
Environment and Climate Regional Accession Network (ECRAN)

Workshop Report Capacity Building on Compliance with Chemical Legislation (3rd Regional Workshop)

01-03 September 2015, Skopje

ENVIRONMENTAL AND CLIMA REGIONAL NETWORK FOR ACCESSION - 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**

(3rd Regional Workshop)

Tirana, 1 – 3 September 2015



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LIST OF ABBREVIATIONS	
BAT	Best Available Techniques
BIH	Bosnia and Herzegovina
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, Reprotoxic
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
DU	Downstream User
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environmental Agency
EEE	Electrical and Electronic Equipment
ESs	Exposure Scenarios
EU	European Union
FAME	Fatty Acid Methyl Esters
GHS	Globally Harmonised System
IED	Industrial Emission Directive
IMPEL	The European Union Network for the Implementation and Enforcement of Environmental Law
IPPC	Integrated Pollution Prevention and Control
KOH	Potassium hydroxide
LPG	Liquid Petroleum Gas
NOAEL	No Observed Adverse Effect Level
PBT	Persistent Bioaccumulative and Toxic substances
PCB	Polychlorinated Biphenyls
PCT	Polychlorinated Terphenyls
PEC	Predicted Environmental Concentration
PIC	Prior Informed Consent
PNEC	Predicted No-Effect Concentration
POP	Persistent Organic Pollutants
QA	Questions and Answers
QSAR	Quantitative Structure-Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restrictions of Chemicals
RMM	Risk Management Measures
ROHS	Restriction of Hazardous Substances
SDS	Safety Data Sheets
ToR	Terms of reference
vPvB	Very Persistent and Very Bioaccumulative



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 Terms of reference (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 European Environmental Agency (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 3 training. The Module 3 training was carried out as a three-day regional training workshop which followed the Modules 1 and 2 training focusing on the general introduction on the main elements and procedures under REACH and CLP Regulation, and the REACH specific procedures. This training emphasized the Technical aspects of 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 FYR of Macedonia, in hotel Arka Skopje, including a site visit on the third day at the MAKPETROL Biodiesel Company in Skopje.

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.



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 objectives

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 European Commission (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 and CLP 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 (Carcinogenic, mutagenic, reprotoxic (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 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



IV. Highlights from the training workshop

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

Day 1 – Hotel Arka, Skopje, 1 September

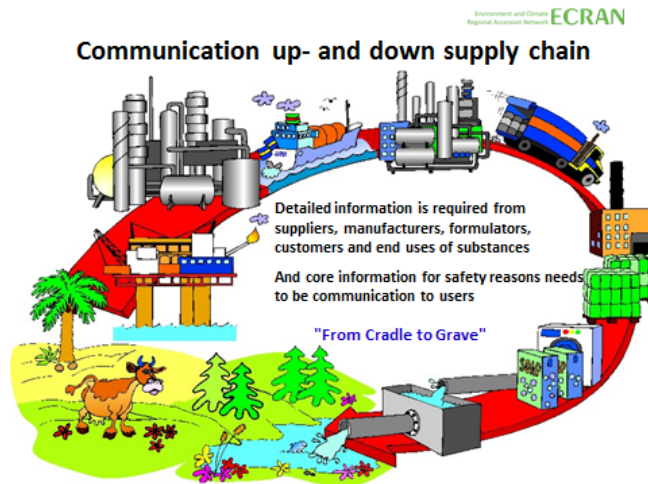
1. The workshop was opened by Mr Nazim Aliti, Head of Department Ministry of Environment and Physical Planning, national coordinator IED/Chemicals WG, Skopje with a welcoming and a short introduction emphasizing the importance of the subject on the health issues.
2. Following Mr. Aliti, Mr. Ike van der 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. Further a general overview of the agenda was given.
3. After the introduction of the trainers 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	7	3	7
Chemicals (REACH/CLP)	9	7	1
IPPC/IED	5	5	2
Others	1	4	6

() A number of 4 persons has followed now 3 courses, 9 persons 2 courses and 7 persons 1 course.

4. Mr. Arnold van der Wielen gave a general introduction on the main elements of REACH and CLP. Starting from the Nature and size of the problem with chemicals that are placed on the European market, an overview was given on the basic principles, main elements and scope of REACH. It was explained that some of the core issues are Responsible Risk Management and Communication of Information up and down the supply chain. The legal structures and implementation timelines of REACH/CLP were presented with specifics of the organization of REACH/CLP, describing the roles of the Commission, EU member states, the chemicals Agency (ECHA) and the Industry.





