

# GHS : a new classification and labelling framework for Natural Complex Substances

General Assembly EFEO  
Grasse, June 15, 2009

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# Content

- Why and what is GHS.
- Special focus on European Union implementation (CLP).
- Example of GHS and CLP classification and labelling for NCS.
- Conclusions



# Why GHS ?

# Why GHS- the global context

- Development of one worldwide system for hazard classification and labelling of chemicals.
- To merge the major world classification systems : EU, US, CAN Supply systems and the international UN Transport system.



# Milestones of the development of GHS

- 1992 : Mandate by United Nations Conference on the Environment and Sustainable Development (UNCED Agenda 21, chapter19)
- End 2001 : Development by IOMC Coordination Group
- **2002 : WSSD (World Summit for Sustainable Development) Johannesburg “GHS to be fully operational by 2008”**
- Dec 2002 : Agreement by UN CETDG/GHS
- July 2003 : GHS adopted by UN ECESOC
- 2005 : GHS Revision 1
- 2007: GHS Révision 2

**Website : [http://www.unece.org/trans/danger/publi/ghs/ghs\\_welcome\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html)**

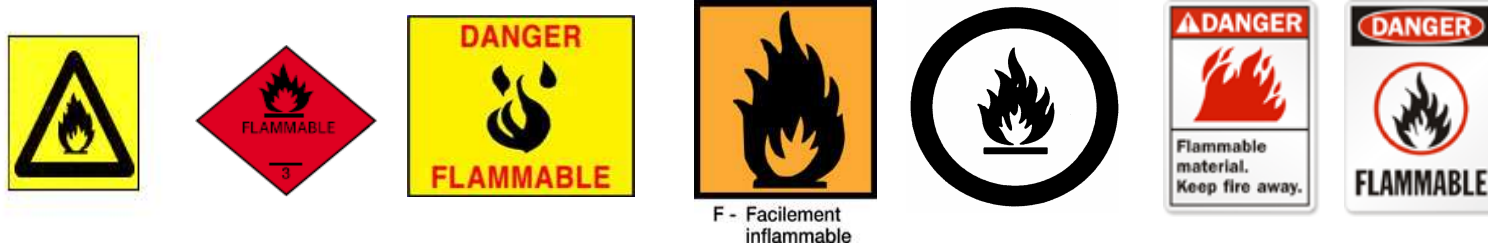
# Which countries are implementing GHS ?

Outside EU many other countries have subscribed to implementing the GHS into domestic law including the US, Canada, New Zealand, Brazil, China, the Philippines, Russia, Japan, Mexico, South Africa and various African countries.

The stage of implementation ranges from those countries which already have or are about to have place their own GHS implementing scheme (e.g. **EU, Japan, New Zealand, South Korea**) to those countries where focussed activities on and development of a GHS implementing scheme are on-going (e.g. the US) and to further countries which have just started their discussions with the view to implement the GHS.

# Why GHS ?

- **Different hazard classification** : ex : acute oral toxicity LD50=257 mg/kg EU : harmful/ USA : toxic/ Canada : toxic/ Transport liquid : slightly toxic solid: not classified/ Australia : harmful/ Japan : toxic/ Thailand : harmful/ China : harmful/ Korea : toxic/...
- **Different hazard labels** : ex : flammable :



- **Different (material) safety data sheets** : European (16 sections), USA (no specific format required (voluntary industry standard ANSI Z400.1), Thailand (8 sections), Singapore (15 sections),...

# WHAT IS GHS ?

# What is GHS ?

GHS is based on the major world classification systems.

The harmonised elements of the GHS may be seen as a collection of “**Building Blocks**” from which to form regulations.

GHS is **Hazard Based**, i.e. considering the **intrinsic properties of chemicals**

## **Definition of Hazard Assessment:**

- Hazard identification, evaluation and classification

## **Definition of Standardised Hazard Communication:**

- Label
- Safety Data Sheets

# GHS Key Elements

- **Hazard identification/hazard assessment :**
  - Tiered approach depending on availability of data for substances and mixtures (bridging principles and expert judgment).
  - Summation methods /mixture rules
  - Cut-off values/concentration limits
  - For acute toxicity new methodology for non tested mixtures (“ATE”)
  - For aquatic toxicity introduction of M-factor for very toxic substances (acute/chronic cat 1) “super R50s”.
  - Constituents approach 1.3.3.1.3 GHS
- **Hazard communication**
  - MSDS 16 sections format
  - Labels for Transport and Supply : aims at harmonisation with international UN TDG rules.

