Environment and Climate Regional Accession Network ECRAN

Environment and Climate Regional Accession Network (ECRAN)

Regional Workshop Report Compliance with REACH/CLP Regulations

14-15 October 2015, Izmir

Enviroment and Climate Regional Accession Network ECRAN

ENVIRONMENTAL AND CLIMA REGIONAL NETWORK FOR ACCESSION - ECRAN

WORKSHOP REPORT

Activity 1.2.4

COMPLIANCE WITH REACH/CLP REGULATIONS

14-15 October 2015, Izmir, Turkey

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LIST OF ABREVIATIONS	
ANK	AkzoNobel Kemipol
ATP	Adaptation to Technical Progress
CA	Competent Authority
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, Reprotoxic
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environmental Agency
GHS	Globally Harmonised System
HPV	High Production Volume
IED	Industrial Emissions Directive
IPPC	Integrated Pollution Prevention and Control
IRAM	Integrated Risk Assessment Method
MoEU	Ministry of Environment and Urbanisation
MoEW	Ministry of Environment and Water
MS	Member State
MSDS	Material Safety Data Sheet
NEA	Dutch Emission Authority
OEM	Original Equipment Manufacturer
OR	Only Representative
PBT	Persistent Bioaccumulative and Toxic substances
PNEC	Predicted No-Effect Concentration
RAPEX	Rapid Alert System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restrictions of Chemicals
RGS	Reach Global Service
SDS	Safety Data Sheets
SEA	Strategic Environmental Assessment
SVHC	Substance of Very High Concern
TFS	Transfrontier Shipment of Waste
vPvB	Very Persistent and Very Bioaccumulative

I. Background/Rationale

Within the RENA programme, the objective of the ECENA Working Group on Environmental Compliance and Enforcement was to improve the ability of RENA member countries to implement and enforce the EU environmental and climate acquis by increasing the effectiveness of inspecting bodies and promoting compliance with environmental requirements.

The activities for the period 2010-2013 were based on a Multi Annual Work Plan, covering the following areas:

- Training and exchange;
- Institutional and methodological development;
- Cross border enforcement.

The activities planned under ECRAN in this area will build on the results achieved under RENA. Since the work of inspectors and permit writers has to be more coordinated and connected to other activities within the environmental protection area, it has been decided that ECENA under ECRAN should be of cross cutting nature. This is particularly important as the work of ECENA is dealing with both implementation and enforcement of the EU acquis. Cooperation with policy makers and law drafters has to be strengthened in order to enable developing better implementable legislation.

The work plan covers the full period of ECRAN (i.e. October 2013 – October 2016). Under this ECENA work plan, the following specific activities have been decided to be implemented:

1.2.1 Capacity building on compliance with environmental legislation

1.2.2 External country assessments

1.2.3 Methodological development - application of IRAM/easy Tools

1.2.4 Compliance with REACH/CLP Regulations;

1.2.5 Trans frontier Shipment of Waste (TFS);

1.2.6 Inspection and enforcement in other policy areas;

1.2.7 Inspector's participation in networking activities.

The beneficiaries are the Ministries of Environment of the beneficiary countries (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 need to be actively engaged in so far as their work is relevant for the scope of ECRAN.

The overall objective of ECRAN 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

[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.

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on their way towards the transposition and implementation of the EU environmental and climate policies, political targets and instruments which is a key precondition for EU accession.

Activity1.2.4 Compliance with REACH/CLP Regulations

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) sets the framework for the control of chemicals in the EU for the foreseeable future.

It entered into force on 1 June 2007. However, most of its provisions only came into force on 1 June 2008. CLP stands for Classification, Labelling and Packaging. The CLP Regulation entered into force in January 2009, and the method of classifying and labelling chemicals it introduced is based on the United Nations' Globally Harmonised System (GHS). REACH and CLP regulations are closely linked to each other. Introductory presentations for inspectors have been given on the REACH and CLP regulations in the Cluster 1 activity of RENA WG 4, including some downstream consequences and linkages of REACH/CLP with IED, SEVESO and Waste management.

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.

Enforcement of REACH and CLP is a national responsibility, therefore each EU Member State, 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 enforcement of the requirements of the REACH and CLP Regulations involves many different enforcement authorities and other bodies. The environmental inspectorate can play a coordinating role. There is a need for a national strategy defining the needs for co-operation and coordination between these enforcement authorities to ensure effective and efficient enforcement of REACH and CLP. A key element in any strategy is to define the roles and responsibilities of the various groups involved. This would allow for an efficient enforcement process, avoiding gaps and dealing with any overlaps in the enforcement competencies and responsibilities.

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 and

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compliance. 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.

In the series of two 2-day workshops, including a 1-day site visit/common inspection the following subjects are to be handled:

- Background and basics REACH and CLP;
- Roles and responsibilities under REACH;
- Enforcement strategies;
- Cooperation and coordination between enforcement authorities;
- Minimum Criteria for REACH and CLP inspections;
- Linkage of REACH and IED;
- Downstream consequences of REACH/CLP on other legislation (including SEVESO and Waste).

The present training course in Izmir is the second in the series.

Chapter 2 describes the background and objectives of activity 1.2.4 with the 2nd ECRAN Regional Workshop on Compliance with REACH/CLP regulations.