5. The next presentation was given by Mr. Martin Murin on Environmental risk assessment and ecotoxicological endpoints. This covered Basic knowledge on environmental risk assessment and explanations on major ecotoxicological endpoints such as EC50, PNEC, etc. An explanation was given on ecotoxicological risk assessment, covering Hazard assessment and Effect assessment leading to an estimation of the Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC). With questions and answers (QA) sessions basic elements and terminology were explained (for example: QSAR's, EDCs, PBT/vPvB, Inherent biodegradability, BCF, secondary poisoning). The various test systems in ecotoxicology were described with the endpoints and comparisons in assessments of human health toxicity and eco toxicity.



After the presentation of the basics in eco-toxicology, some exercises were carried out in classifying chemicals based on provided hazard data (dioctylphtalate, caprolactam and diphenylamine).

The exercises were followed with a presentation on persistent (P), bio-accumulative (B) and toxic (T) chemicals (PBTs) and very persistent and very bio-accumulative chemicals (vPvBs). The reasons for their importance are:

- Very high uncertainty in predicting PEC and/or PNEC;
- A "safe" concentration cannot be established;
- Traditional risk assessment may not address the risks adequately;

- Draw parallel with known dangerous substances;
- Early identification and fast implementation of risk reduction measures necessary to prevent future generations from long-term exposure;
- Specific concerns occur specifically for substances that are highly accumulative and persistent;
- Very high uncertainty in predicting PEC and/or PNEC;
- A "safe" concentration cannot be established;
- Traditional risk assessment may not address the risks adequately;
- Draw parallel with known dangerous substances;
- Early identification and fast implementation of risk reduction measures necessary to prevent future generations from long-term exposure.

It was noted that current risk assessment methods are considered inadequate.

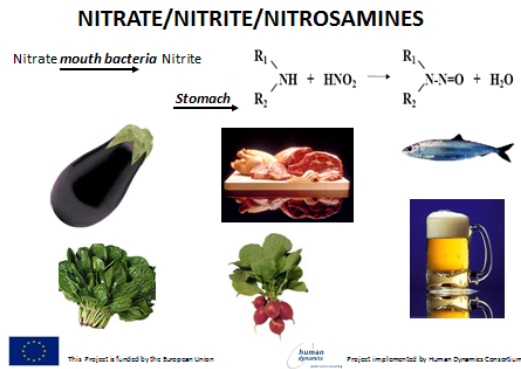
The testing Strategies for PBTs (TGD, 2003) are:

- P: Use of standard biodegradation testing methods and (Q)SARs;
- B: Use of log Kow and QSARs for BCF;
- T: Use of short-term toxicity data or other indicators for toxicity;
- How to proceed when screening data indicate potential concern: Test first P, then B, then T (reduce animal testing).

PBT and vPvB assessment under REACH are required:

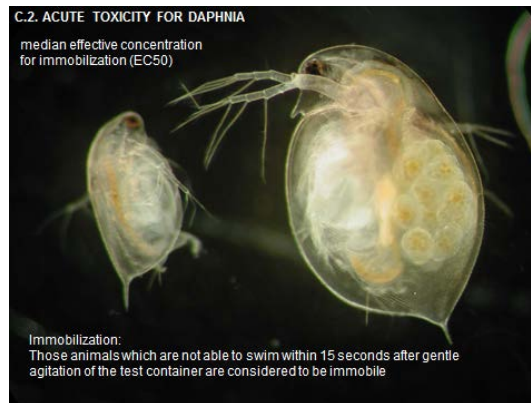
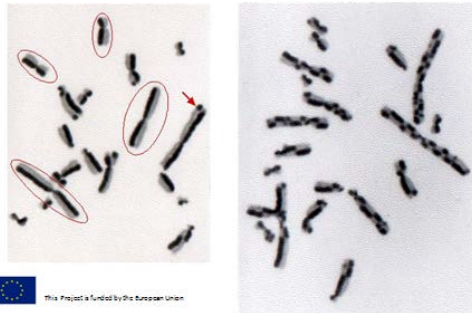
- for all substances for which a chemical safety assessment (CSA) must be conducted and reported in the chemical safety report (CSR);
 - in general all substances M/I in amounts of ≥ 10 t/a that are not exempted from the registration requirement under REACH;
 - exemptions apply as described in Article 14(2), e.g. for substances present in a preparation if the concentration is < 0.1 % weight by weight (w/w), for on-site or transported isolated intermediates, and for Product and Process Oriented Research and Development.
6. Mr van der Putte gave an introduction on Human health risk assessment with Basics in toxicology and human health risk assessment and explanations of on basic toxicological parameters such as LC50, LD50, NOAEL etc. His presentation was started with an exercise on LC50/LD 50 assessment, followed by a lecture on general items in human health risk assessment and toxicology.





This presentation was followed by a presentation on endpoints in testing with an explanation of eco(toxicological) endpoints which are used for classification of chemicals and an introduction on the testing relevant to these eco(toxicological) endpoints.

