Social dialogue

WG Health, Safety and Responsible Care

CLP Regulation

Regulation on **C**lassification, **L**abelling and **P**ackaging of substances and mixtures

Publication in Official Journal 31 Dec. 2008,

Regulation (EC) **1272/2008**, OJ L 353

Chemical legislation

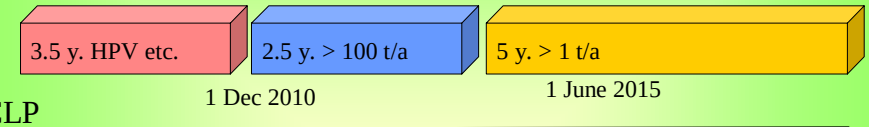
- DSD
- Dangerous Substance Directive 97/548/EEC

- DPD
- Dangerous Preparations Directive 1999/45/EC

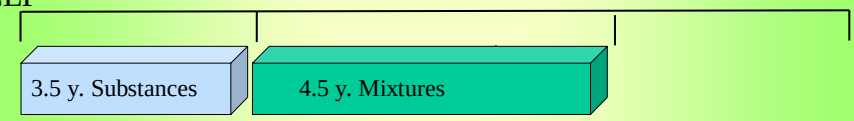
→ CLP Regulation (EC) **1272/2008**

Transitional Period

REACH



CLP



For substances and mixtures:
Exist. system: binding
CLP: optional;
Label: CLP if use option

For substances:
CLP: obligatory*
SDS must contain exist. and CLP classification
For mixtures: EU-System: binding
CLP: optional; Label: CLP if use option

After the entire transition period:
For substances & mixtures:
CLP: obligatory*
Exist. system: loses its legal status

*derogation for already placed on the market:
- substances until 1.12.2012
- mixtures until 1.6.2017

Some key differences from the old DSD EU system

- **Acute Toxicity Category Cut-Offs changed, plus extra Category**
- Conversion to an estimated Acute Toxicity point Estimate
- Mixtures classification process changed for Acute Effects- no Specific Concentration Limits

- Corrosive Cat 1 divided in to Cat 1A/1B/1C
- Criteria Differences for skin and eye irritation – mild eye irritation
- **CMR Category Numbering Changes**
- Significant Changes to Reproductive Toxicity
- Possibility of Route Specific Labelling for CMRs
- Cut-offs for communication on SDS for CMRs and STOT

Health Hazards

	Health Hazard Classes	Hazard Category				
1	Acute Toxicity, Oral	1	2	3	4	5
1	Acute Toxicity, Dermal	1	2	3	4	5
1	Acute Toxicity, Inhalation	1	2	3	4	5
2	Skin Corrosion/Irritation	1	1A/B/C	2	3	
3	Eye Damage/Irritation	1	2	2A/B		
4	Respiratory Sensitisation					
4	Skin Sensitisation	1				
5	Germ Cell Mutagenicity	1	1A/B	2		
6	Carcinogenicity	1	1A/B	2		
7	Reproductive Toxicity	1	1A/B	2	Lactation	
8	Target Organ Tox – Single	1	2	3		
9	Target Organ Tox – Repeat	1	2			
10	Aspiration Hazard	1	2			