Chapter 3 describes the EU policy and legislation covered by the training;

Chapter 4 presents the workshop proceedings and Chapter 5 presents the evaluation. Furthermore the following Annexes are attached:

_ Annex I: the agenda;

_ Annex II: List of participants;

_ Annex III: Power point presentations (downloadable under separate cover):

http://www.ecranetwork.org/ECENA

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II. Objectives of the training

General 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

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 enforcement aspects of the REACH and CLP Regulations, interlinked amongst other with the Industrial Emissions Directive as these are covering major chapters in chemicals legislation and industrial pollution control.

Target group

The target institutions and beneficiaries are the environmental inspectors and permit writers of the Ministries of Environment in Albania, Bosnia and Herzegovina, the Former Yugoslav Republic of Macedonia, Kosovo*, Montenegro, Serbia and Turkey.

Expected results

The following result are expected for this activity

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

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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: Ref 1.[2], (Ref 2)[3]

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

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

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

[2] REF 1) 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] REF 2) 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.

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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.

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IV. Highlights from the training workshop

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

Day 1 – Hotel Konak Best Western, Izmir, 14 October

1. A welcome was given by Mr. Kemal Dag, Deputy General Director- General Directorate of the Ministry of Environment and Urbanization, Turkey. A brief overview was given on the developments in Turkey with the national regulations on chemicals (classification – CLP, restrictions, registry and SDS). The regulations are in line with REACH/CLP but not completely harmonised yet as Turkey is not yet an EU member state. After accession some pieces of the Turkish national legislation on chemicals have to be repealed. It was mentioned that although there are many inspectors available in the field (1150), this number was not sufficient and a system with so-called environmental officers appointed in permitted factories has been started. Thanks were given to the trainers for organizing the event.
2. The workshop was chaired by Mr. Ike van der Putte (ECRAN ECENA coordinator) and Ms. Pinar Topkaya (National ECENA coordinator) starting with a short welcoming and introduction on ECRAN and the ECENA Programme. The information on ECRAN and ECENA has been given including a project summary. The trainers and experts , Mr. Arnold van der Wielen (ECRAN SSTE), TAIEX experts Mr. Martin Murin, Mr. Robert Rocek and invited experts from Turkey, Ms. Ahu Cekim (Expert Chemicals Management Department, Ministry of Environment and Urbanization) and Ms. Burcu Ozer (Health and Safety Environmental Manager of the paint producing industry Kansai Altan) were introduced.
3. An introductory round was held among the participants with the question on the years of experience as inspectors, permit writers and policymakers/other fields. The results showed that most of participants have extensive knowledge and experience in inspection and permit writing. Four persons also have participated in the workshops of the IED/Chemicals Working Group of ECRAN.

	Years of experience		
	1 – 5 years	***5 – 10 years***	***More than 10 years***
Inspectors	3	6	7
Permit writers	1	4	1
Policy makers/others	4	3	3

A limited number of 7 participants also participated in the first REACH/CLP compliance training workshop. As a consequence it is required for the trainers to repeat some of the basics of the REACH/CLP regulations as given in the 1st training.

4. *Introduction on the REACH and CLP Regulations*. Mr. Ike van der Putte gave a brief overview of the main elements of REACH and CLP with an introduction on the history, the problems with chemicals and the legal structures. The REACH and CLP organisation, critical timelines and the relationship of REACH/CLP with other parts of chemicals legislation received special attention. Emphasis was given on the obligations of authorities and the enforcement of REACH.

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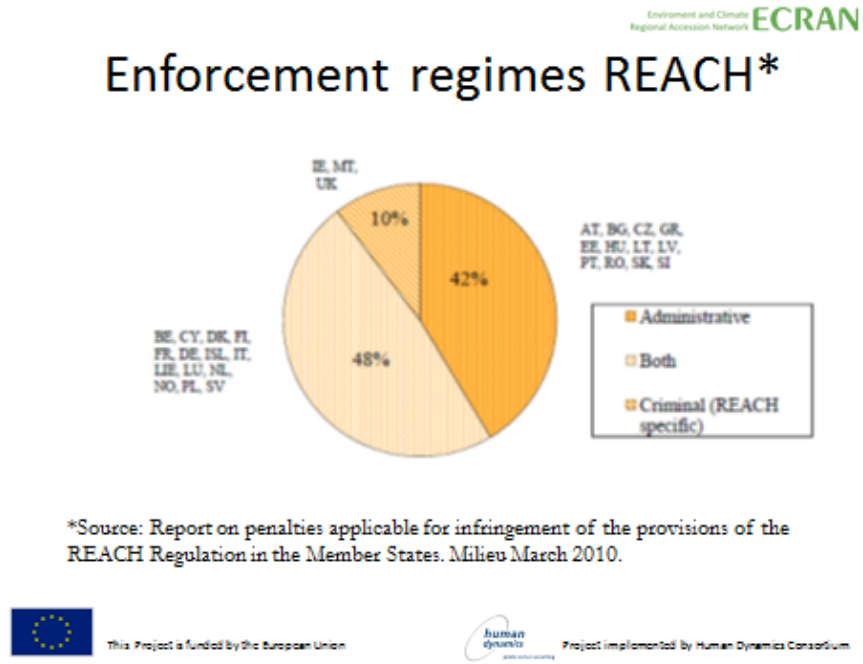
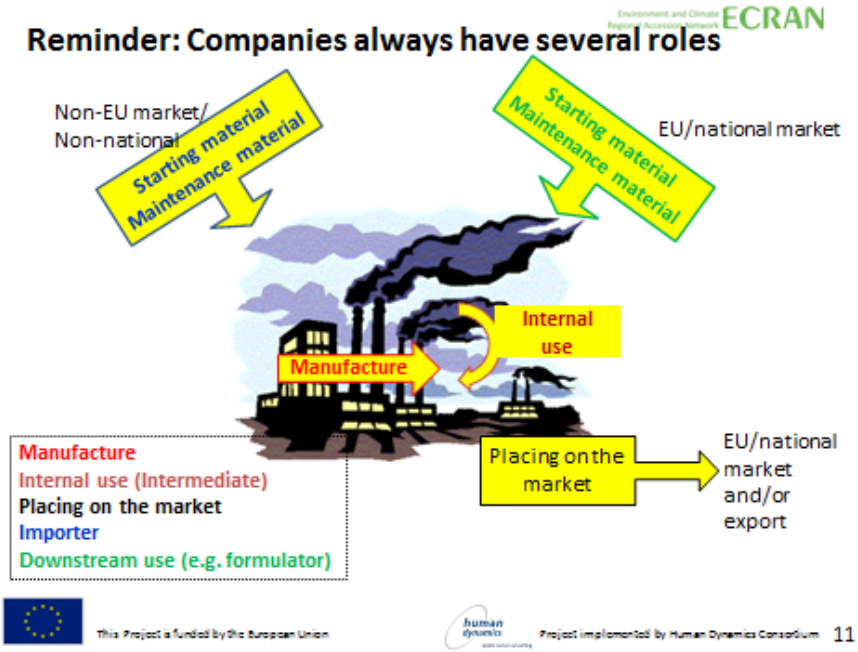