Example Genotoxicity
Sister Chromatid exchange



7. Mr. van der Wielen finalized the series of presentations on day 1 with a presentation on exposure scenarios:
- The format and content of exposure scenarios
 - Major terms used in exposure scenarios.
 - Understanding of exposure scenarios

The exposure scenario is a document generated by the registrant during REACH registration. The exposure scenario describes the conditions that ensure adequate control of risk when a substance is

manufactured and used. It addresses the risk to workers, consumers and the environment, as appropriate. Exposure Scenarios (ESs) are attached to the Safety Data Sheet (SDS/eSDS).

It was explained what the content should be of an ES with some examples, how to read these and how to check these:

- ES – check if company’s use is covered in the title section;
- ES – Check if the technical measures in section 2 (operational conditions/technical measures) will match;
- ES – Check if the organizational measures in section 2 (Operational conditions/Organizational measures) will match ;
- ES – check if the RMM in section 2 (Risk Management Measures) will match;

The outcome of the ES check can lead to 3 options:

- Use and conditions of use are covered -No action needed;
- Conditions of use slightly differ - Check if conditions of use may be covered by similar use of broader scope (by scaling, if applicable);
- Use and/or conditions not covered - Company needs to take actions!

Scaling is a mathematical method to show that the substance is used under use conditions described in the ES, but some parameters are slightly different. It can be used when:

- There is an exposure limit (DNEL/PNEC);
- The supplier (registrant or DU) has used an exposure model for the assessment;
- The supplier provides information for scaling;

In case the use/conditions have not been covered by the ES, a company can/has to select one of the following options:

- 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;
- Prepared 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.

8. In the roundtable different issues were discussed regarding the implementation of REACH/CLP in the beneficiary countries. As reported by Ms Rovena Agalliu of the Albanian Ministry of Environment, Albania has made use of asking for extra assistance via ECRAN and TAIEX for transposition and implementation. Five missions have been carried out to Albania in which a working group was formed with the Environmental Ministry, Health Ministry, Customs and the National Licensing Centre. The TAIEX expert mission provided assistance to the Albanian Ministry of Environment on the compliance checking of the following draft legislation prepared:

- a. Framework law on chemicals legislation;



- b. Classification, packaging and labelling of substances and chemical mixtures (CLP);
- c. Import and export of hazardous substances;
- d. Approval of substances and chemicals, manufacture, placing on the market and use of which is restricted or prohibited (Annex XVII of REACH);
- e. List of hazardous substances which by their nature pose a serious risk to life, human health and the environment (Annex XIV of REACH).

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 some other countries a start was made with the helpdesks (Bosnia and Herzegovina (BiH)), other countries have an operational helpdesk (Serbia and Macedonia). Montenegro has not yet a helpdesk, but a plan to have one in 2017. The recommendation from Albania to other countries was 1) to start with the legislation; 2) to train the people to create capacity; 3) to involve/ask assistance from experts who know the situation in the region.

Day 2 – Hotel Arka, Skopje, 2 September

1. Following the first training day, Mr. Arnold van der Wielen started the second day with explaining Restriction under REACH especially with how the EU MSs deal with Annex XVII to REACH (restricted chemicals under REACH). Special attention was paid to history, structure of REACH Annex XVII, overlap by other legislation and challenges in enforcement. An example is given on a consumer product for repairing bicycles.

Legal issues regarding enforcement of REACH restrictions refer to:

- Misunderstanding scope of legislation on cosmetics, medical devices, human and veterinary drugs, pesticides and biocides Within the scope of REACH:
 - Ingredients of cosmetics;
 - Precursors of end-use substances in medical devices, human and veterinary drugs;
 - Precursors of active ingredients for pesticides and biocides.
- Overlap with ROHS (Restrictions of use of certain hazardous substances in electrical and electronic equipment (EEE)).

It was concluded that there is a possibility for conflicts in restrictions between REACH and Restriction of Hazardous Substances (ROHS) regarding control of electric & electronic equipment on the market.

2. Mr. Martin Murin described the background of Persistent Organic Pollutants (POP) and Prior Informed Consent (PIC) Conventions and the links of PIC and POP Conventions with other EU legislation. The Stockholm Convention (POP Convention) covers 23 priority POPs produced both intentionally and unintentionally (e.g. by sources like waste incinerators).



EU legislation: Persistent organic pollutants (POPs)

If you are an exporter of products, such as electric transformers or textiles containing flame retardants, you have to make sure that your products do not contain Persistent Organic Pollutants (POPs) that are prohibited in the EU.



