



**Globally harmonised system  
(GHS)**

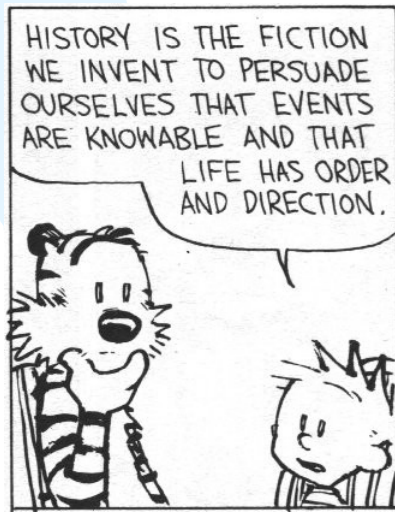
**Eurofer workshop on C&L  
May 28, 2008**





# ENVA

## introduction



# What is the Globally Harmonised System?

GHS provides a common basis to define and classify chemicals according to their hazards and to communicate this information via labels and safety data sheets.

## Target audiences include:

- consumers
- workers & transport workers
- emergency responders

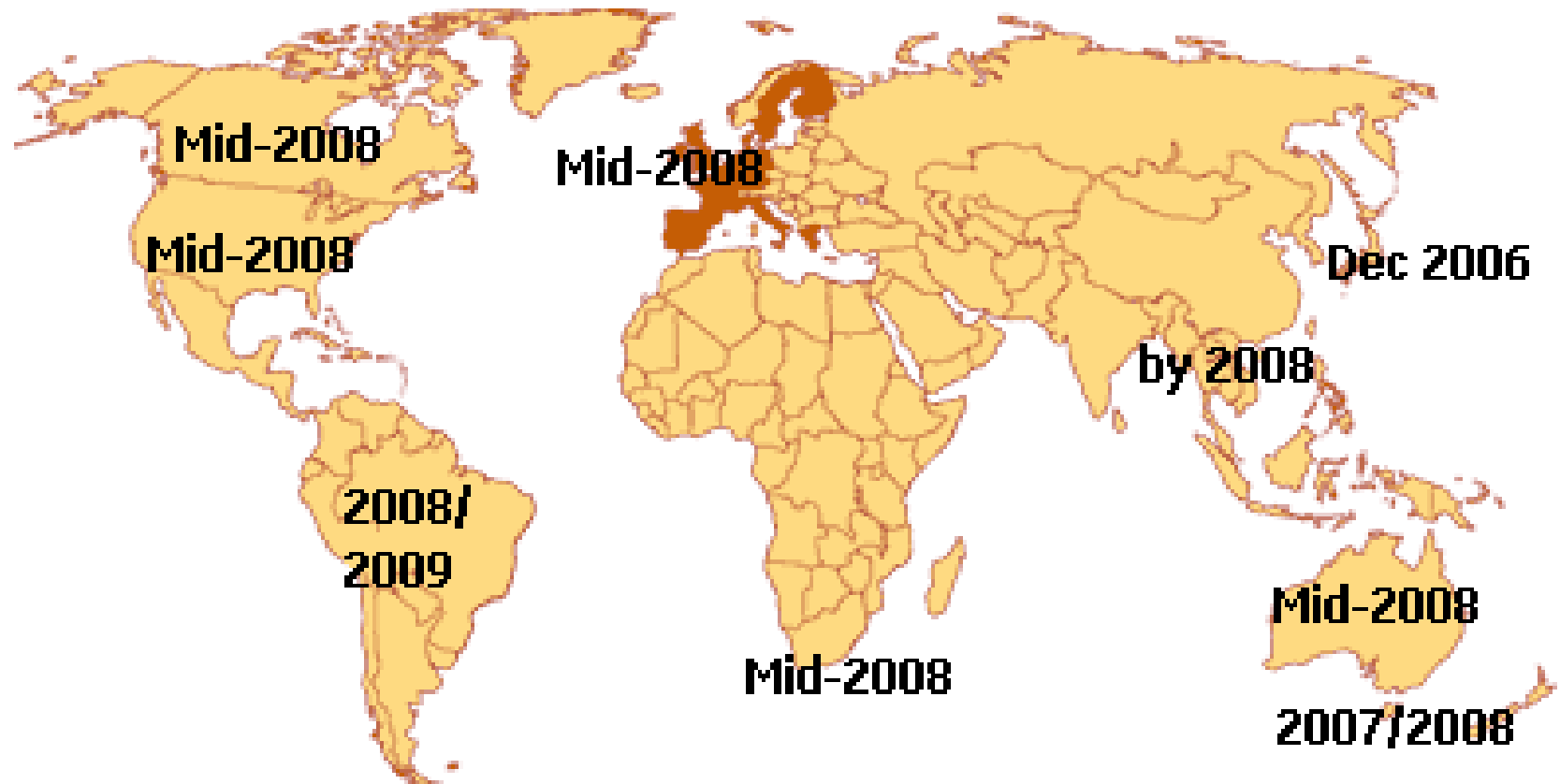
# UN GHS

- Implementation agreed at WSSD in Johannesburg 2002
- Non-binding scheme
- Living document, updates every 2 years
- Commitment to implement: Countries are announcing GHS adoption schedules regularly at this point
- Building-block approach

Why? Existing global Disharmony in Classification and Labelling

EU	Harmful (St Andrew's Cross)
US	Toxic
CAN	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
New Zealand	Hazardous
China	Not Dangerous
Korea	Toxic
GHS	Danger (Skull & Cross Bones)

## GHS Implementation around the World



**Global Implementation expected 2008-2009**

[http://www.unece.org/trans/danger/publi/ghs/implementation\\_e.html](http://www.unece.org/trans/danger/publi/ghs/implementation_e.html)

# GHS: scope and general principles

## *Global Harmony...*

- internationally comprehensible system for hazard communication
- provides a recognized framework for those countries without an existing system
- reduces the need for testing and evaluation of chemicals
- facilitates international trade in chemicals whose hazards have been properly assessed and identified on an international basis...

## *Global disharmony...*

- GHS has a “building-block” approach - national systems are “built” accordingly - not total harmonization