# GHS key elements : Hazard Classes

- **16 physical hazards** (from UN TGD)
- **10 health hazards**
  - ✓ acute toxicity (oral/dermal/inhalation)
  - ✓ Skin corrosion/irritation
  - ✓ Serious damage to eyes/eye irritation
  - ✓ Respiratory /skin sensitisation
  - ✓ Germ cell mutagenicity
  - ✓ Carcinogenicity
  - ✓ Reproductive toxicity
  - ✓ Specific target organ systemic toxicity (TOST) single exposure
  - ✓ Specific target organ systemic toxicity (TOST) repeated exposure
  - ✓ Aspiration hazard
- **1 environmental hazard**
  - ✓ Hazardous to the aquatic environment (acute/chronic)

Do you speak  
GHS ?

# **GHS Key Elements : harmonised labels**

- **Symbols/pictogram**
- **Signal words** (“danger”, “warning”)
- **Hazard statements** (H xyz phrases).
- **Product identifier/ingredient disclosure**
- **Precautionary statements** (P xyz phrases).

# GHS Key Elements : Pictograms

- New exclamation mark for low level health hazard
- New symbol for chronic health hazard



Explosives  
Flammables  
Self  
Reactives  
Organic  
Peroxides



Flammables-  
Self heating  
Self reactives-  
Pyrophorics  
Emits  
Flammable  
Gas



Irritant  
Dermal  
Sensitiser  
Acute  
toxicity



Carcinogen  
Respiratory Sensitiser  
Reproductive toxicity  
Target Organ Toxicity s.e  
Target Organ Toxicity r.e  
Mutagenicity



Acute toxicity



Corrosives



Oxidisers  
Organic peroxides



gases under  
pressure



Environmental  
Toxicity

# Codification of hazard statements

**Hazard statements** describes the nature of the hazards of a hazardous product including where appropriate the degree of hazard.

They are assigned a unique alphanumeric code which consists of one letter and three numbers, as follows :

- The letter “H” (for “hazard statement”)
- A first number designating the type of hazard :
  - “2” for physical hazard e.g. : **H221 Flammable liquid**
  - “3” for health hazard e.g. : **H315 Cause skin irritation**
  - “4” for environmental “hazard” e.g. **H412 Harmful to aquatic life with long lasting effects**
- Two following numbers corresponding to the sequential numbering of hazards arising from the intrinsic properties of the substance or mixture ( e.g. flammability codes from 220 to 230).

# Codification of precautionary statements

A **precautionary statement** which describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous product or improper storage or handling of a hazardous product.

There are **five types** of precautionary statements :

Hazard statements describes the nature of the hazards of a hazardous product including where appropriate the degree of hazard.

They are assigned a unique alphanumeric code which consists of one letter and three numbers, as follows :

- The letter “P” (for “hazard statement”)

-One number designating the type of precautionary statements as follows :

- “1” for general precautionary statements e.g. **P101 : If medical advice is needed, have product container or label at hand**
- “2” for prevention precautionary statement e.g. **P201 Obtain special instructions before use**
- “3 for response e.g. **P301 : if swallowed:**
- “4” for storage e.g. **P401 : Store...**
- “5” for disposal e.g. **P501: Dispose of contents/container to...**

- Two numbers corresponding to the sequential numbering of precautionary statements.

