workshop held in Podgorica, Montenegro on 13 – 15 May 2014. The current workshop focuses on the procedural aspects of REACH Regulation, with the emphasis on:

- Roles and responsibility;
- Helpdesk;
- Enforcement;
- Development and implementation of inventory/register for chemicals;
- Checking of SDS;
- Basic understanding of toxicology
- Interactions of IED and REACH.

**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:

The beneficiaries are the Ministries of Environment of Albania, Bosnia and Herzegovina, Croatia, 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 : December 2, 2014

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

**Chair and Co-Chairs: Ike van der Putte**

**Venue: Tirana, Albania**

| Start | Finish | Topic | Speaker | Sub topic/Content |
|---|---|---|---|---|
| 08:30 | 08:45 | **Registration** | | |
| 08.45 | 09.00 | Opening | Host country representative – tbd<br>Ike van der Putte (ECRAN –ECENA Coordinator) | - Welcome<br>- Introduction of trainers<br>- Introduction of participants |
| 09.00 | 09.15 | Introduction | Ike van der Putte (ECRAN –ECENA Coördinator) | - Explanation of the training programme<br>- Information on ECRAN<br>- Defined ECENA activities |
| 09.15 | 09.30 | General introduction on REACH Regulation | Ike van der Putte, ECRAN | - Introduction on the main elements of REACH (such as What, Who, When and How) |
| 09.30 | 10:00 | REACH Specifics – Roles & Responsibility (incl. example) | Arnold van der Wielen, ECRAN | - Actors and roles under REACH<br>- The responsibilities for different roles<br>- Specific responsibility of authority under REACH |
| 10:00 | 10:45 | REACH Specifics – Roles & Responsibility case study | Arnold van der Wielen, ECRAN | - Identifying the roles of organization<br>- Defining the responsibility for specific role |
| 10.45 | 11.00 | ***Coffee Break*** | | |
| 11:00 | 11:45 | REACH Specifics – Helpdesk | Shufan Keetlaer-Qi, ECRAN | - Responsibility, function and structure of helpdesk<br>- Helpdesk network<br>- Dutch helpdesk as an example |
| 11:45 | 12.30 | REACH Specifics - Enforcement | Ike van der Putte, ECRAN | - Requirements for enforcement<br>- The function and activities of Forum<br>- Example: enforcement in the |

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| | | | | Netherlands |
| 12.30 | 13.30 | ***Lunch Break*** | | |
| 13.30 | 13.45 | Inventory/register for chemicals | Martin Murin, Ekotoxikologické centrum Bratislava s.r.o. TAIEX Expert | - Introduction on the inventory/register for chemicals used in EU Member States |
| 13.45 | 15.00 | Status of development and implementation of inventory/register on chemicals in the participating countries | Martin Murin, Ekotoxikologické centrum Bratislava s.r.o. TAIEX Expert /participating countries | - Each participating country has to present the development and implementation status of inventory/register on chemicals in own country |
| 15.00 | 15.15 | ***Coffee Break*** | | |
| 15:15 | 16.00 | SDS and inspection on SDS | Arnold van der Wielen, ECRAN | - Structure and content of SDS<br>- Check on SDS |
| 16.00 | 17.00 | SDS and inspection on SDS exercises | Arnold van der Wielen, ECRAN | - |

