



Environment and Climate
Regional Accession Network **ECRAN**

**ECRAN Regional Workshop on Compliance with REACH/CLP
Regulations**

Croatia experience in the implementation REACH/CLP Regulations in relation with other regulation



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Content

- Legal framework
- REACH and CLP
- Safety Data Sheet and Exposure Scenario
- Enforcement strategies
- Inspection
- Conclusion

REACH enforcement in Croatia

The competent authority(CA) for chemicals and biocidal products in Croatia is Ministry of Health (policy maker, help-desk); www.zdravlje.hr

Regulation (EU) No. 1907/2006 (REACH),

Regulation (EU) No. 1272/2008 (CLP),

Regulation (EU) No. 689/2008 (Export/Import/PIC)

Supervision on chemicals (production, use, import):
Sanitary Inspection

The Chemical Law (O.J. 18/2013, Art.7):2

CA cooperates with Croatian Institute for Toxicology and Antidoping

(SDS register, education, useful information, help-desk); www.hzt.hr



Overview of legislative background

REACH and CLP are regulations and are directly applicable to national law

There are linkages of REACH/CLP with IED, SEVESO and Waste management in the national legislation

- Environmental Protection Act, (O.G. 80/13, 153/13, 78/15)
- Act on sustainable waste management, (O.G. 94/13)
- Regulation on the prevention of major accidents involving dangerous substances, (O.G. 114/2008)
- Regulation on the prevention of major accidents involving dangerous substances (O.G. 44/14)



REACH/CLP and other EU chemicals legislation



REACH and CLP work together with other EU/national legislation such as:

- Chemical agents at work Directive 98/24/EC
- Carcinogens or mutagens at work: Directive 2004/37/EC
- Industrial Emissions Directive 2010/75/EU
- Biocidal Products Regulation 528/2012

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INDUSTRIAL APPROACH



- The Croatian chemical industry has a longstanding commitment to improving the safety of its plants and processes for people and the environment.
- The industry adheres to Croatian legislation on process safety and the prevention industrial accidents.

Aims of REACH and CLP



- Ensure a high level of protection of human health and the environment
- Ensure promotion of alternative methods for assessment of hazards of substances
- Ensure the free movement of chemicals
- Enhance competitiveness and innovation

Key elements of REACH

Registration

- **Substances manufactured and imported into EEA are registered with ECHA**
- **Information for safe use is communicated in the supply chain**

Evaluation

- **Examination of registrant testing proposals**
- **Compliance check of registration dossiers**
- **Evaluation of substances**

Regulatory Risk Management

- **Authorisation**
- **Restriction**
- **Harmonised classification**

Key elements of CLP

Classify

- **Manufacturers, importers and downstream users classify substances and mixtures**

Label and package

- **Suppliers label and package them in accordance with CLP**

Communicate

- **Manufacturers, importers and downstream users notify substance to ECHA's classification and labelling inventory**
- **Suppliers communicate information to Croatian Institute for Toxicology (CITA)**

Harmonise

- **CLP implements UN Globally Harmonised System**
- **The classification of certain substances is harmonised**

Main roles of industry in REACH & CLP



Manufacturer:
manufactures a substance

Importer:
imports chemicals from outside the EEA



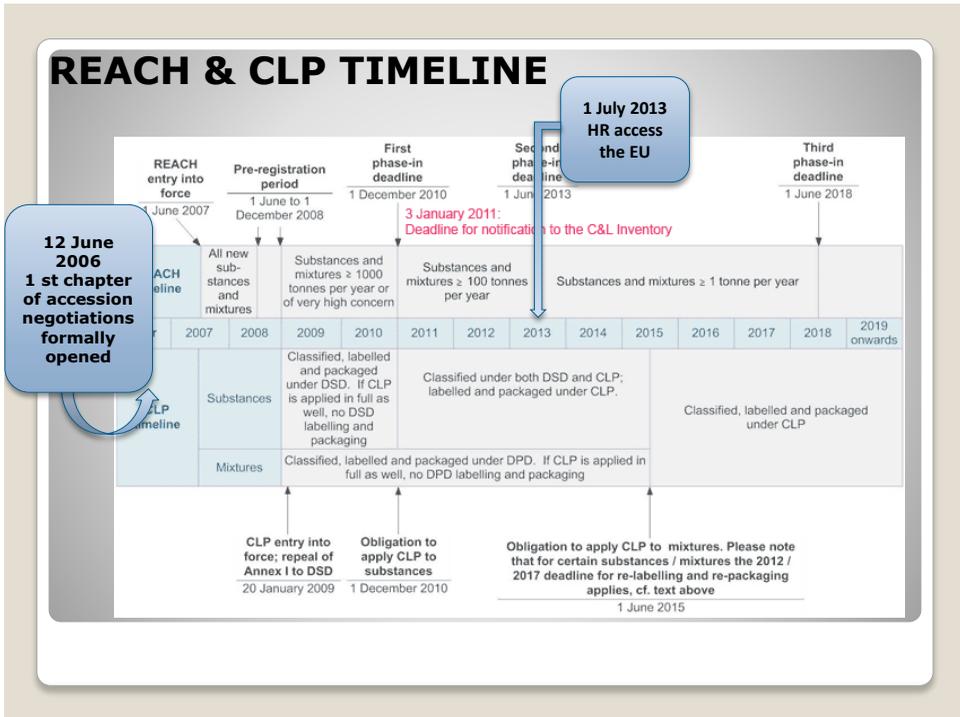
Downstream users: uses chemicals, e.g.: formulates, transfers or uses mixtures, produces articles