- implementation of different approaches in different countries may still lead to differing classifications

# Global Disharmony: Differences between the UN and Global GHS Proposals

<b>Japan</b> <b>South Africa</b>	Human Health and Environmental follow criteria and endpoints outlined by UN. Japan maintains a GHS classification database for substances.
<b>EU</b>	<p><b>Human Health:</b> Cat. 5 Acute Toxicity, Cat 3 skin irritation, Cat 2b eye irritation, &amp; Cat 2 Aspiration hazard are not adopted</p> <p><b>Environmental:</b> Aquatic Acute 2 &amp; 3 deleted</p> <p>Hazardous for Ozone layer (R59) maintained</p> <p>(Annex VI Classifications have been made in the EU GHS proposal)</p>
<b>New Zealand</b>	<p><b>Human Health:</b> CMR Categories 1A &amp; 1B and 2 are now Cat 1 and Cat 2</p> <p><b>Environmental:</b> 3 additional terrestrial endpoints</p> <p>(Categories have unique numbering scheme and a searchable database available for classifications)</p>
<b>Australia</b>	<p><b>Human Health:</b> Cat. 5 acute toxicity not adopted</p> <p><b>Environmental:</b> Not in scope</p>
<b>United States</b>	<p><b>Human Health:</b> Cat. 5 acute toxicity not adopted</p> <p><b>Environmental:</b> Not required by OSHA, may be adopted by EPA</p>
<b>Canada</b>	<p><b>Human Health:</b> Cat 4 and 5 acute toxicity, aspiration hazard and STOT under discussion</p> <p><b>Environmental:</b> Under discussion</p>



GHS in the EU

## GHS in the EU (1)

***REACH does NOT include CRITERIA for C&L***

- It refers to Substance & Preparation Classification
- Aim of the European Commission: GHS entry into force as close as possible to REACH entry into force
- *REACH, as well as the implementation of GHS within the EU will lead to a major revision of the EU classification and labelling system*