5. *REACH specifics with roles & responsibilities*. Mr. Arnold van der Wielen especially paid attention to the roles of the various actors in REACH. A focus was placed on the requirements of REACH.

REACH requirements are related to specific activities as:

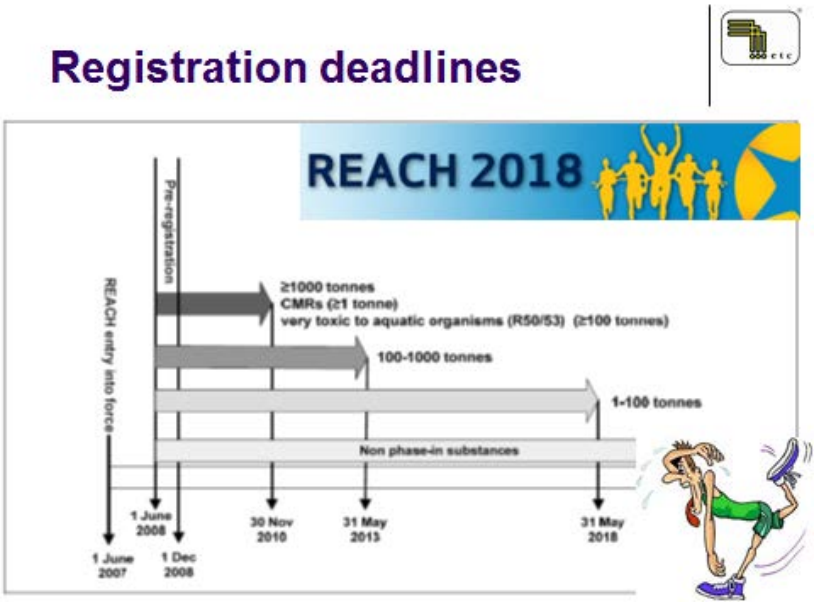
- *Manufacturer* of a substance;
- *Importer* of a substance on its own, as component in a preparation, or in an article;
- *User (Downstream User e.g. Formulator)* of a substance or preparation (professional);
- *Distributor,* distributive trades;
- *Producer* of an article.



The main tasks are depending on each role and are summarized as follows:

- **Manufacturer / importer / only representative:**
  - Preregister phase-in (=existing) substances
  - Register substances > 1 tpa within the legally defined deadlines according to volume and hazardous properties
  - Classify & label the substance
  - Draft and distribute (e)SDS in case of substances placed on the market
  - Communicate down the supply chain
- **Downstream user:**
  - Implement recommended risk reduction measures in (e)SDS, or draft a Chemical Safety Report for own use
  - Classify & label formulated mixtures
  - Draft and distribute (e)SDS of formulated mixtures
  - Communicate up the supply chain
- **Producer of an article:**
  - Register a substance > 1 tpa in an article if intended to be released during normal or reasonable foreseeable conditions of use, if not registered for that use
  - To submit notification of a substance > 1 tpa in an article being identified as SVHC (listed as candidate for authorisation)
- **Distributor:**
  - Distribute (e)SDSs
  - Communicate up- and down supply chain.

6. *REACH specifics: Registration, Evaluation and Restriction*. Mr. Martin Murin presented a brief overview of registration requirements with various registration deadlines.



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This was followed by an introduction on chemical safety assessment (risk assessment) of substances that is required for registration, with hazard assessment, exposure assessment and risk characterization as important elements. The methodologies and terminologies were summarized and explained.