Distributor:
stores or distributes chemicals



A company may have multiple roles – the role depends on the activity being undertaken with a given substance

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Information in the supply chain

Safety Data Sheet and Exposure Scenario

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Communication in the Supply Chain

According to Article 31. and Annex II of Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP)

SDS
(Safety data sheet)

Croatian Institute for Toxicology and Antidoping (CITA)

Register of safety data sheets, declarations and instructions for substances produced and imported in Croatia



The safety data sheet (SDS)



Safety Data Sheet Exposure Scenarios

REACH defines

- **When** a SDS must be provided
 - **What to do** when you receive a SDS
 - What a SDS should **contain**
 - What is the **format** of a SDS
 - When **exposure scenarios** should be annexed
- **Classification and labelling** information must be provided in accordance with the CLP Regulation
 - For **mixtures**, a transition period to CLP from previous legislation applies until June 2015 (with provisions for mixtures until June 2017)

When to expect a safety data sheet (SDS)

When substance or mixture is hazardous

- Substance or mixture is classified as hazardous
- Substance is PBT/vPvB
- Substance is on Candidate List
- Non-classified mixture contains certain substances above specified limits (on request)

It is sold to downstream user(s)

- SDS are not required for the general public
- Sufficient information for safe use must be provided

Or it has been requested

- If a substance or mixture is sold to both downstream users and general public, SDS need not be supplied, unless requested by downstream user or distributor

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When to expect an exposure scenario (ES)

When it is a substance

- Exposure scenarios are included as an annex to safety data sheet for substances.
- For mixtures, the supplier may communicate the information from exposure scenarios for ingredient substances in a number of ways

And registered > 10 tonnes/year

- The substance is registered, and a chemical safety assessment is required on registration because the quantity manufactured or imported by the registrant, exceeds 10 tonnes per year

And it is hazardous

- The substance is classified as hazardous or is PBT/vPvB

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HANDLING WITH HAZARDOUS SUBSTANCES -Implementing the 'SEVESO' Directive

The EU's Seveso legislation, in its various steps (Seveso I Directive 82/501/EEC in 1982, Seveso II Directive 96/82/EC in 1996, modified in 2003 as Directive 2003/105/EC, and Seveso III in July 2012, as Directive 2012/18/EU), focuses on the prevention and control of major industrial accidents involving dangerous substances.



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Focus is on Major Accidents

➤ Seveso III

- “an occurrence such as a major emission, fire or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by this Directive, and leading to a serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances.”

➤ General duty of Operators

- “to take **all necessary measures** to prevent major accidents and to limit their consequences for human health and the environment”

Principal Obligations

Obligation	Lower Tier	Upper Tier
Notification to Competent Authorities	✓	✓
Major Accident Prevention Policy (MAPP) & Safety Management System (SMS) to implement it	✓	✓
Hazard Identification and Risk Assessment (HAZID)	✓	✓
Internal Emergency Plan	~	✓
Information to Authorities for External Emergency Plan	~	✓
Safety Report	✗	✓
Information to the Public	✗	✓
Information to Planning Authorities	✓	✓
Consider inter-site domino effects	✓	✓

