



Session 1 – Setting the scene

REACH/CLP data for cross-cutting chemicals legislation

**ECHA Workshop on use of REACH/CLP information at
industrial sites**

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Objective:

- Introduction to use of REACH/CLP data for cross-cutting chemicals legislation

Content:

- REACH is generating data/knowledge for
 - +----- the OSH legislation
 - +----- the SEVESO Directive
 - +----- the Industrial Emissions Directive
 - +---- use in other areas?

REACH elements

- Registration: all substances ≥ 1 tonne/year
- Evaluation of substances – by Member States, supported by the European Chemicals Agency
- Authorisation for substances of very high concern
- Restrictions when there is an unacceptable risk arising from the manufacture, use or placing on the market

REACH elements

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NO DATA – NO MARKET

REACH is generating knowledge

Registration:

- **Chemical Safety Report (CSR) with a Chemical Safety Assessment (CSA)**
(... for all substances above 10 tonnes/year)
- **Exposure Scenarios (ES)**
(... to demonstrate that the risks from exposure during substance manufacture and use are controlled when specific operational conditions (OC) and risk management measures (RMM) are applied)
- **Derived No Effect Levels – DNELs**
(... for most registered substances ~12.500)

REACH is generating knowledge

DNELs are

- Derived No Effect Levels
- based on hazard information
- derived for all relevant routes of exposure
(... *inhalation – dermal – and/or oral routes*)

DMELs:

- Derived Minimum Effect Levels
- for substances where no safe threshold can be set (*e.g. genotoxic carcinogens*)

Communication: Safety Data Sheets

eSDS Section 8 ...

Exposure controls/personal protection

(... describing the applicable occupational exposure limits and necessary Risk Management Measures-RMM)

... and presents both:

- **DNELs** (DMELs) and ...
- Occupational Exposure Limits (**OELs**)

Risk Management: Authorisation

- DNELs/DMELs established by registrants are part of the risk characterisation in the Authorisation process to assess if the applicant's proposed RMMs are appropriate and effective
- ECHA's Risk Assessment Committee (RAC) may re-define DNELs/DMELs during evaluation of Applications for Authorisations (AfA) and establish a kind of 'reference' DNEL (*... and dose response curves for non-threshold substances*)

Risk Management: Restrictions

- DNELs/DMELs are part of the risk characterisation to determine an unacceptable risk (*... arising from manufacture, use or placing on the market of substances*) that would justify a restriction
- Member States Competent Authorities or ECHA and ECHA's Risk Assessment Committee (RAC) set-up the DNELs/DMELs on the basis of the registration dossiers and information from OSH. This value may be modified on the basis of information provided during a Public Consultation

Classification & Labelling

- Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)
- CLP Inventory at ECHA:
 - Information on notified and registered substances received from manufacturers and importers
 - List of harmonised classifications
 - Classifications derived from joint submissions to the REACH registration

Classification & Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)




General Information

Index Number	EC Number	CAS Number	International Chemical Identification
605-001-00-5	200-001-8	50-00-0	formaldehyde ... %

ATP Inserted / Updated: CLP00/ATP06

CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Acute Tox. 3 *	H301	H301		GHS06 GHS05 GHS08 Dgr	Skin Corr. 1B; H314: C ≥ 25% * Skin Sens. 1; H317: C ≥ 0,2% Eye Irrit. 2; H319: 5% ≤ C < 25% STOT SE 3; H335: C ≥ 5% Skin Irrit. 2; H315: 5% ≤ C < 25%	Note D Note B
Acute Tox. 3 *	H311	H311				
Skin Corr. 1B	H314	H314				
Skin Sens. 1	H317	H317				
Acute Tox. 3 *	H331	H331				
Muta. 2	H341	H341				
Carc. 1B	H350	H350				

Signal Words	Pictograms
Danger	  

tion,
ures

nces

to

Occupational Safety & Health legislation

The principles of EU worker protection legislation

➤ **Tri-partite** approach:

Member States – Industry – Workers

- via Advisory Committee on Safety and Health

➤ Directives are transposed by Member States at national level (TFEU)

➤ underpinned by scientific advice: SCOEL

(Scientific Committee on Occupational Exposure Limits)

