

# SDS and what is new under REACH and EU GHS?

PRISM2 Workshop  
Promoting Responsibility in SME's  
**08 April Slovakia**



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# Why do we need GHS?

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Substance - oral toxicity LD<sub>50</sub> = 257 mg/kg

GHS	Danger (Skull & Cross Bones)
Transport	liquid: slightly toxic; solid: not classified
EU	Harmful (St Andrew's Cross)
US	Toxic
CAN	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
Thailand	Harmful
New Zealand	Hazardous
China	Not Dangerous
Korea	Toxic

# GHS - Context

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**GHS is not legally binding but countries encouraged to implement at WSSD**

**GHS provides common basis for classification and hazard communication for transport and supply and use**

**GHS includes a “building block” approach to facilitate implementation => freedom to take up hazard classes and/or categories but NO change of criteria for classes/categories taken up**

**GHS will not be completely “harmonised“ at first**

**GHS and “old” EU system have many similarities**

# CLP Regulation - Scope

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Regulation on Classification, labelling and packaging of substances and mixtures (CLP)

## Regulatory Instrument

- **Regulation based on Art. 95 of the EU Treaty (harmonisation of the internal market)**

## Scope

- **substances and mixtures including C&L of Plant Protection Products and Biocides**



# CLP Regulation- Principles

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Applies the general principles of the GHS

Introduces the GHS criteria for data interpretation, classification and labelling

Uses the GHS Building Block Approach and a few other “optionalities” **to adapt the system to EU needs**

Keeps the scope as close as possible to the old system

Ensures consistency with transport rules

Stays as close as possible to the GHS format and terminology e.g.

- “**Mixtures**” not “preparations”
- “**Hazardous**” not “dangerous”

# European legislative process

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Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP) **adopts in Europe the GHS**

Formal adoption by the EU Parliament and the Council 16 December 2008

- **Publication in Official Journal 31 Dec. 2008, Regulation (EC) 1272/2008, OJ L 353**

Entry into force 20 January 2009



# Transitional period

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**Entry into Force 20 January 2009**

**Transitional period staggered:**

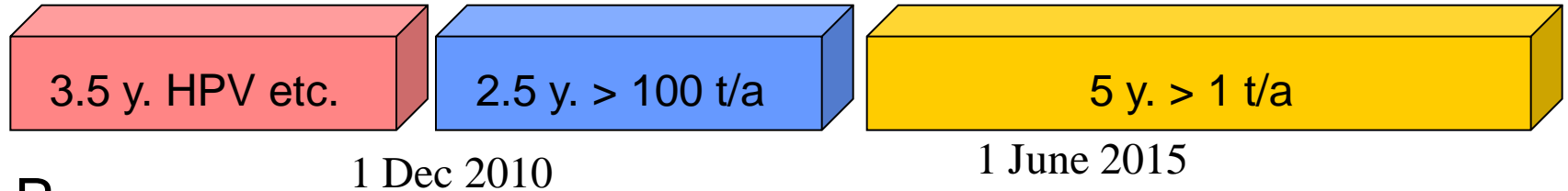
- substances 1 Dec 2010
- Notification to C&L Inventory within one month after placing a substance on the market
- mixtures 1 June 2015

**Repeal of old directives (Dir 67/548/EEC and Dir 1999/45/EC) by 1 June 2015**

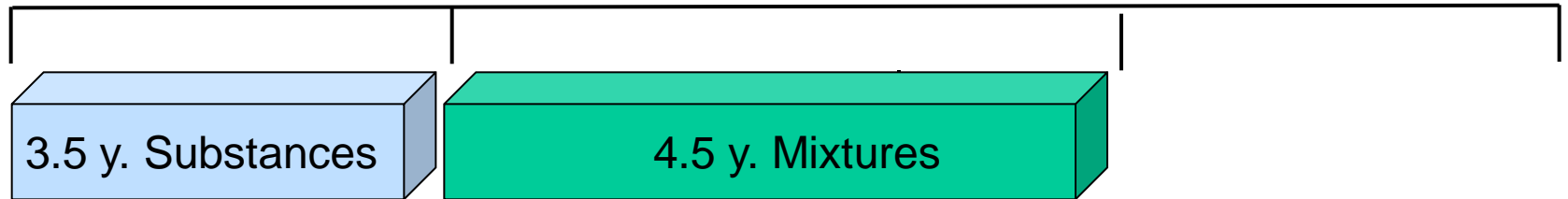
# Transitional Period



## 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



# Purpose of SDS

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Not intended for **Consumers**