System for Classification of Materials

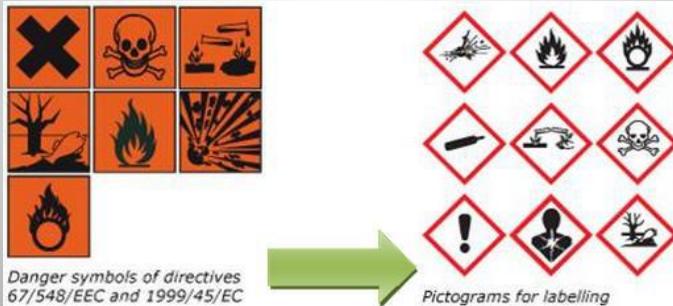
- Seveso –Major Accidents involving Dangerous Substances
 - Fire Hazard (Flammable / Explosive / Oxidising)
 - Acute Toxic Hazard
 - Eco-Toxic Materials
 - Other (water reactives, some carcinogens)
- Seveso II –Dangerous Substances Directive (DSD)
- DSD is being phased out Replaced by Classification Labelling and Packaging (CLP) Regulation
- Seveso III Directive –applicable to national legislation by April 2014

Seveso III Substances

- Materials identified in Annex I of Seveso III Directive
 - Part 1 –Categories of Dangerous Substances
 - Part 2 –Named Dangerous Substances
- Categories of Dangerous Substances
 - H –Health Hazards (acute toxicity)
 - P –Physical Hazards (various fire / explosion hazards)
 - E –Environmental Hazards (aquatic environment)
 - O –Other Hazards (water-reactives, some carcinogens)
- Named Substances generally fall within these categories
- Addition Rule for combining materials with similar hazards

System for Classification of Materials

- Changes from DSD to CLP
 - Hazard Labels ➔ Pictograms
 - Risk Phrases ➔ Hazard Statements



Hazard Statements

- 200: Physical Hazards
 - Fires, explosions, corrosives etc.
- 300: Health Hazards
 - Acute and chronic effects
- 400: Environmental Hazards
 - Aquatic environment and ozone
- Other Hazards (EUH Statements)
 - Specific to EU (various older R nos.)

CLP Regulation (EC) No. 1272 / 2008
on the classification, labelling and packaging of substances and mixtures

Hazard Statements (H- Statements)⁽¹⁾

GHS01

GHS02

GHS03

GHS04

(1) Are still discussed in the UN, changes may still arise.

H 300 - Series: physical Hazards

- H200 Unstable explosive
- H201 Explosive; mass explosion hazard
- H202 Explosive; severe projection hazard
- H203 Explosive; fire, blast or projection hazard
- H204 Fire or projection hazard
- H205 May mass explode in fire
- H220 Extremely flammable gas
- H221 Flammable gas
- H222 Extremely flammable aerosol
- H223 Flammable material
- H224 Extremely flammable liquid and vapour
- H225 Highly flammable liquid and vapour
- H226 Flammable liquid and vapour
- H228 Flammable solid
- H240 Heating may cause an explosion
- H241 Heating may cause a fire or explosion
- H242 Heating may cause a fire
- H250 Catches fire spontaneously if exposed to air
- H251 Self-heating; may catch fire
- H252 Self-heating in large quantities; may catch fire
- H260 In contact with water releases flammable gases which may ignite spontaneously
- H261 In contact with water releases flammable gas

Example – Hydrogen Fluoride

Dangerous Substances Directive		CLP Regulation	
Very Toxic (T+)		Acute Toxic (Cat 2) H300: Fatal if swallowed	
R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed		Acute Toxic (Cat 1) H310: Fatal in contact with skin	
		Acute Toxic (Cat 2) H330: Fatal if inhaled	
Corrosive (C)		Skin Corrosive (Cat 1A)	
R35: Causes severe burns		H314: Causes severe skin burns and eye damage	