The risk assessment process, in relation to both human health and the environment, entails a sequence of steps:

1. Assessment of effects:
   (a) hazard identification: identification of the adverse effects which a substance has an inherent capacity to cause;
   (b) dose (concentration) - response (effects) assessment: estimation of the relationship between dose, or level of exposure to a substance, and the incidence and severity of an effect, where appropriate
2. Exposure assessment: estimation of the concentrations/doses to which human populations (i.e. workers, consumers and man exposed indirectly via the environment) or environmental compartments (aquatic environment, terrestrial environment and air) are or may be exposed.
3. Risk characterization: estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include "risk estimation", i.e. the quantification of that likelihood.

An overview was given on the specifics in risk assessment, including the outcomes of the assessment of effects with PNEC, DNEL and DMEL, dose descriptors and assessment factors.

Restriction was explained as:

- the alternative method in REACH of controlling hazardous substances that do not fully meet the criteria for authorisation;
- harmonised controls on the uses of such substances across the EU, up to and including a complete ban as appropriate. Current restrictions are listed in REACH Annex XVII.

On authorization the following remarks were made:

- Authorisation is required for all uses of substances of very high concern (e.g. CMR, PBT vPvB substances);
- Authorisation is granted if risks are under "adequate control";
- adequate control allows authorities to prioritise action to hazardous substances that are difficult to control;
- If adequate control is not possible, authorisation may still be granted on socio-economic grounds (i.e. no suitable safer alternative);
- Companies are required to make efforts to find safer alternative as part of their application for authorisation;
- Any substitute must be "feasible" and deliver lower overall risks.

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The presentation was finalised by giving examples of dangerous substances in non-food products as derived from the RAPEX (Rapid Alert System for dangerous non-food products).

7. *Overview of current Turkish legal framework for chemical management legislation*. The overview was given by Ms. Ahu Çekim, expert of the Ministry of Environment and Urbanization, Turkey.

The institutional organisation and the various laws on chemicals control in Turkey are given in the overviews below. It is clear that the legislation in Turkey has been built in parallel to the EU legislation or the implementable parts thereof.

INSTITUTIONAL FRAMEWORK

INSTITUTION	TASK
Ministry of Environment and Urbanization	industrial chemicals and coordination
Ministry of Health	biocidal products
Ministry of Food, Agriculture and Livestock	plant protection products
Ministry of Labour and Social Security	health and safety in workplace
Ministry of Transport Maritime and Communication	transportation of chemicals
Ministry of Science, Industry and Technology	chemical weapons
Ministry of Economy	import and export of chemicals
Ministry of Customs and Trade	control of chemicals at customs and detergents, some cleaning products, poolchemicals

Ahu ÇEKİM 2

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

By Law on Inventory and Control of Chemicals (26.12.2008/27092)
(in parallel to 793/93/EEC) NATIONAL NEEDS

Ahu ÇEKİM 3

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A central role is played by the By-Law on Inventory and Control of Chemicals, in which an inventory is required of Turkish manufacturers or importers of substances, on its own or in a preparation in quantities of

- one thousand tonnes per year or more
- one tonne or more but less than one thousand tonnes

The inventory is not applied for substances in transit or substances manufactured or imported for military purposes. There is no fee required in the submission and the inventory is based on available data. The submission can be done by a representative in Turkey. The main outputs are approximately 12,000 entries for substances manufactured or imported ≥1 t/pa

Published Lists include:

- List of substances on its own or in a preparation, in quantities exceeding 1 tonnes per year in Turkish market;
- List of High Production Volume (HPV) Chemicals;
- List of priority substances or groups of substances (131 substances).

TONNAGE RANGE	NUMBER OF ENTRIES
1-10	5986
10-100	3687
100-1000	1563
1000-	891
	12127
Total 3000 different substances	

The By Law on the classification, labelling and packaging of substances and mixtures has the aim to protect human health & the environment and defining rules and principles for classification labelling and packaging.

The differences between the CLP By-Law and the EU CLP regulation are:

- ✓ Some Boron Derivatives are excluded from Annex VI;
- ✓ No need to inform the poison centre;
- ✓ MoEU /ECHA;
- ✓ in accordance to 3rd ATP;
- ✓ 4 additional annexes.

The notification requires the same input as in the EU CLP. The obligations on notification of importers could be performed through a representative that is established in Turkey (appointed with an agreement determined by the natural or legal persons settled abroad). There are transitional provisions that have been explained in detail.

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In the By Law on Safety Data sheets of Hazardous Substances and Mixtures, the manufacturer, importer and distributor responsible for placing on the market of a dangerous substance or preparation has to provide the professional user of this dangerous substance or preparation a safety data sheet. This should be:

- ✓ Without Fee requirement;
- ✓ In the Turkish language;
- ✓ Supplied via paper or electronically;
- ✓ With a copy is to be sent to relevant instruction and an electronic copy to the Ministry of Environment and Urbanisation (MoEU);
- ✓ **Prepared by persons certified** by institutions which are accredited perform this activity.

An overview was given of the electronic Chemicals Registration System, followed by an overview of substances and compounds that are presently prohibited or restricted, based on the By Law on Restriction and Prohibitions of Substances and Mixtures.

A Chemicals Helpdesk is operational and draft legislation has been prepared fully in line with the EU REACH regulation.