A few examples of  
UN GHS “hazard classes”  
versus EU DSD/DPD  
“categories of danger”

# Flammable liquids

## EU

Class	Flash point	Boiling Point
F+ Extremely flammable	< 0	< 35
F Highly flammable	< 21	-
Flammable	55 > x > 21	-

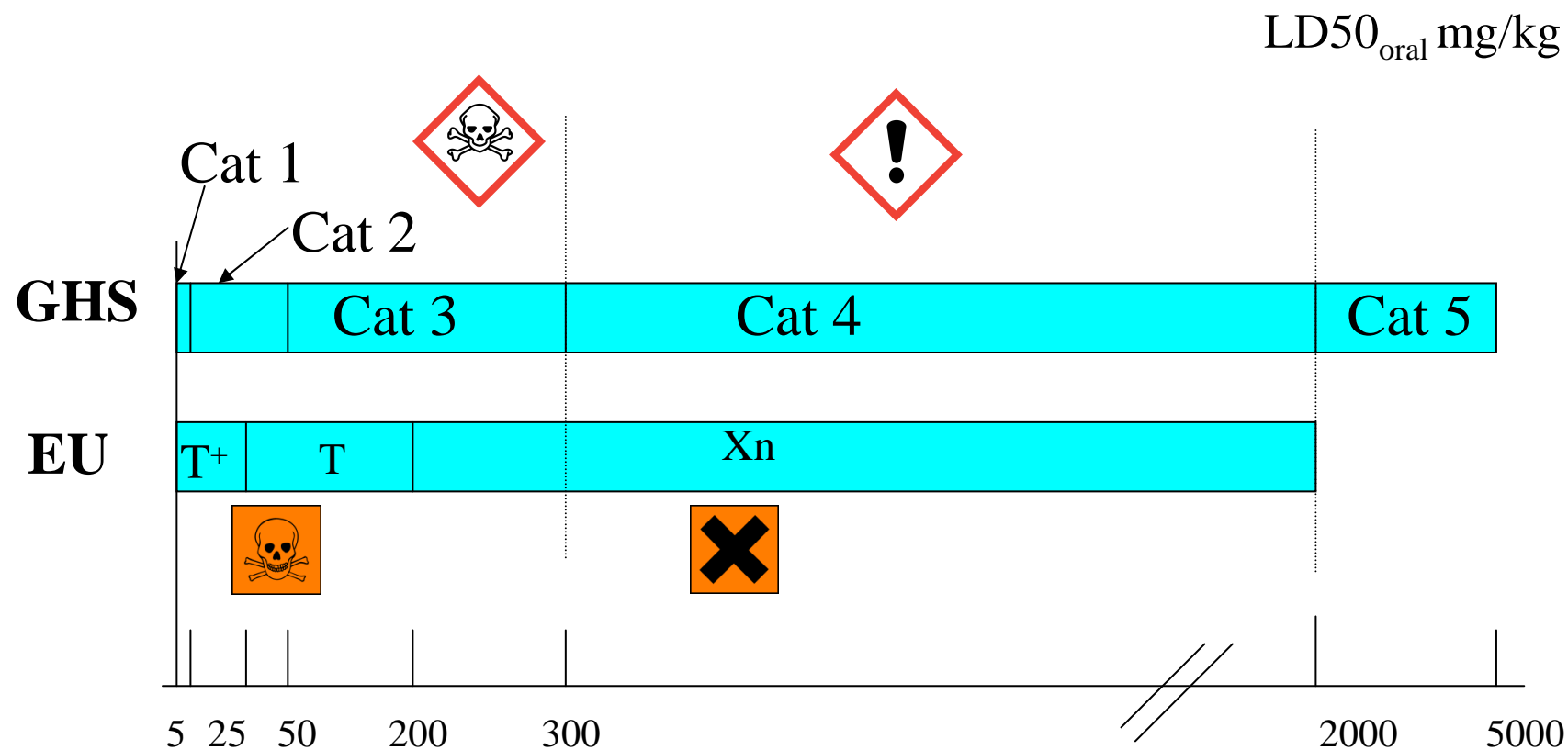


## UN GHS

Flash Point	Boiling Point	Category
<23	< 35	Category 1 Extremely flammable liquid & vapour
<23	> 35	Category 2 Highly flammable liquid & vapour
60 > x > 23	-	Category 3 flammable liquid & vapour
93 > x > 60	-	Category 4 Combustible liquid



# Acute oral toxicity



**GHS will classify many EU “harmful” as “toxic”**

# Acute oral toxicity-Mixture

Additivity formulae for non-tested mixtures more complex as in the current EU system

Classification is not based on the sum of classified substances in mixture but estimation of the acute oral toxicity required

Classification of mixtures for acute toxicity can be carried out for each route of exposure, but only needed for one route of exposure as long as this route is followed (estimated or tested) for all ingredients

If the acute toxicity is determined for more than one route of exposure, the more severe hazard category will be used for classification.