Example –Methanol

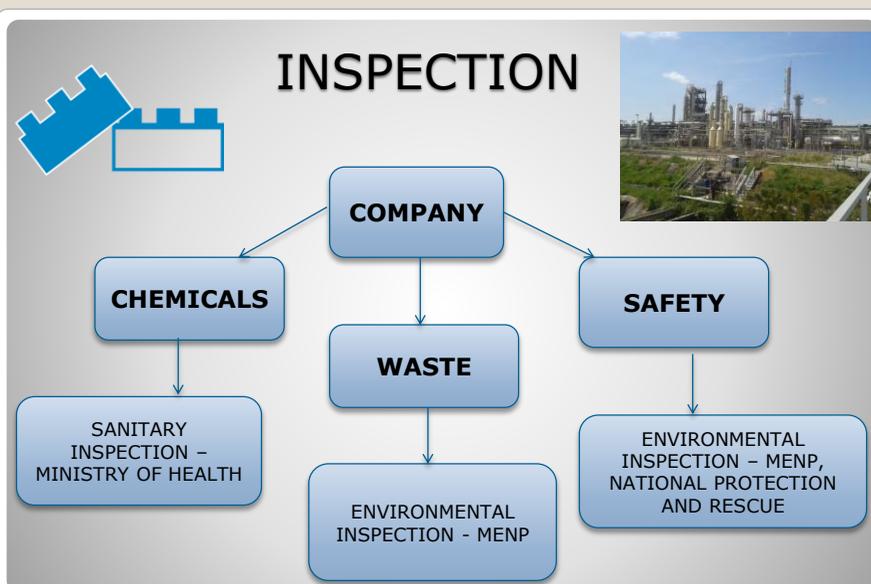
Dangerous Substances Directive		CLP Regulation	
R11: Highly Flammable		H225: Highly Flammable Liquid and Vapour (Cat 2)	
Toxic (T)		Acute Toxic (Cat 3)	
R23/24/25: Toxic by inhalation, in contact with skin and if swallowed		H301: Toxic if swallowed	
R39/23/24/25: Danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed		H311: Toxic in contact with skin	
		Acute Toxic (Cat 3)	
		H331: Toxic if inhaled	
		STOT SE 1	
		H370: Causes damage to organs	

ENFORCEMENT STRATEGIES

- a range of actions that national authorities initiate to verify the compliance with REACH and CLP Regulations
- the principles that will be followed:
 - priority setting,
 - frequencies of inspections,
 - how to deal with inspection outcomes,
 - which quantitative and qualitative resources are needed,
 - which inspection and enforcement tools are needed and how to apply them

Cooperation and coordination between enforcement authorities

- Agreement on co-operation between inspection services in the field of environment, from 5 Jun 2008
 - Co-ordinated inspection controls of IED and SEVESO installations
 - Annual plan, submitted report on co-ordinated inspection available on web
- The environmental inspectorate play a coordinating role.



ON SITE VISIT



PREPARING THE INSPECTION

- announcement letter to the operator
- coordination with other inspectors
- preparatory meeting
- close up meeting with operator

studeni					
56.	Tvornica oplemenjenih folija d.d. Dmiš	6.7. SEVESO Niša razred	<ul style="list-style-type: none"> • Vodoprana – Slavica Okrotić • MUP (Inaštelna Policijska uprava) • Sanitarna - Petra Čigot i Božiljka Čigotić • Elektroenergetika - Ksenija Tomić • Oprema pod tlakom – Ivana Perić • Zaštita na radu • DUZS - Nevenka Sugrenić 	2. - 6.	Ante Belamarić
57.	PETROKEMIA d.d. Kutina www.petrokemija.hr	1.1, 4.2 (a), (b), (c), (d) 4.3, 4.4. SEVESO	<ul style="list-style-type: none"> • Vodoprana - Slavica Okrotić • MUP (Inaštelna Policijska uprava) • Sanitarna - Tilda Župić • elektroenerg. – Zvonko Handl-Hardin • Oprema pod tlakom – Ivan Bašinec • Zaštita na radu • DUZS - Nevenka Sugrenić 	2. - 6.	Lidija Tadić
58.	Prehrabrena industrija Vindija d.d., Varaždin www.vindija.hr	6.4 (c)	<ul style="list-style-type: none"> • Vodoprana – Neven Mikšić • MUP (Inaštelna Policijska uprava) • Sanitarna - Valerijana Zorenić, Rubes i Ivica Kraljić • elektroenerg. - Zvonko Handl-Hardin • Oprema pod tlakom - Božidar Borovec • Zaštita na radu • Veterinarska - Željka Domljan 	9. - 13.	Dubravka Pajkin Tučkar
59.	CEMEX Hrvatska d.d., Sv. Kajo tvornica cementa www.cemex.hr	3.1.	<ul style="list-style-type: none"> • Vodoprana – Slavica Okrotić • MUP (Inaštelna Policijska uprava) • Sanitarna - Jurica Topić • Elektroenergetika - Ksenija Tomić • Oprema pod tlakom – Ivana Perić • Zaštita na radu • Poljoprivredna - Damir Božiljević 	9. - 13.	Ante Belamarić
60.	JANAF d.d. - Terminal Virje www.janaf.hr	SEVESO	<ul style="list-style-type: none"> • Vodoprana – Josip Herent • MUP (Inaštelna Policijska uprava) • Sanitarna - Viktorija Vidovec • Elektroenerg. - Zvonko Handl-Hardin • Oprema pod tlakom - Božidar Borovec • Zaštita na radu • DUZS - Nevenka Sugrenić 	16. - 20.	Miljenka Kliček
61.	HEP-PROIZVODNJA d.o.o. Pogon TE-TO Zagreb proizvodnja toplinske i električne energije www.hep.hr	1.1. SEVESO	<ul style="list-style-type: none"> • Vodoprana - Zvonimir Mayer • MUP (Inaštelna Policijska uprava) • Sanitarna - Zvonimir Komarčić • Elektroenerg. - Zvonko Handl-Hardin • Oprema pod tlakom – Ivan Bašinec • Zaštita na radu • DUZS - Nevenka Sugrenić 	16. - 20.	Snežana Šumnić
62.	Butan plin d.o.o. Novigrad postrojenje Zaprešić	SEVESO	<ul style="list-style-type: none"> • Vodoprana - Zvonimir Mayer • MUP • Sanitarna - Anita Simonov • Elektroenerget. – Mirjana Padovan • Oprema pod tlakom – Ivan Bašinec • Zaštita na radu • DUZS - Nevenka Sugrenić 	23. - 27.	Robert Roček