Substances	Requirements	Why	How to comply
Persistent Organic Pollutants (POPs); organic compounds, resistant to environmental degradation, e.g. chemical substances such as DDT and PCBs.	Products containing or treated with POPs are forbidden and will be rejected from the EU market.	To reduce the risks for public health and of the environment in the EU.	Make your products do not contain any POPs, or at least do not exceed the set maximum residue level.



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Regulation EC 850 /204 on persistent organic pollutants aims to give effect to the main provisions of the Stockholm Convention. Other legal instruments in the EC dealing with POPs are:

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - provisions specifying how substances should be assessed with regard to their POP characteristics. Under REACH, the production and use of substances exhibiting POP characteristics can be prevented and new POP candidates can be identified.
- Regulation (EC) No 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals (PIC Regulation) prohibits the export of 10 out of the 12 POP substances currently listed in the SC.
- Council Directive 96/59/EC of 16 September 1996 on the disposal of Polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) aims to completely dispose of PCBs and equipment containing PCBs as soon as possible and equipment with PCB volumes of more than 5 litres before the end of 2010. It also sets requirements for the environmentally sound disposal of PCBs.
- Directive 96/61/EC (the IPPC Directive) lays down control measures to reduce emissions of u-POPs by covering the major industrial stationary sources of these POPs.
- Directive 2000/76/EC on the incineration of waste covers all waste incineration facilities that are a very important source of POPs by-products. The Directive sets strict limits for emission rates of dioxins /furans in the air.

The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International forms the basis for the PIC Regulation. The PIC Regulation, Regulation (EU) No 649/2012, is the regulation of the European Parliament and of the Council concerning the export and import of hazardous chemicals. It applies to industrial chemicals and pesticides (including biocides) that are banned or severely restricted for health or environmental reasons. It places obligations on companies who wish to export these chemicals to non-EU countries. The export of such chemicals is subject to two types of requirements: export notification and explicit consent. The various benefits of the PIC procedure is explained.



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3. Mr. Arnold van der Wielen explained the structure and content of Safety Data Sheets. The SDS is the key instrument for the information flow down the supply chain, because:
- it informs the downstream user about the dangerous properties & potential hazards during normal handling and use;
 - it recommends necessary measures to manage the risk to health & environment (storage, use, disposal);
 - it provides the basis for the assessment of hazards / risks.

Next to the function of the SDS, Mr. Van der Wilen also explained when an SDS should be provided.

The control of SDSs consist of four steps:

- Step 1: Control of general requirements;
- Step 2: Control of hazard identification and composition;
- Step 3: Consistency check of the information in the different sections of SDS;
- Step 4: Consistency check with Exposure Scenario sections.

Every step was explained, also using examples of Safety Data Sheets.

4. Ms. Luleva Parvoleta, described the Enforcement of REACH in Bulgaria and the recent developments in the ECHA Forum. The presentation covered
- Legal framework;
 - Competent/enforcement authorities;
 - Administrative capacity and resources;
 - Organisational structure and competencies;
 - Enforcement strategy;
 - Documents and tools.

The tasks of the various REACH Enforcement Authorities are:

- Regional Inspectorates of Environment and Water: registration, data sharing, communication in the supply chain (focused on production and formulation of chemicals at industrial sites), DUs' duties, authorisation, restrictions (substances of ENV concern);
- Regional Health Inspectorates: communication in the supply chain (focused on retailers and distributors placing chemicals on the market), restrictions (substances of HH concern);
- Executive Agency "General Labour Inspectorate": access to information for workers, safety and health at workplace involving hazardous chemicals (in particular SVHCs), exposure control at working environment;

In general, enforcement responsibility is determined by the type of REACH duty to be enforced:

- REGISTRATION RELATED DUTIES: Environmental Inspectorates (due to the leading role of MoEW as REACH Competent Authority)
- SUPPLY-CHAIN RELATED DUTIES: Human Health Inspectorates (until retail sale)



- PRODUCTION AND USE RELATED DUTIES: Environmental Inspectorates (safe storage) and Labour Inspectorates (health and safety at work).

The Enforcement activities in Bulgaria between 2008 and 2015 refer to:

- ‘No data, no market’ enforcement
- Inspection campaigns centred around certain hazardous substances
- EU co-ordinated projects:
 - REACH-EN-FORCE-1 – pre-registration
 - REACH-EN-FORCE-2 – information in the supply chain (SDS and downstream users)
 - REACH-EN-FORCE-3 – registration and only representatives (prolonged in 2014, follow-up actions in the supply chain outside the country)
 - REACH-EN-FORCE-4 – restrictions
- Pilot projects: intermediated, authorisation, child resistant fastenings, etc.

Reactively driven enforcement issues

A brief overview was given on the activities and projects of the ECHA Forum for Exchange of Information on Enforcement (Forum).