Two formulae :

## Formula A

If the total concentration of the ingredients with unknown acute toxicity is  $\leq 10\%$ .

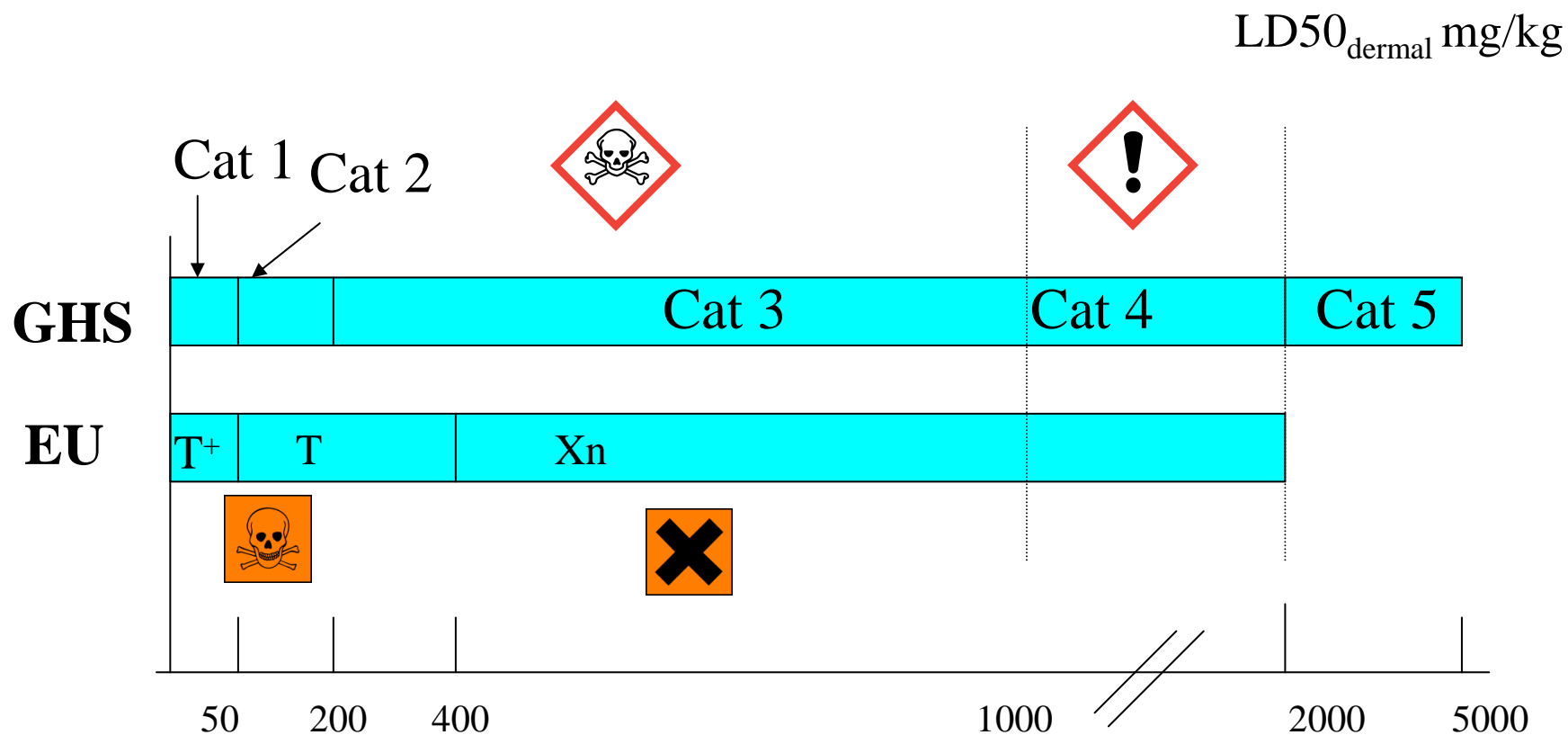
$$\frac{100}{ATE_{mix}} = \sum \frac{C_i}{\eta ATE_i}$$