## GHS in the EU (2)

### ➤ Status “EU-GHS”

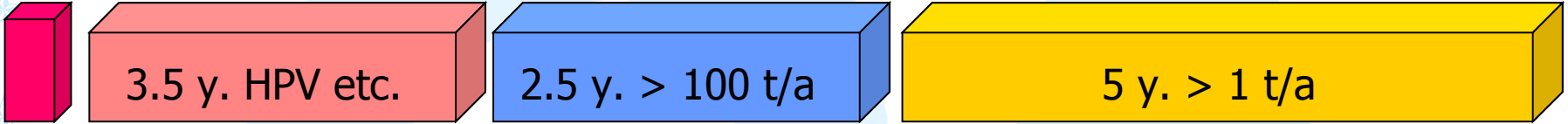
- Commission’s internet consultation on early proposal: August 2006
- Latest draft proposal Regulation published on 27<sup>th</sup> June 2007
- Adoption by Parliament and Council - plenary vote September 2008
- Expected to be in force by end 2008/early 2009
- Reach Implementation Project (RIP) 3.6 will develop GHS C&L standards/criteria under REACH (has started in October 2007)

## GHS in the EU (3)

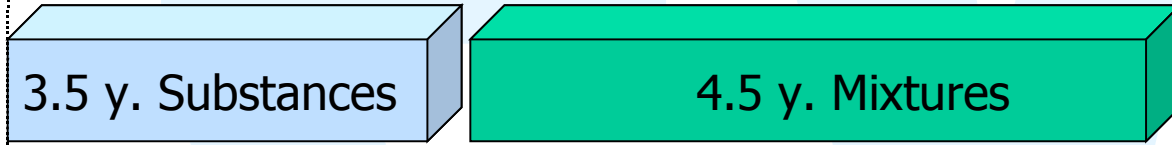
- Applies the general principles of the GHS
- Ensures consistency with transport
- Uses the GHS BB Approach and a few other “optionalities” to adapt the system to our needs
- Stays as close as possible to the GHS format and terminology e.g.
  - Takes up all GHS Hazard Classes
  - Mixtures not preparations
  - Hazardous not dangerous
- Keeps the scope as close as possible to the existing EU system
  - Does not include categories not part of current EU system (acute toxicity category 5, acute aquatic toxicity categories 2,3)
  - Maintains the current level of protection by including EU “left-overs” not yet covered by the GHS (e.g. ozone depletion, reacts violently with water, etc...)

# GHS - Commission Proposal : Transitional Period

REACH



GHS



**For substances and mixtures:**  
EU-System: binding  
GHS: optional;  
Label: GHS if class.

**For substances:**  
GHS: obligatory for the label  
SDS must contain EU and GHS classification  
**For mixtures:** EU-System: binding  
GHS: optional; Label: GHS if class.

After the entire transition period:  
For substances & mixtures:  
GHS: obligatory  
EU-System: loses its legal status

★  
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# Reach Implementation Project 3.6