5. Ms. Gisela Holzgraefe gave an introduction and explanation of the Manual for REACH inspection with the recent relevant developments in IMPEL. In 2013 and 2014 IMPEL carried out two projects on „Interlinks of the REACH Regulation with the Directive on Industrial Emissions“
 - Focus on the following questions:
 - How can permit writers benefit from REACH information?
 - How can REACH / IED inspectors benefit from IED / REACH information?
 - Interlink analyses REACH / IED and vice versa;
 - Interaction REACH and IED (operators / DU);
 - Work in practice – permitting and inspection.
 - 2013: exploring the basic information, interlink analysis, supporting tools and material
 - 2014: dissemination of results, exploring practical work and identification of needs

The Conclusions of the IMPEL project 2013 are:

- Operators can benefit from the information generated under REACH and IED for cross-legislation compliance in many different situations.
- It is a benefit for all parties if the information generated under one legislative regime can be used by industrial operators / downstream users to facilitate compliance under a second regime.
- Authorities can benefit from REACH information for the assessment of substances used, produced or imported mentioned in applications.
- There is a need raise awareness and provide all the actors having a role in cross-legislation issues with guidance and tools on how to deal with and use the synergies identified.



- Link: <http://impel.eu/projects/linking-the-directive-on-industrial-emissions-ied-and-reach-regulation/>

The findings of the IMPEL project 2014 are:

- Most countries have general guidance for dealing with REACH in inspection in place
 - several countries use the manuals / checklists of the FORUM REACH EN-FORCE-projects,
 - others have own checklists for REACH in inspections in place
- For producing good and coherent harmonised results
 - IED permitting and IED inspection authorities should closely cooperate with REACH authorities
 - by allowing access to permits e.g. via databases
 - by providing information about relevant results of inspections
 - by taking up colleagues into mailing lists for information exchange
 - meetings for information exchange should be carried out
 - This may be a problem when authorities belong to different organisations

The Manual of the Forum Project on pre-registration / registration of phase in substances and SDS was described with a number of important recommendations for inspection.

6. For preparation for the site visit on day 3, the participants were divided into three groups, each group had to formulate questions to assess the issues related to:

- 1) SDSs;
- 2) Process;
- 3) Waste.

Day 3 – MAKPETROL, Skopje, 3 September



For the site visit the PILOT FACTORY (Biodiesel production facility- MAKPETROL) FAME has been selected.



Makpetrol was founded in 1947 as a state owned company responsible for strategic supply of crude oil and oil products in the R. of Macedonia. Makpetrol AD is the biggest company in the Republic of Macedonia for distribution and trade with oil products and gas, having more than 65 years of experience.

WAREHOUSES, country wide

Total disposable capacity of 150,000 cubic meters of storages for oil and oil products is arranged in 13 warehouses located in different regions throughout the territory of the Republic of Macedonia

Two warehouses for storing Liquid Petroleum Gas (LPG) with total capacity of 1500 MT. Makpetrol A.D. provides permanent and unhindered supply of fuels for the Macedonian market, aiming at the enlargement of the products and services by modernization of the existing storage capacities through installation of the latest controlling, storage and distribution systems, for the safe handling of the fuels.

PILOT FACTORY – Biodiesel, Skopje.

Production and application of Bio-fuels is a global trend as a replacement of the liquid fossil fuel consumption. Makpetrol AD is positioning itself as a producer of bio diesel and a distributor of the blend of biodiesel and fossil diesel mixed with biodiesel called “BIODIZEL B8 SF (Sulphur free)”.

This specific fuel contains 92% percent fossil diesel and 8% Biodiesel (100% FAME).

Biodiesel production started in 2007 and production is 20 -50 tons per year



The Plant manager Mr. Philip Swanson assisted by his team for environment and waste management, introduced the factory and its processes. After which a guided tour was started in which questions could be asked.

Biodiesel is a natural fuel defined mainly as methyl esters (FAME) of long-chain fatty acids derived from renewable biological sources, such as vegetable oils and animal fats. Compatibility of biodiesel with mineral oils allows to combine them in order to obtain a stable fuel mixture. It can be used in the form of pure methyl esters of fatty acids as well as mixed with diesel fuel containing up to 30% of bio-component.



This Project is funded by the
European Union



A project implemented by
Human Dynamics Consortium

The factory receives its rapeseed oil from Serbia (by train).

The different steps in biodiesel production are:

- Refining of imported rapeseed oil: The high contents of free fatty acids and water in the collected oil are responsible for secondary reactions during transesterification. Therefore, a pre-treatment of oil is necessary before load the reactor to produce biodiesel. Oil refining aims to remove the excess of phospholipids, salts of iron or copper and obtain low peroxide number as well as low acid number (less than 1mg KOH/g) i.e. low content of free fatty acids which react with basic catalyst during transesterification to form soap making difficult purification of glycerine phase and increasing the demand for catalyst.