## Formula B

If the total concentration of the ingredients with unknown toxicity is  $> 10\%$

$$\frac{100 - \sum C_{unknown}}{ATE_{mix}} = \sum \frac{C_i}{\eta ATE_i}$$

# Acute dermal toxicity



GHS will classify many EU “harmful” as “toxic”

# Skin corrosion/irritation-mixture

EU

Classification of substance	Concentration in preparation	Classification of preparation
C,R35	> 10 %	C, R35
C,R35	5% < x < 10 %	C, R34
C, R35	1 % < x < 5 %	Xi, R38
C, R34	> 10 %	C, R 34
Xi, R38	> 20 %	Xi, R38



G  
H  
S

Classification of substance	Concentration in mixture	Classification of mixture
Cat 1	> 5 %	Cat 1
Cat 1	1 % < x < 5 %	Cat 2
Cat 2	> 10 %	Cat 2
Cat 2	1 % < x < 10 %	Cat 3
Cat 3	> 10 %	Cat 3



**GHS will create many more skin irritants**

# Serious Eye Damage/irritation-mixture

EU

Classification of substance	Concentration in preparation	Classification of preparation
R 41	> 10 %	R 41
R 41	5% < x < 10 %	R 36
R 36	> 20 %	R 36



G  
H  
S

Classification of substance	Concentration in mixture	Classification of mixture
Cat 1 (Eye/Skin)	> 3 %	Cat 1
Cat 1 (Eye/Skin)	1 % < x < 3 %	Cat 2
Category 2/2A	> 10 %	Cat 2



**GHS will create many more classifiable mixtures**

# CM & Reproductive Toxicity- mixture

Classification of substance	Concentration in preparation	Classification of preparation
R 60 R 61	> 0.5 % > 0,5 %	R 60 R 61
GHS Cat 1	> 0,1 % > 0,3 %	Cat 1 (SDS only) Cat 1 (SDS & Label)
R 62 R 63	> 5 % > 5 %	R 62 R 63
GHS Cat 2	> 0.1 % > 3 %	Cat 2 (SDS only) Cat 2 (SDS & Label)



**Whilst the mixture rules stay the same for germ cell mutagenicity and for carcinogenicity the GHS much stricter than EU for reproductive toxicity.**

# Hazardous to Aquatic Environment

Acute/chronic	Category	Criteria	R.Biodeg.	Bioaccum.
acute	1	96h LC50 fish < 1mg/l or 48h EC50 daphnia < 1 mg/l or 72 h IC 50 algae < 1mg/l		
chronic	1	96h LC50 fish < 1mg/l or 48h EC50 daphnia < 1 mg/l or 72 h IC 50 algae < 1mg/l	no	BCF> 500 (or log Po/w>4 if BCF n.a.)
acute	2	96h LC50 fish < 10 mg/l or 48h EC50 daphnia < 10 mg/l or 72 h IC 50 algae < 10 mg/l		
chronic	2	96h LC50 fish < 10 mg/l or 48h EC50 daphnia < 10 mg/l or 72 h IC 50 algae < 10 mg/l	no	BCF> 500 (or log Po/w>4 if BCF n.a.)
acute	3	96h LC50 fish < 100 mg/l or 48h EC50 daphnia < 100 mg/l or 72 h IC 50 algae < 100 mg/l		
chronic	3	96h LC50 fish < 100 mg/l or 48h EC50 daphnia < 100 mg/l or 72 h IC 50 algae < 100 mg/l	no	BCF> 500 (or log Po/w>4 if BCF n.a.)
chronic	4	Above limits but poorly soluble	no	BCF> 500 (or log Po/w>4 if BCF n.a.)