## RIP 3.6

### ECB RIP 3.6 working groups

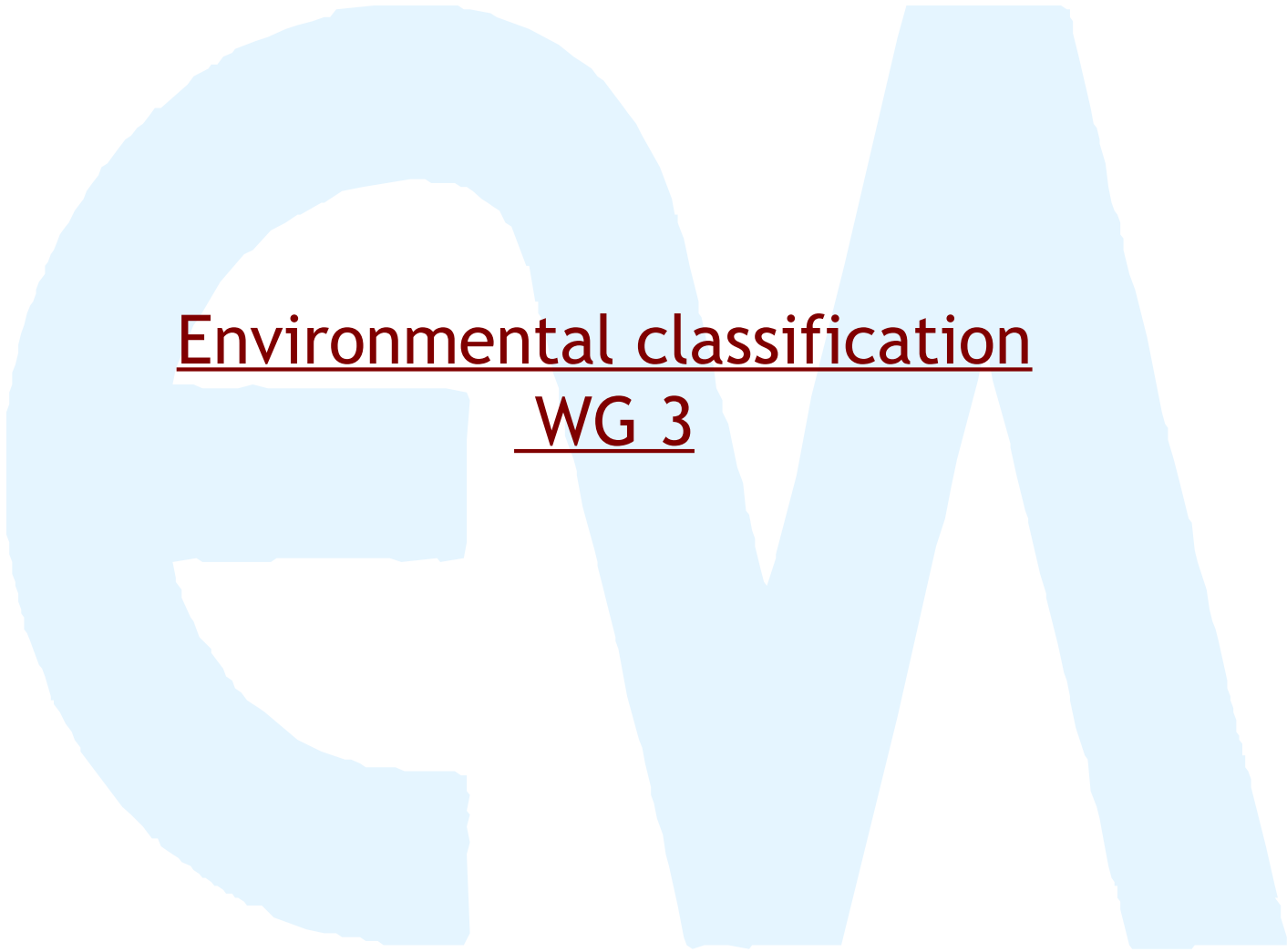
WG 2: human health classification (S. Hubbard, Rio Tinto)

WG 3: environmental classification (K. Delbeke, ECI and L. Regoli, IMO)

WG 4: combined issues, via CEFIC

SEG

EM Classification and Labelling working group  
GHS Project Team



Environmental classification

WG 3

# RIP 3.6 WG 3 Environment activities

## RIP 3.6 env - Guidance outline

- 1.1 Introduction
- 1.2 Scope
- 1.3 Definitions
- 1.4 Classification of substances Hazardous to the aquatic environment  
Weight of evidence = CEFIC
- 1.5 Classification of mixtures = UK
- 1.6 Metal and metal compounds (introduction) = EM
- 1.7 Hazard communication in form of labelling for hazards to the aquatic environment
- 1.8 Re-classification of substances classified as hazardous to the aquatic environment according to Directive 67/548/EEC