Optional Sub Categories

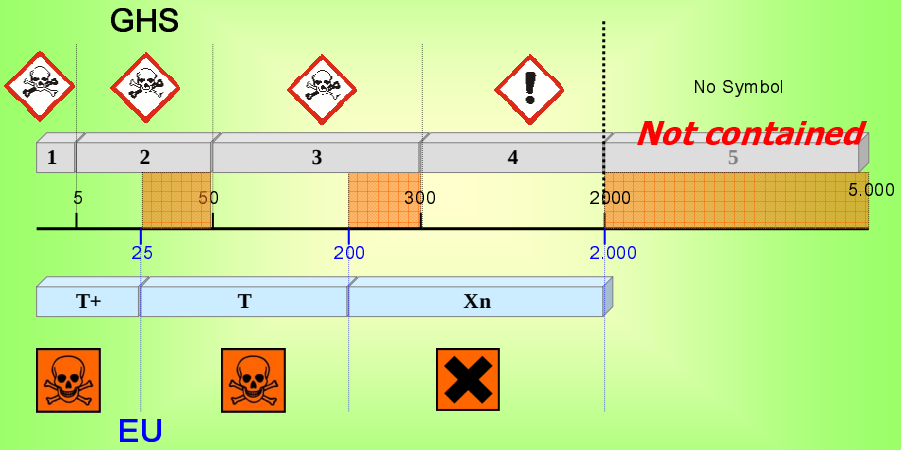
Optional Categories

Acute Toxicity -Substances Oral

Acute Toxicity – Comparison between GHS, EU and UN Transport

GHS			EU Supply			UN Transport		
Hazard Category	LD_{50} mg/kg		Risk Phrase	LD_{50} mg/kg		Packing Group	LD_{50} mg/kg	
	Lower	Upper		Lower	Upper		Lower	Upper
1		≤ 5				I		≤ 5
2	> 5	≤ 50	R28 T+		≤ 25	II	> 5	≤ 50
3	> 50	≤ 300	R25 T	> 25	≤ 200	III Solid Liquid	> 50	≤ 200 ≤ 500
4	> 300	≤ 2000	R22 Xn	> 200	≤ 2000			
5	> 2000	≤ 5000*						

EU GHS



- **Health Hazards: e.g. acute oral toxicity (mg / kg)**

Acute toxicity

Acute toxicity label elements

Classification	Category 1	Category 2	Category 3	Category 4
GHS Pictograms				
Signal Word	Danger	Danger	Danger	Warning
Hazard Statement: — Oral	H300: Fatal if swal-lowed	H300: Fatal if swal-lowed	H301: Toxic if swal-lowed	H302: Harmful if swal-lowed
— Dermal	H310:Fatal in contact with skin	H310:Fatal in contact with skin	H311: Toxic in contact with skin	H312: Harmful in contact with skin
— Inhalation (see Note 1)	H330:Fatal if inhaled	H330: Fatal if inhaled	H331: Toxic if inhaled	H332: Harmful if inhaled

Carcinogenity

Hazard categories for carcinogens

Categories	Criteria
CATEGORY 1:	Known or presumed human carcinogens A substance is classified in Category 1 for carcinogenicity on the basis of epidemiological and/or animal data. A substance may be further distinguished as:
Category 1A:	Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, or
Category 1B:	Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.
	The classification in Category 1A and 1B is based on strength of evidence together with additional considerations (see section 3.6.2.2). Such evidence may be derived from: — human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or — animal experiments for which there is sufficient (1) evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case-by-case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.
CATEGORY 2:	Suspected human carcinogens The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B, based on strength of evidence together with additional considerations (see section 3.6.2.2). Such evidence may be derived either from limited (1) evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.

Carcinogenity

Label elements for carcinogenicity

Classification	Category 1A or Category 1B	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H351: Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

Carcinogenicity – Substances

Category 1A: KNOWN to have carcinogenic potential for humans; the placing of a chemical is largely based on human evidence.

Category 1B: PRESUMED to have carcinogenic potential for humans; the placing of a chemical is largely based on animal evidence.

Category 2: SUSPECTED human carcinogens

Carcinogenicity – Mixtures

Ingredient classified as	**Cut-off/concentration limits triggering classification of a mixture as:**	
	Category 1 Carcinogen	**Category 2 Carcinogen**
Category 1 Carcinogen	**≥ 0.1 %**	
Category 2 Carcinogen		**> 0.1 %** **≥ 1.0 %**

Lower cut-off used for optional communication

Occupational safety & health directives

- Five OSH downstream directives make reference to the EU C&L system
  - » To define aspects of the scope of application
- **Directives:**
  - Chemical Agents Directive 98/24/EC
  - Carcinogens and Mutagens Directive 2004/37/EC
  - Safety Signs Directive 92/58/EEC
  - Pregnant Workers Directive 92/85/EEC
  - Young People at Work Directive 94/33/EEC

Rámcová smernica 89/391/ES

Zákon č. 330/2006 Z.z (BOZP), Zákon č.126/2006 Z.z (Ochrana zdravia ľudí), Zákonník práce

- Smernica 98/24/EC o ochrane zdravia a bezpečnosti pracovníkov pri riziku spojeného s chemickými faktormi - NV 355/2006 Z.z
- Smernica 2004/37/EC o ochrane pracovníkov pred expozíciou karcinogénov a mutagénov - NV 356/2006 Z.z.
- Smernica 92/58/EEC o minimálnych požiadavkách pre označovanie pracoviska
- Smernica 92/85/EEC o ochrane tehotných žien a dojčiacich matiek - NV 272/2004 Z.z.
- Smernica 94/33/EEC o ochrane mladých ľudí pri práci - NV 286/2004 Z.z.