- Transesterification of rapeseed oil: In a standard process of production biodiesel from rapeseed oil there are following process steps i.e. esterification of rapeseed oil, separation of esterification products, methanol distillation and purification of the ester (FAME). The main stage of the process is based on the transesterification reaction of rapeseed oil with an alcohol (methanol) which results in formation of esters of alcohols and glycerol. The reaction is reversible due to formation of water, which is responsible for shifting the equilibrium towards the reagents. In order to move the chemical equilibrium towards the ester, an excess of alcohol is used. There are used various chemical catalysts in the transesterification reaction i.e. acids, alkalis and enzymes. Some of them are the most effective i.e. alkaline catalysts (KOH) and their methoxides.

In the transesterification reaction, the oil is converted to FAME (Fatty Acid Methyl Ester). The flow, which goes out from the reactor, should be purified. First, the methanol is recovered (94%) and then residue is carried to separation of glycerine. Next, the obtained biodiesel is purified to commit the standards of quality. Glycerol is a by-product formed in the esterification of rapeseed oil. In this process also are created soaps and free fatty acids. Glycerol phase constituting concentrated glycerol (about 80% solution) may be transferred to facilities specializing in treatment of glycerol (e.g. cosmetic, pharmaceutical).

Biofuel is sold for the Macedonian Market (REACH registration is not performed yet). The European Directive on biofuels is not (yet) implemented in Macedonia. Manufacturers or importers of chemical substances need to register those substances. Fuels are not exempt from REACH! In REACH terms, biodiesel is a substance with a complex and/or variable composition and in certain circumstances its different variants require registration.

- If you use fresh/virgin (i.e., non-waste) vegetable oil or animal fat to make biodiesel in quantities of 1tonne or more per year, either to use yourself or to supply to other people (even if it's for export), then you will have a registration duty for the biodiesel. In these circumstances you have manufactured the biodiesel.

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

The conclusions of each group are given below.



Group 1 (SDSs)

Basically there are not many chemicals in use. What is imported is also accompanied by SDSs. Importer translate these SDSs and also update.

Group 2 (Process)

SDSs of dangerous chemicals are available on site and are translated to local language. Hazardous material procedures are available which are drafted according to IPPC. Emissions only come from the boilers. Monitoring takes place with SO₂ being measured 4x/year. The factory has an IPPC permit and is a higher Tier SEVESO site (Methanol storage). The SEVESO safety report is confidential.

Group 3 (Waste)

Biodiesel is produced in a closed process. Biofuel is sold for the Macedonian Market (REACH registration is not performed yet). The European Directive on biofuels is not (yet) implemented in Macedonia. Glycol as a by-product is sold in part and partly used for heat generation.

Waste include absorbents, filter materials. Hazardous wastes are handled by a licensed company (Ekotin, Croatia). There is an administration and a database.



V. Evaluation

Statistical information

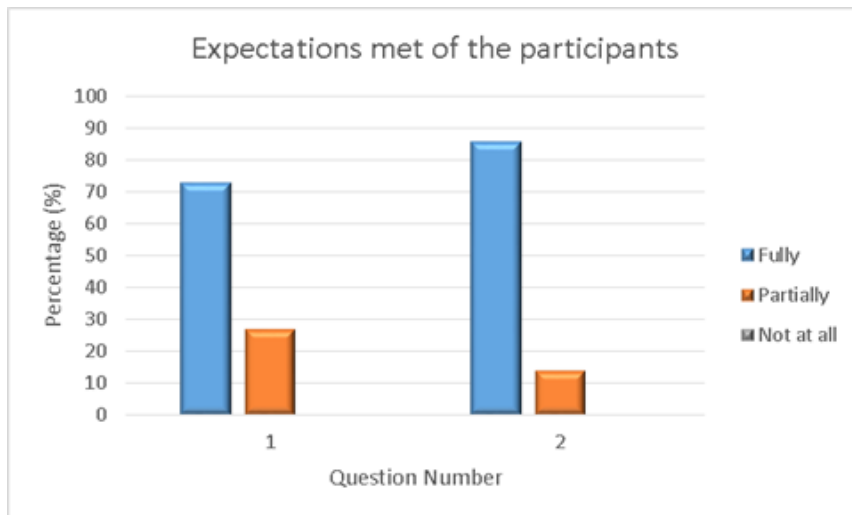
1.1	Workshop Session	Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – Technical aspects, 01-03 September 2015, Skopje, Formal Yugoslav Republic of Macedonia
1.2	Facilitators name	As per agenda
1.3	Name and Surname of Participants (evaluators) optional	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. Improved functioning of the environmental authorities and related authorities envisaged to be responsible for implementation of the REACH/CLP regulations and IED	■■■■ ■■■■ ■■■■ ■■■■ ■ (73%)	■■■■ ■ (27%)	
2. Improved knowledge on streamlined working methods and implementation of best practice in the region moving towards EU standards	■■■■ ■■■■ ■■■■ ■■■■ ■■■■ (86%)	■■■ (14%)	