**REACH, art 31-4** : *The safety data sheet need not be supplied where dangerous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.*

# Purpose of SDS

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**Providing professional users with the necessary information for:**

- **Enabling them to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment**
- **Being able to convey information down the supply chain when they are not final user (i.e. to compile the SDS for their own mixtures)**

# Modifications to SDS

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**3 mains sources for modifications of SDS requirements in article 31 and annex II of REACH:**

➤ **REACH**

➤ **CLP**

➤ **the UN GHS**

# Modifications per 1st June 2007

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## FROM UN GHS:

- **Interversion of sections 2 and 3:**
  - ***2- Hazard identification***
  - ***3 - Composition/information on ingredients***
- **e-mail address of the competent person responsible for the SDS**



# Modifications per 1st June 2007

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## FROM REACH:

- SDS to be provided for PBTs and vPvBs
- SDS to be provided on request for mixtures containing  $\geq 0,1\%$  of a PBT or vPvB substance

*Same requirements for substances with serious properties on health or environment such as endocrine disruptors (art. 57 f of REACH)*

# Modifications per 1st June 2015

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## FROM UN GHS:

**SDS to be provided on request for non hazardous mixtures containing  $\geq 0,1\%$  of a substance:**

- **Carcinogen, cat 2**
- **Reprotox, cat 1A, 1B, 2**
- **Sensitizing**
- **Effects on or via lactation**

# Modifications after substance registration

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- **Identification of the substance and the company consistent with the registration (section 1)**
- **Indication of the registration number (sections 1 and 3)**
- **Information consistent with the information provided in the registration (sections 9, 11, 12)**
- **Exposure Scenarios to be placed in an annex to the SDS**
- **Consistency of sections 1, 7, 8, 11, 12 and 13 with Chemical Safety Reports (CSR), when required**

# Modifications after substance registration: identified uses

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*Where a Chemical Safety Report is required, the Safety Data Sheet shall contain information on all the identified uses relevant to the recipient of the Safety Data Sheet. This information shall be consistent with the identified uses and exposure scenarios set out in the annex to the Safety Data Sheet.*



# Indication of registration number

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**If the full registration number of a substance appears on the SDS of a substance/mixture:**

- **Concerns over the disclosure of the supply chain**
- **Practical difficulties (change of supplier...)**

# Indication of registration number

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Agreed solution for down stream users in annex II = Omit the part of the registration number referring to the individual registrant (4 last digits) with provisions ensuring access to the full registration number by enforcement authorities.

M/I should indicate full registration number  
Industry wishes this possibility to be applicable to all suppliers of substances and mixtures (manufacturers, importers, distributors, DU)

# Introduction of CLP classification/labelling

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- **Sections 2 (substance/mixture) and 3 (ingredients/components) + consistency with other sections**
- **Provisions for the transition period:**
  - **Indication of « EU » classification until 1 June 2015 for substances/mixtures classified and labelled « CLP »**
  - **Possibility to indicate CLP classification before applying it fully (i.e labelling): in section 16**

# Harmonisation with UN GHS

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- **More precisions required on properties, i.e. summary of studies...**
- **Label elements to be moved from section 15 to section 2, including graphical representation of the hazard pictograms (black and white allowed), or of the symbol only**

## Annex II Introduction

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*The information in the Safety Data Sheet shall be written in a clear and concise manner. The Safety Data Sheet shall be prepared by a competent person who shall take into account the specific needs of the user audience, as far as it is known.*

*Persons placing substances and preparations on the market shall ensure that competent persons have received appropriate training, including refresher training.*

# Links

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- **Cefic website:**

**<http://cefic.org/en/reach-for-industries-GHS.html>**

- **ECHA website:**

**[http://echa.europa.eu/legislation/classification\\_legislation\\_en.asp](http://echa.europa.eu/legislation/classification_legislation_en.asp)**

**Thank you**

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