**NOEC important for chronic categorization**

# Hazardous to Aquatic Environment-Mixture

Classification of a mixture for acute hazards, based on summation of classified components

Sum of components classified as :	Mixture is classified as :
Acute Cat 1 x M $\geq$ 25 %	Acute Cat 1
(Mx10xAcute Cat 1) + Acute Cat 2 $\geq$ 25 %	Acute Cat 2
(Mx100xAcute Cat 1) + (10xAcute Cat 2) + Acute Cat 3 $\geq$ 25 %	Acute Cat 3



# Hazardous to Aquatic Environment-Mixture

Classification of a mixture for chronic (long term) hazards, based on summation of classified components

Sum of components classified as :	Mixture is classified as
Chronic Cat1 x M $\geq$ 25 %	Chronic Cat 1
(M <sup>1</sup> x10xChronic Cat 1) + Chronic Cat 2 $\geq$ 25 %	Chronic Cat 2
(Mx100xChronic Cat 1) + (10xChronic Cat 2) + Chronic Cat 3 $\geq$ 25 %	Chronic Cat 3
Chronic Cat 1 + Chronic Cat 2 +Chronic Cat 3 + Chronic Cat 4 $\geq$ 25 %	Chronic Cat 4



<sup>1</sup>Multiplying factors M for highly toxic components of mixtures (M=1 when  $0,1 < L(E)C50 \leq 1$ , M=10 when  $0,01 < L(E)C50 \leq 0.1$ , etc...)

# Comparative EU DSD-DPD and GHS

- **Flammable liquid** : GHS will lead to more classifications
- **Acute oral toxicity** : GHS will classify many EU “harmful” as “toxic”
- **Acute oral toxicity (mixtures)** : GHS will classify many EU “not classified” as “toxic” cat 3 or harmful (cat 4).
- **Skin corrosion/irritation** : cat 2&3 will trigger classification as eye irritant
- **Skin corrosion/irritation (mixtures)** : GHS will create more skin irritants
- **Serious eye damage** : GHS and EU systems identical
- **Eye irritation**: GHS will create more eye irritants
- **Serious eye damage/irritation mixtures** : GHS will create many more classifiable preparations.
- **Respiratory or skin sensitisation** : GHS and EU systems identical
- **Germ cell mutagenicity, carcinogenicity, reproductive toxicity** : FGS and EU system identical but for mixtures GHS is much stricter for reprotox.
- **Specific target organ systemic toxicity Single and repeated exposure** : new hazard classes in GHS
- **Aspiration hazard** : GHS worse than EU systems due to extended viscosity range.
- **Hazardous to the aquatic environment** : Small differences in both systems

# Special focus on EU GHS implementation

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# CLP

# Content of Regulation n°1272/2008 (“CLP”)

- Classification:
- Building block approach: no complete take over of the UN GHS.
  - **No “flammable liquid cat 4”**
  - **No “skin corrosion/irritation cat 3”**
  - **No aspiration hazard cat 2**
  - **No acute aquatic toxicity cat 2 and 3**
  - **No acute toxicity cat 5**
- Acute toxicity calculations of mixtures with toxicity data or estimates (“ATE”)
- M-factor for very aquatic toxic substances (acute/chronic cat 1)
- Generic and specific concentration limits (exceptional cases only)
- Additional EUH statements