8. *Chemicals Management in Kansai Altan*. Kansai Altan is the paint producing factory to be visited on day 2 of the course. Presentations were given by Ms. Alev Parildar, Ms. Sevde Bozacioglu and Ms. Burcu Ozer, as representatives of Kanzai Altan. The subjects covered REACH and CLP related activities in the import of substances and ingredients and the production (formulation) of paints and subsequent sale and export.

The company has started in 2007 with the determination of REACH related substances. In the beginning the list of chemicals and products were handled manually. The lists included amongst others:

- List of products exported to the EU;
- Raw materials inventory with calculated tonnages of substances;
- Exempted substances identified etc.

The company has many customers and products with many kinds of raw materials and suppliers. Due to the complexities software had to be designed to meet the various requirements. The software handles now information and refers to:

- A substances identification data base;
- A raw material's ingredients data base;
- REACH related substances;
- The generation of reports by different queries;

For (EU) pre-registration of substances and monomers an only representative (OR) has been used (Reach Global Service – RGS). A number of 120 substances had been pre-registered.

The various routines of the company were described with:

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- Annual reports (on review of substance volume and REACH status);
- Updating database on REACH (substance database, raw material ingredients database);
- Supply chain communication – Supplier (REACH registration number is asked from suppliers; checking MSDSs of new raw materials);
- Supply chain communication – Customer (substance report and declaration on REACH compliance is sent to customer or importer).

The company makes use of a registration number tracking system (Registration number control – ECHA-), sent by suppliers (via MSDS or mail).

An algorithm has been developed to judge and evaluate the REACH status of a raw material based on the responses of all suppliers.

A finally an outlook was given on the various targets of the company, when the Turkish REACH system will be implemented.

A presentation was given on how the company handles SDSs and Labels. Software is being used (Chem Ges) for preparing SDSs. Labelling is performed, meeting the configuration requirements of the customers.

For internal risk communication the following codes are used with:

S: Santé (Health) rating 0 – 4

I: Inflammability (Flammability) rating 1 – 4

R: Reactivity rating 0 – 4

E: Equipment ranging from A – H and Z: from gloves (A) to special measures (Z)

9. *REACH CLP downstream consequences*. Mr. Ike van der Putte presented a brief overview of the SEVESO III Directive, with various requirements of low tier and high tier installations. Specific attention was paid to the consequences of the REACH/CLP regulations on the identification of low tier and high tier installations.

With the new classification system induced by REACH/CLP in SEVESO III also the methodology in the aforementioned identification has to be adapted. A case study with an exercise was performed to illustrate the assessment of low tier and high tier installations.

10. REACH/ CLP implementation and enforcement in Bulgaria. Ms. Parvoleta Luleva, Head of Hazardous Chemicals Department, Preventive Activities Directorate of the Ministry of Environment and Water, Bulgaria, described the practical experience in enforcement of REACH/CLP in Bulgaria. The following is taken up in Chapter V “Measures for Implementation of REACH and CLP”, of the Bulgarian Chemicals Act:
    - Minister of Environment and Water- designated as a national competent authority to perform the tasks allotted to it in REACH (2007) and CLP (2010);
    - Expert Committee on Substance Evaluation (2015)- appointed by the MoEW to perform the tasks on substance evaluation, proposals for identification of substances of a very high

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concern (SVHC) for authorisation, restrictions or harmonisation of classification and labelling of hazardous substances under REACH and CLP;
- National REACH (2007) and CLP (2010) Helpdesk (Hazardous Chemicals Department)- advice and assistance to industry, especially SMEs for performing their obligations,

Chapters VII and VIII "Enforcement and Administrative Provisions", of the Bulgarian Chemicals Act cover powers, penalties and cooperation:

- Powers and responsibilities of the national enforcement authorities (NEAs);
- 'Effective, proportionate and dissuasive' penalties for non-compliance of REACH and CLP;
- Cooperation with Customs in relation to the import and placing on the market of hazardous chemicals subject to authorisation or restriction (final draft of a joint Memorandum of Understanding on market surveillance of chemicals has recently been developed and now under ongoing inter-service consultations).

The various tasks and duties of the enforcement authorities are described with involvement of the Ministry of Environment and Water (regional inspectorates), General Labour Inspectorate, the Ministry of Health (regional inspectorates) and the Ministry of Economy. There is an active and reactive enforcement approach:

Active enforcement is based on:

- Annual inspection plans,
- Risk based approach for selection of duty holders and chemicals for targeted enforcement;
- Topic specific campaigns on (pre-)registration (charcoal, individual submissions, intermediates), SDSs and communication in the supply chain, safe storage of chemicals, restrictions (asbestos in cars, chromium VI in cement, nickel in jewellery, azocolourants in textile and clothes), etc.;
- EU wide and national coordinated enforcement projects.

Reactive enforcement is carried out:

- Based on information provided by competitors, consumers or other NEAs (e.g. RAPEX notifications, information on imports by Customs)
- Upon request by ECHA, European Commission or other NEAs MSs.

A description was given on the enforcement projects in Bulgaria, some of which are performed in cooperation with ECHA – Forum (REACH ENFORCE projects).