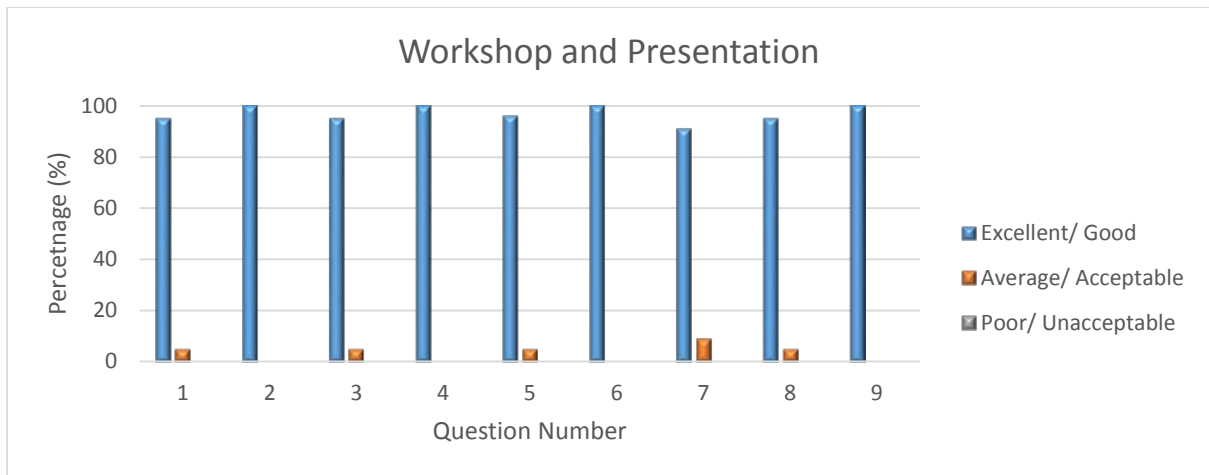


Workshop and Presentation

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	 (86%)	 (9%)	I (5%)			
2 The quality of the workshop was of a high standard	 (64%)	 (36%)				
3 The content of the workshop was well suited to my level of understanding and experience	I (50%)	 (45%)	I (5%)			
4 The practical work was relevant and informative	I (50%)	I (50%)				
5 The workshop was interactive	 (64%)	II (32%)	I (5%)			
6 Facilitators were well prepared and knowledgeable on the subject matter	 (82%)	 (18%)				
7 The duration of this workshop was neither too long nor too short	 (36%)	II (55%)	II (9%)			
8 The logistical arrangements (venue, refreshments, equipment) were satisfactory	I (50%)	 (45%)	I (5%)			
9 Attending this workshop was time well spent	 I (73%)	I (27%)				





Comments and suggestions

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

Workshop Sessions:

- Experience of countries that are doing monitoring – minimum and optimum;
- Maybe it would be good to include more lectures regarding IED and experience from different countries.

Facilitators:

Workshop level and content:

- More IED related topics;
- The workshop was in a good level and content, we have enough time for ask and answer. The visit in biodiesel factory complete the topic of this workshop.

ANNEX I – Agenda

Day 1 : September 1, 2015

Topic: Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – Technical aspects

Chair and Co-Chairs: Ike van der Putte/Nazim Aliti

Venue: Hotel Arka, Skopje

Start	Finish	Topic	Speaker	Sub topic/Content
08:30	08:45	Registration		
08:45	09:00	Opening	Host country representative – Nazim Aliti (national coordinator) tbc Ike van der Putte (ECRAN –ECENA Coordinator)	<ul style="list-style-type: none"> - Welcome - Introduction of trainers - Introduction of participants
09:00	09:15	Introduction	Ike van der Putte (ECRAN –ECENA Coördinator)	<ul style="list-style-type: none"> - Explanation of the training programme - Information on ECRAN - Defined ECENA activities
09:15	10:00	General introduction on REACH Regulation	Arnold van der Wielen (ECRAN expert)	<ul style="list-style-type: none"> - Introduction on the main elements of REACH Regulation (such as What, Who, When and How)
10:00	10:45	Environmental risk assessment and ecotoxicological endpoints	Martin Murin (TAIEX expert)	<ul style="list-style-type: none"> - Basic knowledge on environmental risk assessment - Explanations on major ecotoxicological endpoints such as EC50, PNEC, etc.)
10:45	11:00	<i>Coffee Break</i>		