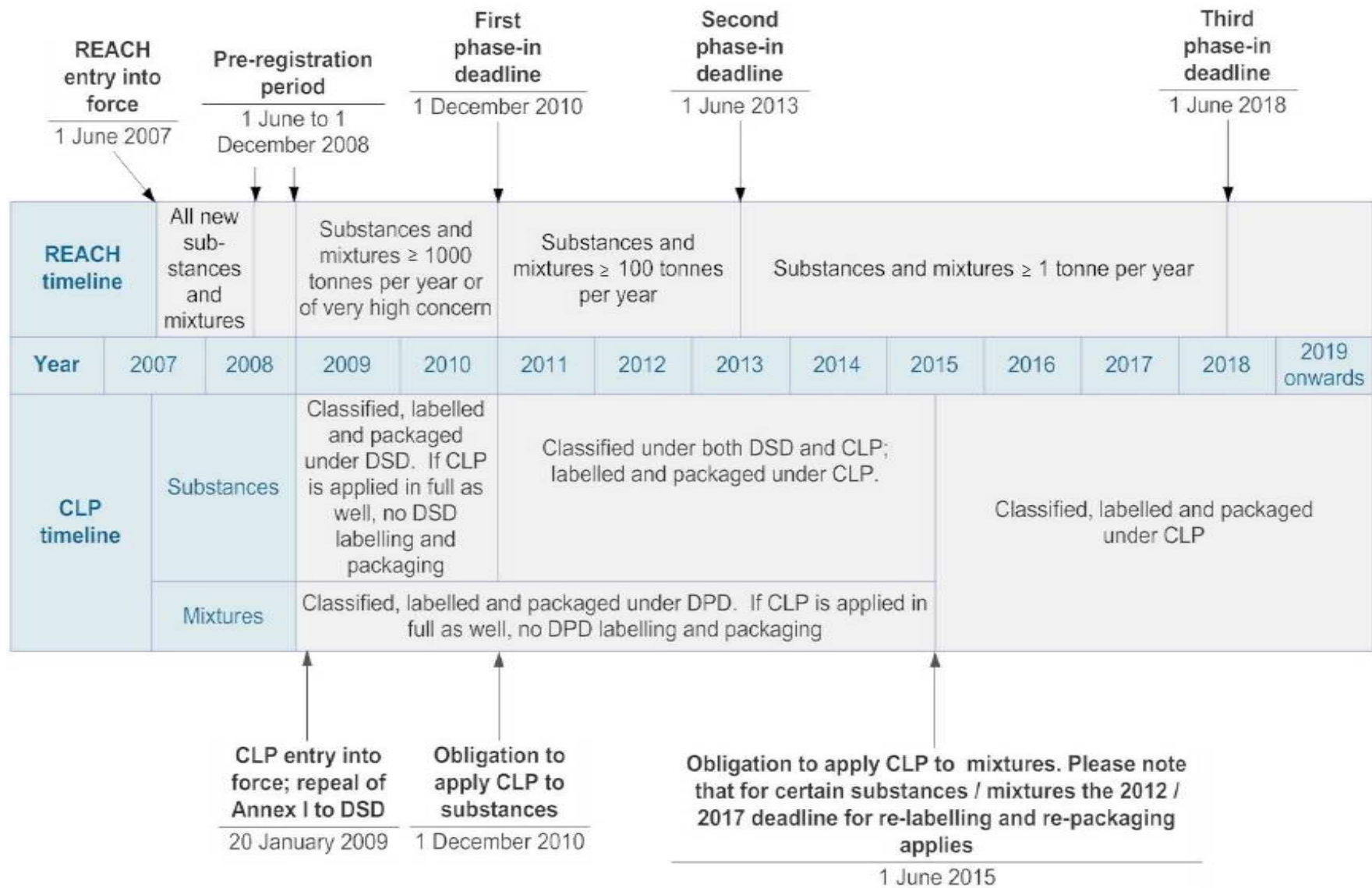
# Content of Regulation n°1272/2008 (“CLP”)

- Constituents approach established Art. 11 (UVCBs).
- Obligatory use of Harmonised official classifications of annex VI (about 8000 substances); EU community remains responsible for classification of substances for CMR and respiratory sensitisation.
- Notifications:
  - M/I/DU may notify to the Agency substances with CMR and RS hazards (e.g. BMHCA)
  - **C&L Inventory** : M/I or group of M/I of substances are obliged to notify to the Agency classification and labelling elements of hazardous substances which are not registered under REACH (no cut-off).

# Product identifier (article 18 of CLP)

Parag. 3 : The product identifier for a mixture shall consist of both of the following:

- (a) the trade name or the designation of the mixture;
- (b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or **aspiration hazard**.
- Where, in the case referred to in (b), that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless more than four names are needed to reflect the nature and the severity of the hazards.
- The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements.



**EXAMPLE OF  
NEW GHS and CLP  
CLASSIFICATION/LABELLING  
FOR NCS**

# Example of class. & labelling for NCS according GHS and CLP

- Cinnamon Bark oil
- *Cinnamomum zeylanicum* syn. *C. verum* (ISO 4720)
- **ORIGIN:** Steam distilled from the wood bark and branches in Sri Lanka.
- **IDENTIFICATION:**
- CAS 84649-98-9
- EINECS 283-479-0
- Alternative 8015-91-6
- FEMA 2291
- EC 133n
- FDA 182.20
- INCI 'Cinnamomum zeylanicum ext.'; uses-tonic, deodorant, cleansing, refreshing