There is an ongoing process for improving the interlinks and synergy with other pieces of legislation () including:

- Seveso III (chemicals hazards in classification of upper- and lower-tier establishments, safety measures for major accidents prevention) and Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA, land-use planning);
- Industrial Emissions Directive (IPPC permits);

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- Water Framework Directive (Priority Substances);
- Waste Framework Directive (Waste Classification, End-of-Waste Criteria);
- Work safety legislation (chemical agents, carcinogens and mutagens at work), etc.

11. *REACH/CLP regulations in relation with other legislation*. Mr. Robert Rocek, Senior Environmental Enforcement Officer at the Ministry of Environmental and Nature Protection in Croatia, presented the Croatian experience in the implementation of REACH/CLP Regulations in relation with other legislation. The competent authority (CA) for chemicals and biocidal products in Croatia is the Ministry of Health (policy making institute and help-desk) with its sanitary inspection responsible for supervision on chemicals (production, use and import). The key elements of REACH, CLP, SDS, SEVESO II and SEVESO III, in relation to chemicals were explained and discussed. The enforcement strategies with cooperation and coordination between inspectorates were described. There is an agreement on co-operation between inspection services in the field of environment starting from 5 June 2008. The environmental inspectorate plays a coordinating role. Now coordinated inspections are carried out of IED and SEVESO installations with an annual plan and report available via internet.

12. In preparing for the site visit the participants were divided in 3 groups. An explanation was given by Mr. Martin Murin on the role of the factory to be visited as formulator/downstream user:" Formulators are downstream users who produce mixtures and usually supply them further down the supply chain or directly to consumers. They mix together substances and/or mixtures, with no chemical reaction taking place during the process. Examples of such mixtures include paints, adhesives, cosmetics, lubricants, detergents and diagnostic kits".

The tasks of the 3 groups was to formulate each 3 REACH/CLP related questions considering respectively:

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- The supply of chemicals and raw materials (group 1);
- The process (group 2);
- The products and waste (group 3).

Day 2 – Visit to Kansai Altan Boya Sanayi A.Ş., Izmir, 15 October

The visit started with introductory presentations by Mr. Mustafa Konya (consultant to the Management), Ms. Burcu Ozer (health, Safety and Environment Manager) and Ms. Alev Parildar (Analysis Laboratory Manager).

Kansai Altan Boya Sanayi A.Ş. is a paint company with an annual production capacity of 80 thousand tons, situated on a 100 thousand m² land in Izmir. It manufactures 78% of its polymer requirement in its own polymer production facility which is located in the same site and has 17,5 thousand tons of production capacity per annum. 4750 types of products designed for 6 different sectors are being produced in 8 production halls for approximately 430 customers in Turkey and abroad.

The main activities of Kansai Altan can be classified in 2 groups:

- Automotive Coatings;
- General Industrial Coatings.

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Apart from its primary activities, Kansai Altan also does toll production for all the activity areas of AkzoNobel Kemipol (ANK), in accordance with the contract between the two companies.

The Automotive Coatings department has been serving the Turkish Automotive OEM (Original Equipment Manufacturer) industry since its foundation in 1982 under the name of Kemipol. Customers mainly are automotive OEM producers and metal & plastic parts producers.

The General Industrial Coatings Department of Kansai Altan Boya Sanayi ve Ticaret A.Ş. is responsible for the design, development, production, marketing and sales of waterborne and solvent borne coatings for industrial applications. Kansai Altan General Industrial Coatings Department serves a large market consisting of steel construction and building materials producers, outdoor advertising, transformer, tractor, agricultural and heavy duty machinery producers, panel radiator and condenser producers, drum and barrel producers, and all kinds of other producers who manufacture for the metal industry and use liquid paint.

Statistical data:

Total Area	• 100.000 m^2
Buildings	• 35.058 m^2
Total Closed Area	• 45.969 m^2
PAINT PRODUCTION CAPACITY (3 shifts/6 days)	• 70.000 ton/year
POLYMER PRODUCTION CAPACITY (3 shifts/6 days)	• 16-17.000 ton/year
PAINT PRODUCTION	• 54.312 ton/year (2014)
POLYMER PRODUCTION	• 14.205 ton/year (2014)
TOTAL NUMBER OF EMPLOYEES	• 765 (Aug.2015)

The training participants have been divided into three groups to assess specific issues in relation with REACH/CLP and were guided separately through the factory:

<u>*Group 1.*</u> *Supply of chemicals and raw materials* .An important issue was the quality of toxicity data considering the supply of materials. The data are gathered using a special software system. For the selection of suppliers considering the quality of their data, an algorithm/decision tree was used to assess the best/ allowable suppliers. The company is complying with the CLP requirements. Here it was noticed by the Ministry representatives that the labels should be translated in Turkish (required under Turkish legislation). This was not the case in all labels seen during the site visit. The internal code to indicate safety levels and protection measures was not considered to be sufficient. The third issue was the use of nano materials. This was not the case yet but will not be ruled out in the near future. The use of lead and chromium based pigments will be stopped within 2 years based rules of the main user (AKZO).

<u>*Group 2.*</u> *Production process safety*. There is an emergency plan with detailed instructions for the employees. A number of seven fire drills and one drill on skills on chemicals are performed per year. Kansai Altan is considered to be an upper tier SEVESO site and a safety report should be submitted.