11:00	11:45	Environmental risk assessment case study	Martin Murin	<ul style="list-style-type: none"> - Exercise for the participants with the purpose of understanding how the environmental risk is assessed.
11:45	12:30	PBT & vPvB assessment	Martin Murin	<ul style="list-style-type: none"> - Definitions of PBT and vPvB chemicals - Determination of PBT and vPvB chemicals
12:30	13:30	Lunch Break		
13:30	14:15	Human health risk assessment	Ike van der Putte	<ul style="list-style-type: none"> - Basic toxicology and human health risk assessment theory - Explanations on basic toxicological parameters such as LC50, LD50, NOAEL etc.
14:15	15:00	Endpoints and testing	Ike van der Putte	<ul style="list-style-type: none"> - Explanation on eco(toxicological) endpoints with are used for classification of chemicals - Introduction on the testing relevant to the eco(toxicological) endpoints mentioned above
15:00	15:15	Coffee Break		
15:15	16:00	Exposure scenarios in general	Arnold van der Wielen	<ul style="list-style-type: none"> - The format and content of exposure scenarios - Major terms used in exposure scenarios - Understanding of exposure scenarios
16:00	17:00	Round table discussion of the participating countries	Ike van der Putte Participants and trainers	Existing organisation structures for implementation of REACH in the participating countries.



Day 2 : September 2, 2015

Topic: Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to IED – Technical aspects

Chair and Co-Chairs: Ike van der Putte/Nazim Aliti

Venue: Hotel Arka, Skopje

Start	Finish	Topic	Speaker	Sub topic/Content
9:00	9:15	Welcome coffee and summary of day 1	Ike van der Putte	
9:15	10:00	Restriction under REACH	Arnold van der Wielen	- How the EU MSs deal with Annex XVII to REACH (restricted chemicals under REACH) as one of the outcomes of REACH
10:00	10:45	PIC and POP Conventions	Martin Murin	- Background of PIC and POP Conventions - The links of PIC and POP Conventions with other EU legislation
10:45	11:00	Coffee Break		
11:00	12:00	Inspection on SDS (including case study)	Arnold van der Wielen	- Structure and content of SDS - Check on SDS
12:00	12:30	Enforcement of REACH in Bulgaria and development of Forum	Parvoleta Luleva (TAIEX Expert)	- Experience sharing on how REACH is implemented in Bulgaria - Introduction on the recent development in Forum
12:30	13:30	Lunch Break		



13:30	14:15	Enforcement of REACH in Bulgaria and development of Forum (continue)	Parvoleta Luleva	<ul style="list-style-type: none"> - Experience sharing on how REACH is implemented in Bulgaria - Introduction on the recent development in Forum
14:15	15:00	Manual for REACH inspection	Gisela Holzgraefe (TAIEX Expert)	<ul style="list-style-type: none"> - Introducing and explanation of the Manual for REACH inspection - Recent relevant developments in IMPEL
15:00	15:15	<i>Coffee Break</i>		
15:15	16:15	Manual for REACH inspection	Gisela Holzgraefe	<ul style="list-style-type: none"> - Introducing and explanation of the Manual for REACH inspection - Recent relevant developments in IMPEL
16:15	17:00	Preparation visit Factory	Gisela Holzgraefe Participants and trainers	



Day 3 : September 3, 2015

Topic: Visit to PILOT FACTORY (Biodiesel production facility- MAKPETROL - FAME), Skopje

Venue: Hotel Arka, Skopje

Start	Finish	Topic	Speaker	Sub topic/Content
8.30	9.00	Transport of workshop participants to the pilot factory from the hotel		
9:00	12.00	Visit to PILOT FACTORY	All participants	
		Preliminary discussion in the factory office		<ul style="list-style-type: none"> - 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"> - 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.



				- Each member of the group will make their own inspection and make notes and compare results later in the group
		Return to Meeting room at the factory		- General comments on visit site and any further questions
12:00	12.30	<i>Return to the hotel</i>		
12.30	13.30	<i>Lunch Break</i>		
13.30	15.00	Visit report preparation in groups		
15.00	15.15	Coffee Break		
15.15	16.15	Presentation of reports by members of the group		- Conclusions of site visit - Suggested follow-up actions
16:15	17:00	Round table discussion of the participating countries	Ike van der Putte Participants and trainers	- Evaluation and follow-up programme
17:00		<i>Closure</i>		



ANNEX II – Participants

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ANNEX III – Presentations (under separate cover)

Presentations can be downloaded from:

[http://www.ecranetwork.org/Files/Presentations -
REACH CLP Workshop, September 2015, Skopje.zip](http://www.ecranetwork.org/Files/Presentations-_REACH_CLP_Workshop,_September_2015,_Skopje.zip)



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