# Day 2 : December 3, 2014

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

**Chair and Co-Chairs: Ike van der Putte**

**Venue: Tirana, Albania**

| Start | Finish | Topic | Speaker | Sub topic/Content |
|---|---|---|---|---|
| 9.00 | 9.15 | Welcome coffee and summary of day 1 | Ike van der Putte, ECRAN | |
| 9.15 | 10.15 | Basic toxicology with examples | Martin Murin, Ekotoxikologické centrum Bratislava s.r.o. TAIEX Expert | - Basic toxicology<br>- Understanding of basic toxicological parameter (e.g. LC50, LD50, EC50, NOAEL, NOEC etc.) |
| 10.15 | 10.45 | Basic toxicology case study | Martin Murin, Ekotoxikologické centrum Bratislava s.r.o. TAIEX Expert | - On further explanations of Ecotox. parameters |
| 10.45 | 11.00 | ***Coffee Break*** | | |
| 11.00 | 11.30 | Basic toxicology case study (continue) | Martin Murin, Ekotoxikologické centrum Bratislava s.r.o. TAIEX Expert | - On further explanations of Ecotox. parameters |
| 11.30 | 12.30 | Case study on discharge of chemicals and Ecotox. effects | Ike van der Putte, ECRAN | - 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 organisms downstream of a discharge point |
| 12.30 | 13.30 | ***Lunch Break*** | | |
| 13.30 | 15.00 | REACH /IED Interactions incl. | Ms. Gisela Hozgraefe Ministry of Energy | - Mixture or article – obligations for registration |

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| | | examples and case study | Transition, Agriculture, Environment and Rural Areas, Germany, TAIEX Expert | - BREF / BAT emission control<br>- Checklist for SDS<br>- Checklist for Personal Protection Equipment |
| 15.00 | 15.15 | ***Coffee Break*** | | |
| 15.15 | 16.15 | REACH /IED Interactions incl. examples and case study (continue) | Ms. Gisela Hozgraefe Ministry of Energy Transition, Agriculture, Environment and Rural Areas, Germany, TAIEX Expert | - Mixture or article – obligations for registration<br>- BREF / BAT emission control<br>- Checklist for SDS<br>- Checklist for Personal Protection Equipment |
| 16.15 | 17.00 | Preparation visit Factory | Ms. Gisela Hozgraefe Ministry of Energy Transition, Agriculture, Environment and Rural Areas, Germany, TAIEX Expert /Participants and trainers | - Mixture or article? - Obligation for registration.<br>- BREF/BAT- emission control<br>- Checklist for SDS<br>- Checklist Personal Protection Equipment (PPE) |

# Day 3 : December 4, 2014

**Topic: Visit to PILOT FACTORY**

**Venue: Bankers Petroleum Company Fier city ( http://www.bankerspetroleum.com/)**

**Fier Office**

**Bankers Petroleum Albania Ltd.**

**Rruga "Leonardo Murialdo", Lagja "Sheq i Madh",**

**Godina 37, Fier, Albania**

| Start | Finish | Topic | Speaker | Sub topic/Content |
|---|---|---|---|---|
| 07:30 | 09:00 | Departure from the hotel, transport to the pilot site | | |
| 9:00 | 14.30 | Visit to PILOT 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 | | - 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.<br>- Each member of the group will make their own inspection and make notes |

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| | | | | and compare results later in the group |
| | | Return to Meeting room at the factory | | - General comments on visit site and any further questions |
| 14.30 | 16.00 | ***Transport back, return to meeting room in the hotel*** | | |
| 16.00 | 16.45 | Visit report preparation in groups | | |
| 16.45 | 17.30 | Presentation of reports by members of the group | | - Conclusions of site visit<br>- Suggested follow-up actions |
| 17:30 | | ***Closure*** | | |

**This meeting is being co-organised by the**

**Technical Assistance Information Exchange Instrument of the European Commission**

L15 04/090 , B - 1049 Brussels
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TAIEX on Twitter: #EUTaiex
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# Annex II: List of participants

European Commission

| Event ID | ECRAN 58142 | Creation date: 07/11/2014 | Last changed: 21/11/2014 10:42 |
|---|---|---|---|

**Name** TAIEX-ECRAN Multi-Country Workshop on compliance with chemicals legislation

**Subject** 27 Environment [15] (Partial),27.10 Environment [15.10] (Partial),27.10.20 Pollution and nuisances [15.10.20] (Partial),27.10.20.50 Chemicals, industrial risk and biotechnology [15.10.20.50] (Complete)

## List of participants and speakers

Personal data contained in this document will be processed in accordance with the privacy statement of the TAIEX instrument (see http://ec.europa.eu/enlargement/taiex/privacy-statement) and in compliance with the Regulation (EC) N° 45/2001.

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[1]Provisional code that does not prejudge 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.

**Annex III: PowerPoint presentations under separate cover**
**www.ecranetwork.org**