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The latter is in process with a worst case scenario to be overfilling of a tank in the tank farm plus pipe leakage. It was noted that flammable materials were stored in storage halls without specific compartments. Compartmentalization was suggested for specific chemicals. Waste water was pre-treated chemically before discharge in the sewerage network of the municipality. Monitoring results show that the quality fulfils the requirements.

Group 3. Waste and products. Waste is stored in separate areas. Some of the waste is recycled in the process, other are sold to certified customers (empty drums/cans). In packaging waste, advice was received from customers. CLP was used for final products, with the type depending on the demands of the customer. Lead based pigments were not used anymore whereas the use of chromium based pigments will be stopped in 2017.

The meeting and site visit were closed by thanking Ms. Burcu Ozer and Mr. Mustafa Konya and their colleagues of Kansai Altan for their presentations, guidance in the site visit and their openness in answering the questions and the sharing of information. Special thanks were given to Ms. Pinar Topkaya (national ECENA coordinator) for her support.

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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 24 out of 32 participants filled the evaluation form. It shows that the expectations of the workshop were met.

The majority of the trainees indicated that their expectations for the workshop were met. The trainees indicated that the training was of a high quality and fit for its purpose. The trainees also expressed their wish to have more time for REACH CLP training

Statistical information

1.1	Workshop Session	Regional Workshop on Compliance with REACH/CLP Regulations 14-15 October 2015, Izmir, Turkey
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. Gained knowledge on how to improve functioning of the environmental authorities and related authorities to be responsible for implementation and enforcement of the REACH/CLP regulations	IIIII IIIII III (54%)	IIIII IIIII I (46%)	
2. Streamlined working methods and implementation of best practice in the region moving towards EU standards	IIIII IIIII IIIII (62.5%)	IIIII IIII (37.5%)	

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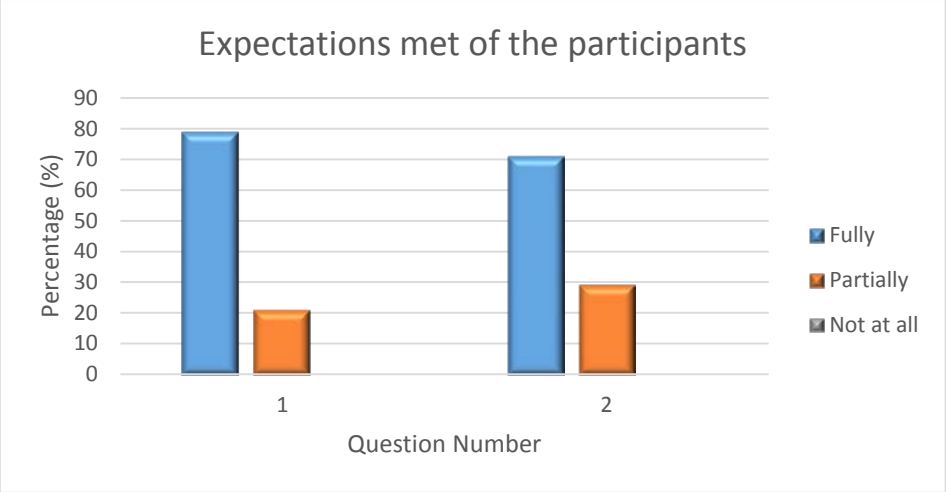

Workshop and Presentation

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 (50%)	IIIII IIII (37.5%)	III (12.5%)			
2. The quality of the workshop was of a high standard	IIIII IIII (39%)	IIIII III (35%)	IIIII I (26%)			
3. The content of the workshop was well suited to my level of understanding and experience	IIIII II (30%)	IIIII IIIII I (48%)	III (13%)	II (9%)		
4. The practical work was relevant and informative	IIIII II (30%)	IIIII IIIII III (57%)	II (9%)	I (4%)		
5. The workshop was interactive	IIIII IIIII I (48%)	IIIII (22%)	IIIII (22%)	I (4%)	I (4%)	
6. Facilitators were well prepared and knowledgeable on the subject matter	IIIII IIIII III (56%)	IIIII I (26%)	IIII (18%)			
7. The duration of this workshop was neither too long nor too short	IIIII IIIII IIII (58%)	IIIII (21%)	IIIII (21%)			
8. The logistical arrangements (venue, refreshments, equipment) were satisfactory	IIIII IIIII IIII (61%)	IIII (17%)	III (13%)	II (9%)		
9. Attending this workshop was time well spent	IIIII IIIII II (52%)	IIIII III (35%)	III (13%)			