Five directives on health and safety at work - refer to classification of chemicals

(1) Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work7 (fourteenth individual Directive within the meaning of Framework Directive 89/391/EEC8).

Article 2 defines the scope of the directive by means of the term 'hazardous chemical agent, which, in turn, is defined by referring to the relevant EU directives on classification and labelling of chemicals.

Five directives on health and safety at work - refer to classification of chemicals

(2) Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual Directive within the meaning of Framework Directive 89/391/EEC).

Article 2 defines the scope of the directive by means of the terms 'carcinogen' and 'mutagen', which, in turn, are defined by referring to the relevant EU directives on classification and labelling of chemicals.

Five directives on health and safety at work - refer to classification of chemicals

(3) Council Directive 92/58/EEC on the minimum requirements for the provision of safety and/or health signs at work10 (ninth individual Directive within the meaning of Framework Directive 89/391/EEC).

Annex III, item 1 refers to the relevant EU directives on classification and labelling of chemicals.

Five directives on health and safety at work - refer to classification of chemicals

(4) Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Framework Directive 89/391/EEC).

Annex I, item 3 on chemical agents refers to risk phrases in the relevant EU directives on classification and labelling of chemicals.

Five directives on health and safety at work - refer to classification of chemicals

(5) Council Directive 94/33/EC on the protection of young people at work. This is an independent directive (i.e. it is not an individual Directive within the meaning of Directive 89/391/EEC).

Item 3 in section I of the Annex on chemical agents refers to the relevant EU directives on classification and labelling of chemicals.

To ensure a continued level of protection, there are three possible policy options

- Policy option 1
- Binding legislative action at EU level:
- To propose a **new legislative** instrument taking the form of a Directive adopted on the basis of Article 153 of the TFEU, laying down the necessary changes to the five directives so as to **align those parts of the directives that refer to chemical classification issues** to the current EU legal situation following the adoption of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

To ensure a continued level of protection, there are three possible policy options

- Policy option 2

- To **amend** the directives in such a way as **to ensure the same level of protection** continues, without making a formal link to the EU chemical classification system, i.e. binding legislative action at EU level to remove the linkage between the EU chemical classification system and the requirements of the five directives.
- Instead, the scope and other requirements, currently defined by classification criteria, would be referred to by the use of descriptor words such as ‘hazardous chemical agent’, ‘carcinogen’, ‘mutagen’, without further qualification.

To ensure a continued level of protection, there are three possible policy options

- Policy option 3

- **Not to amend** the directives, i.e. to maintain the existing text of the five worker protection directives.
- This could have **significant implications from a risk prevention and risk management point of view**, particularly after the end of the second transition period specified in the Regulation.

- For each of the above policy options,
- the need for guidance to assist employers and workers
- to understand the changes to chemical classification and labelling requirements in so far as they relate to worker protection should be considered.
- Such guidance would make a positive contribution to facilitating smooth and effective implementation of the new requirements.

Summary of responses

	Organisation	Business Europe	UEAPME	ECEG	CER	ETUC	CEC
	Question/Affiliation	Employers	Employers	Employers	Employers	Workers	Workers
1	Amend?	Yes	Yes	Yes	Yes	Yes	Yes
2	Approach — single amending directive?	Yes	Yes	Yes	Yes	No Reason: there are 2 directives currently under amendment for other reasons and the CLP issue should be incorporated into these amendments (Carcinogens & Mutagens and Pregnant Workers Directives)	Yes
3	Neutral effect?	Yes	Yes	Yes	Yes	Yes	Yes
4	Young persons directive updating?	Yes	Yes	Yes	Yes	Yes	Yes