Occupational Safety & Health legislation

Key Directives on chemicals risk management:

➤ **Framework** Directive 89/391/EEC (*general approach*)

... *with (potential) benefits from REACH/CLP data:*

➤ **Chemical Agents** Directive 98/24/EC + 3 lists of iOELs (2000/39/EC, 2006/15/EC, 2009/161/EU, with 91/322/EEC)

➤ **Carcinogens & Mutagens** Directive 2004/37/EC

➤ **Asbestos** Directive 2009/148/EC

SEVESO Directive

(Directive 2012/18/EU)

Aims:

- Prevention of major accidents involving dangerous substances
- ... *if such accidents occur:*
- Limitation of the consequences for human health and the environment
- More than 10 000 industrial establishments concerned ("lower/upper tier" with more stringent requirements)
- Covers processing and storage of dangerous substances

SEVESO Directive

(Directive 2012/18/EU)

Obligations for operators:

- Notification of all concerned establishments
- Deploying a major accident prevention policy
- ... *with (potential) benefits from REACH/CLP data:*
- Producing a safety report for upper-tier establishments
- Producing internal emergency plans for upper tier establishments
- ... *if such accidents occur:*
- Providing information on substances involved

General Information

Index Number	EC Number	CAS Number	International Chemical Identification
603-001-00-X	200-659-6	67-56-1	methanol

ATP Inserted / Updated: CLP00

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Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Flam. Liq. 2	H225	H225		GHS02 GHS06 GHS08 Dgr	* STOT SE 1; H370: $C \geq 10\%$ STOT SE 2; H371: $3\% \leq C < 10\%$	
Acute Tox. 3 *	H301	H301				
Acute Tox. 3 *	H311	H311				
Acute Tox. 3 *	H331	H331				
STOT SE 1						

Seveso Data

Signal Word	Other Seveso Categories	Seveso Concentration	Categories
Danger	2 7b	$C \geq 20\%$	0-2
		$10\% \leq C < 20\%$	0-2
		$3\% \leq C < 10\%$	-



Flame

Skull and crossbones

Health hazard

Seveso Data

Seveso Substance	Main Seveso Category	Other Seveso Categories	Seveso Concentration	Categories
Yes (Named substance)	0	2 7b	$C \geq 20\%$	0-2
			$10\% \leq C < 20\%$	0-2
			$3\% \leq C < 10\%$	-

Industrial Emissions Directive (IED)

(Directive 2010/75/EU)

Aims:

- Setting out the main principles for the permitting and control of installations based on an integrated approach and the application of best available techniques (BAT)
- Minimising pollution from various industrial sources throughout the European Union
- More than 50 000 industrial establishments concerned

Industrial Emissions Directive (IED)

(Directive 2010/75/EU)

Obligations for operators:

- Permits must take into account the whole environmental performance of the plant
- If activity involves use, production or release of hazardous substances:
... with (potential) benefits from REACH/CLP data:
- Prepare a baseline report having regard to the possibility of soil and groundwater contamination before starting an operation of an installation or before a permit is updated
 - *use REACH Exposure Scenarios?*

Other cross-cutting EU legislation

... *with (potential) benefits from REACH/CLP data:*

- Water Framework Directive (2000/60/EC)
(41 priority substances)
- Waste Framework Directive (Directive 2008/98/EC)
- Waste stream specific Legislation
(e.g. RoHS, batteries, packaging, landfilling, incineration, shipment of waste ...)
- General Products Safety Directive (2001/95/EC)
- Toys Safety Directive (2009/48/EC)
- Cosmetics Regulation (EC No. 1223/2009)



Other initiatives / strategies

... *with (potential) benefits from REACH/CLP data:*

- Non-Toxic Environment Strategy (7th Environment Action Programme)
- Raw Materials Initiative
- New 'Circular Economy Package'
- Resource Efficiency Strategy

International Conventions

... *with (potential) benefits from REACH/CLP data:*

- Stockholm Convention – POPs
- Basel Convention – Hazardous waste shipments
- Rotterdam Convention – PIC
- SAICM – Strategic Approach to International Chemicals Management

REACH / CLP data still under-used?



European
Commission

Let us have a successful workshop

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Chemicals

<http://ec.europa.eu/environment/chemicals>