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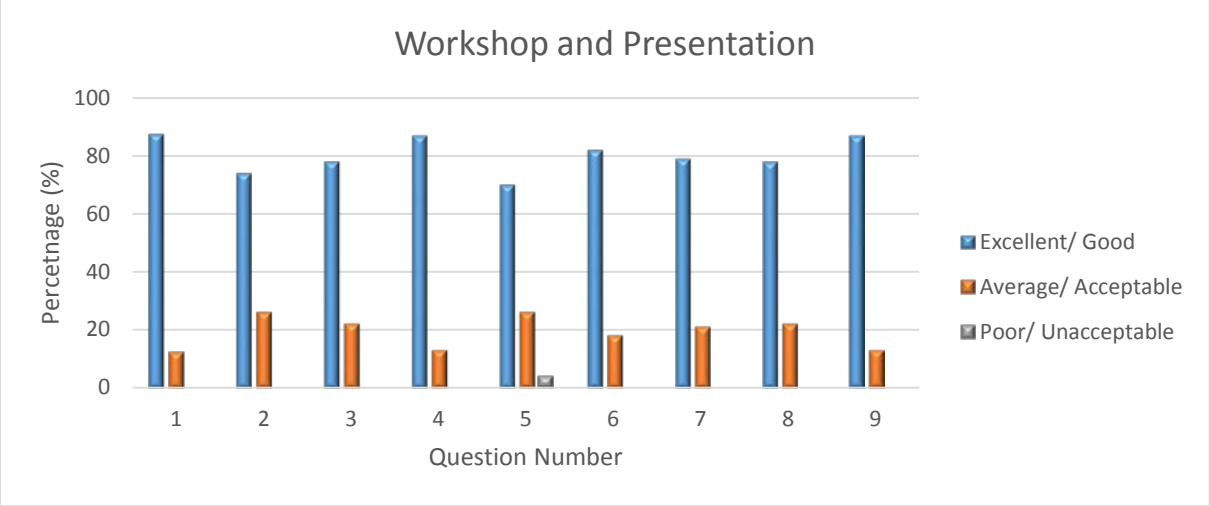

Comments and suggestions

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

Workshop Sessions:

- Ok;
- Ok;
- Monitoring minimum and optimum;
- Good;
- It is recommended to allocate more time for questions related to practice.

Facilitators:

- Ok;
- Ok;
- Very good;
- Some subjects were/had to be repeated.

Workshop level and content:

- Ok;
- Ok;
- Good;
- More on CLP and REACH is required

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ANNEX I – Agenda

Day 1 : Wednesday 14 October 2015

Topic: Capacity building on compliance and enforcement of REACH/CLP regulations **Chair and Co-Chairs: Mrs. Pinar Topkaya/ Mr. Ike van der Putte**				
Start	**Finish**	**Topic**	**Speaker**	**Sub topic/Content**
08:30	**09:00**	**Registration**		
9.00	9.15	Opening	Host country representative Ike van der Putte (ECRAN –ECENA Coordinator)	- Welcome - Introduction of trainers - Introduction of participants
9.15	9.30	Introduction on the REACH and CLP Regulations	Ike van der Putte (ECRAN SSTE)	-Introduction on the main elements of REACH (such as What, Who, When and How)
9.45	10.15	REACH Specifics – Roles & Responsibility (incl. example)	Arnold van der Wielen, ECRAN	- Actors and roles under REACH - The responsibilities for different roles - Specific responsibility of authority under REACH
10.15	10.45	REACH Specifics – Roles & Responsibility case study	Arnold van der Wielen, ECRAN	- Identifying the roles of organization - Defining the responsibility for specific role
10.45	11.00	***Coffee Break***		
11.00	11.45	REACH specific: Registration Evaluation, Authorisation and Restriction	Martin Murin, Ekotoxikologické centrum Bratislava s.r.o.	REACH specific:Registration Evaluation, Authorisation and Restriction

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11.45	12.30	Chemicals management in Turkey-case	Ms. Ozer Kainsai Altan, Izmir	- REACH/CLP applications in the company Kansai Altan will be given
12.30	13.30	***Lunch Break***		
13.30	14.00	REACH/CLP Downstream consequences	Ike van der Putte (ECRAN SSTE)	- Downstream consequences on SEVESO
14.00	15.00	REACH/CLP implementation and Enforcement In Bulgaria	Parvoleta Luleva Head of Hazardous Chemicals Department Preventive Activities Directorate Ministry of Environment and Water, Bulgaria	- Practical experience in enforcement of REACH/CLP in Bulgaria - Interaction with the ECHA FORUM
15.00	15.15	***Coffee Break***		
15.15	16.00	REACH/CLP regulations in relation with other legislation	Robert Rocek Senior Environmental Enforcement Officer Ministry of Environmental and Nature Protection	Croatian experience in the implementation of REACH/CLP Regulations in relation with other regulation
16.00	17.00	Preparation visit Factory	Experts /Participants and trainers	

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Day 2 : Thursday 15 October 2015

Topic: Visit to Pilot Factory

Chair and Co-Chairs: Ike van der Putte/Pinar Topkaya

Venue: Kansai Altan Boya Sanayi ve Ticaret A.Ş
Production and Management Headquarters
Ankara Asfaltı 25. km - 35730 Kemalpaşa, Izmir

Start	Finish	Topic	Speaker	Sub topic/Content
08:00	**09:15**	**Transport from the hotel to the pilot site installation**		
9.15	10.15	Preliminary discussion in the factory office with presentations from the factory	All participants	- 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	All participants	
10.15	12.15	Site visit		
12.15	13.30	***Reporting and discussion by the groups***		
13:30	14.45	Lunch break		
14:45	15.45	***Return to the hotel***		
15.45	16.45	Evaluation forms	All participants	
16.45	17.30	Roundtable	All participants and trainers	- Conclusions of site visits - Suggested follow-up actions
17:30		***Closure***		

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ANNEX II – Participants

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ANNEX III – Presentations (under separate cover)

Workshop presentations and materials can be downloaded from:

http://www.ecranetwork.org/Files/Workshop_materials,_REACH-CLP,_October_2015,_Izmir.zip

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