Report extract for May/June 2015

br.	Naziv i lokacija nadziranog subjekta	Datum nadzora	Djelatnost	izo	vod	zp	san	polj	el	opt	znr	vet	rud	sto	izs
24.	LTH METALNI LIJEV d.o.o., Benkovac	11. - 15. svibnja	2.5.(b)	*	*		*								
25.	BIOTRON d.o.o., pogon Ozalj	18. - 22. svibnja	4.1. (b) SEVESO ² niži razred			*			*						*
26.	Calucec d.o.o. Pula	18. - 22. svibnja	3.1.	<input checked="" type="checkbox"/>	*										
27.	HEP-PROIZVODNJA d.o.o., Pogon Plomin 1&2	25. - 29. svibnja	1.1.	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>									
28.	PAN tvornica papira Zagreb, Zagreb	25. - 29. svibnja	6.1.(b)	*			<input checked="" type="checkbox"/>		*	<input checked="" type="checkbox"/>					
29.	Brodograđevna industrija 3. Maj d.d., Rijeka	1.-5. lipnja	6.7.			*									

Legenda

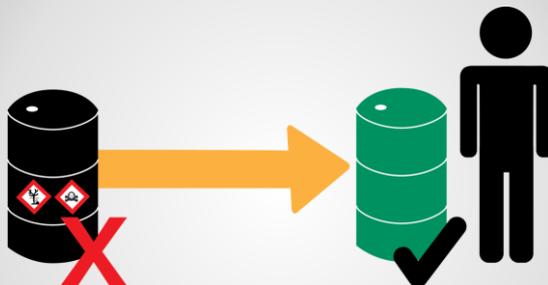
- Nadzorima nisu utvrđene porode papira
- Nadzorima su utvrđene porode papira (odnosno: defekcije ili nepotpuni nadzorni izvještaji)
- Nadzorima su utvrđene porode papira (odnosno: defekcije ili nepotpuni nadzorni izvještaji) - utvrđeno u kontrolnim nadzorima
- Nadzorima su utvrđene porode papira (odnosno: defekcije ili nepotpuni nadzorni izvještaji) - utvrđeno u kontrolnim nadzorima
- Nadzorima su utvrđene porode papira (odnosno: defekcije ili nepotpuni nadzorni izvještaji) - utvrđeno u kontrolnim nadzorima
- Koordinirani nadzor je proveden, ali nije dostavljeno izvješće
- Koordinirani nadzor nije proveden prema planu rada
- Koordinirani nadzorima nije predviđeno sudjelovanje nadležne inspekcije

REACH and CLP – Benefits

- **More and better information** on chemical hazards
- **Improved communication** in the supply chain regarding safe use
- users can **benefit from chemical safety assessments** undertaken by suppliers for
 - Environment
 - Workers
 - Consumers



THAK YOU FOR YOUR ATTENTION



Use chemicals? Use them safely!

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