# Some available data

- RIFM monograph 328, FCT 13 (1) 111 (1975)
- Physico-chemical: Clear yellow; odour spicy
- Flash point :> 100°C [EFE0] 88 [IFEAT 62-88] 88 [FMA] 93 [Quest]
- Log Kow calc. : n/a
- Density : 1.01 g/ml (Merck), 1.02 (FMA)
  
- **TOXICOLOGY:**
- Acute toxicity : LD50 (Oral, rat) : 3400 mg/Kg  
(Dermal, rabbit): 690 mg/Kg
- Local effects : Irritation, no effects human at 8%
- Sensitisation, no effects human at 1%
- Hydrocarbon content: < 1 % (BEOA technical comm.)
- Eco Toxic data : WGK = 2

## « TYPICAL COMPOSITION » OF RELEVANCE and EU DSD CLASSIFICATION

Cinnamic ald	75	Xn; R21, Xi; R38-43	LM
Eugenol	6	Xi; R36-43	LM
Linalool	6	Xi ; R38	LM
Limonene	1	Xi; R38-43, N; R50/53	Annex I
Benzyl benzoate	2	Xn; R22	Annex I

**Evaluation:** To be classified for acute toxicity (data and cinnamic aldehyde), skin irritancy and sensitization (cinnamic aldehyde) and environmental effects (limonene).

**Conclusion:** Xn; R 21-38-43-52/53, S 24-36/37

**Transport:** 6.1, III, 2810 (Toxic liquid, organic, n.o.s.).

# UN GHS CLASSIFICATION

Cinnamic ald	7 5	ATO 5(2900); ATD 4(1260); SCI 2; EDI 2A; SS1; EH A2;
Eugenol	6	ATO 5(2300); SCI 3; EDI 2A; SS 1;EH A2;
Linalool	6	ATO 5(3000); SCI 2; EH A3;
Limonene	1	SCI 2; SS 1; EH A1,C1
Benzyl benzoate	2	ATO 4 (1500), SCI3;

**Evaluation:** To be classified for flammability (FL 4, borderline), acute oral toxicity (ATO 5, LD50 and ATEmix, however ATD classification is more severe), acute dermal toxicity (ATD 3, LD50), skin irritation (SCI 2, cinnamic aldehyde), skin sensitization (SS 1, cinnamic aldehyde, eugenol), eye irritation (EDI 2A, cinnamic aldehyde) and environmental effects (EH A2,C3; cinnamic aldehyde, limonene).

**Conclusion:** FL 4, ATD 3 (700), SCI 2, SS 1, EDI 2A, EH A2,C3

# EU DSD

## Cinnamon bark oil



**Xn-Harmful**

**Contain : cinnamic aldehyde, eugenol, limonene**

- R 21 Harmful in contact with skin.
- R 38 Irritating to skin.
- R 43 May cause sensitization by skin contact.
- R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### **Safety Advices**

# UN GHS\*

## Cinnamon bark oil



**Danger**

**Contain : cinnamic aldehyde, eugenol, limonene**

H227 Combustible liquid

H303 May be harmful if swallowed

H311 Toxic in contact with skin

H315 Cause skin irritation

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation

H401 Toxic to aquatic life

H412 Harmful to aquatic life with long lasting effects

### **Precautionary Statements**

# EU CLP\*

## Cinnamon bark oil



**Danger**

**Contain : cinnamic aldehyde, eugenol, limonene**

H311 Toxic in contact with skin

H315 Cause skin irritation

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation

H412 Harmful to aquatic life with long lasting effects

### **Precautionary Statements**

**Comment : EU DSD/DPD, UN GHS and CLP: some differences !**

# CONCLUSIONS :

Compare to current situation GHS is a new step toward global worldwide harmonisation for classification, labelling and packaging.

A hard work is needed to be compliant to the new GHS rules (conversion of previous classifications, EU inventory, updated software, new SDS, label printers, etc...) while still many local specifications and different timelines for implementation are occurring.

But more crucial is sound classification/labelling and proportionate risk management for our precious natural products.

No doubt that industry's initiatives to address all technical and specific issues related to Natural Complex Substance (like in REACH and with IOFI-IFRA Labelling Manual or EFFA Code of Practice) are today of major importance.

# Thanks for your attention.

Special thanks to Markus Leiendecker and David de Rijke  
for their input on GHS.