**Annexes:** \_\_Aquatic toxicity  
Degradation  
Bioaccumulation  
QSAR?

Metals, including Annex 10 = EM

EM

SP

# Strategy- Opportunities - RIP 3.6 Metals annex

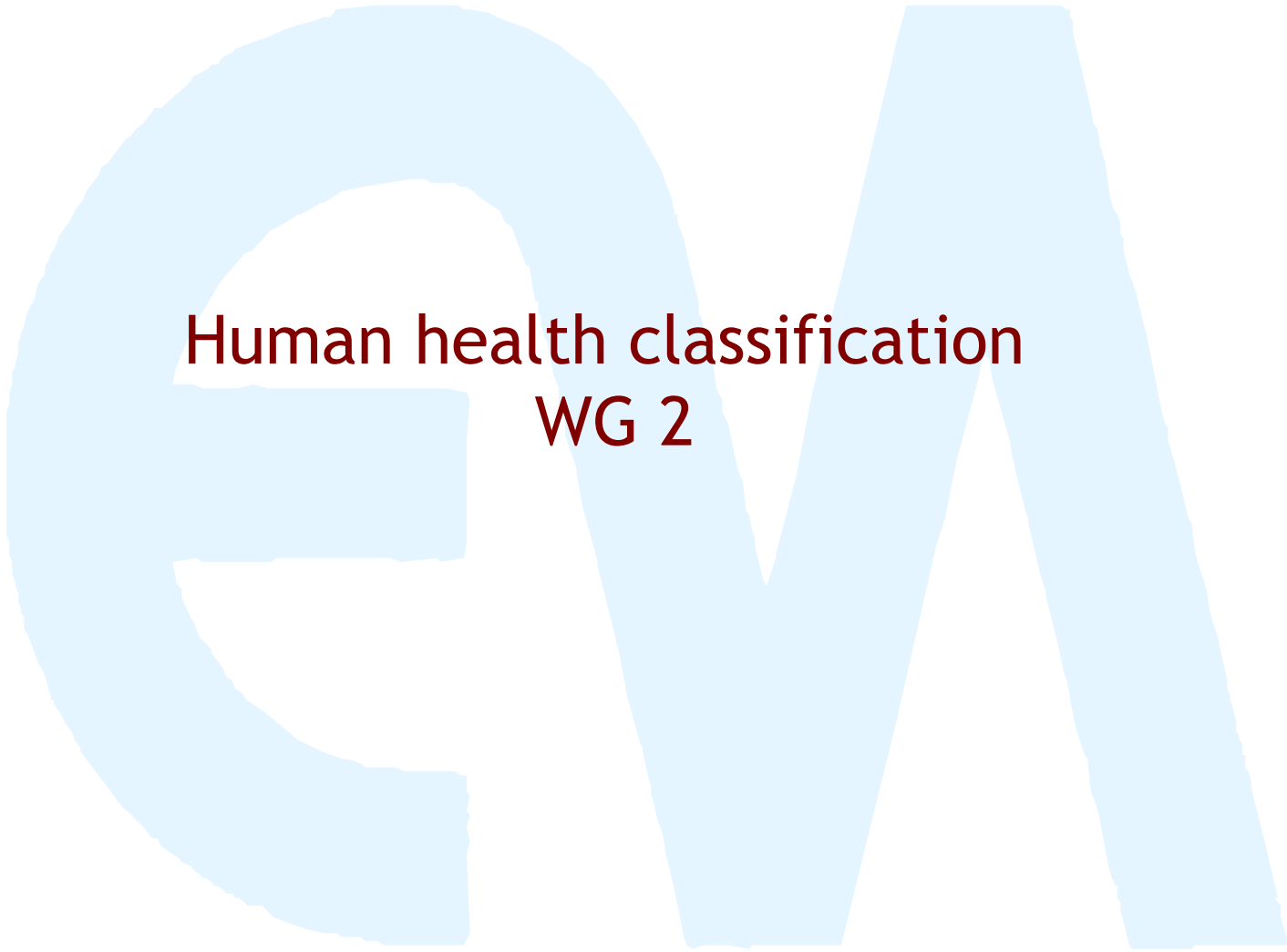
= Translate GHS into EU, make use of examples

1. Write good guidance for industry
2. Include Transformation/dissolution method and Critical Surface Area approach = distinguish classification between soluble metal compounds, metal powders, metal massives
3. Improve the chronic metal classification
  - Fate : removal from the water column :  
Precipitation : example Fe  
Partitioning and sediment binding
  - Evaluate the need of chronic classification from acute to chronic ratio's (Factor 10 in chronic classification proposal)
4. Include section on alloys
5. Provide examples : Alloys, ores, concentrate?



## Timing:

- ✓ Metals draft sent to ECB and WG3 on May 27
- ✓ Request for an additional meeting
- ✓ Comments expected from Spain, UK, NL, SE
- ✓ SEG meeting: June 4



**Human health classification  
WG 2**



Key issues:

- ✓ Carcinogenicity: Sue Hubbard lead
- ✓ Bioavailability and read-across
- ✓ STOT - lung fibrosis -lung overload -used cut-offs

# Use of Bioavailability for Classification

## Of importance for

- When reading across between substances of a category
- multi-constituent substances
- Alloys

## How to assess bioavailability?

- Water solubility (TDP)
- Bio-elution tests
- Toxicokinetics

# STOT - Specific Target Organ Toxicity

## Repeated Dose - Inhalation

→ What is a serious effect ?

- × Lung overload and secondary effects
- × Fibrosis - when does this become a serious effect

→ Form and bioavailability

- × Low solubility, low toxicity particles
- × Low solubility but some or high cytotoxicity
- × Water soluble metal compounds

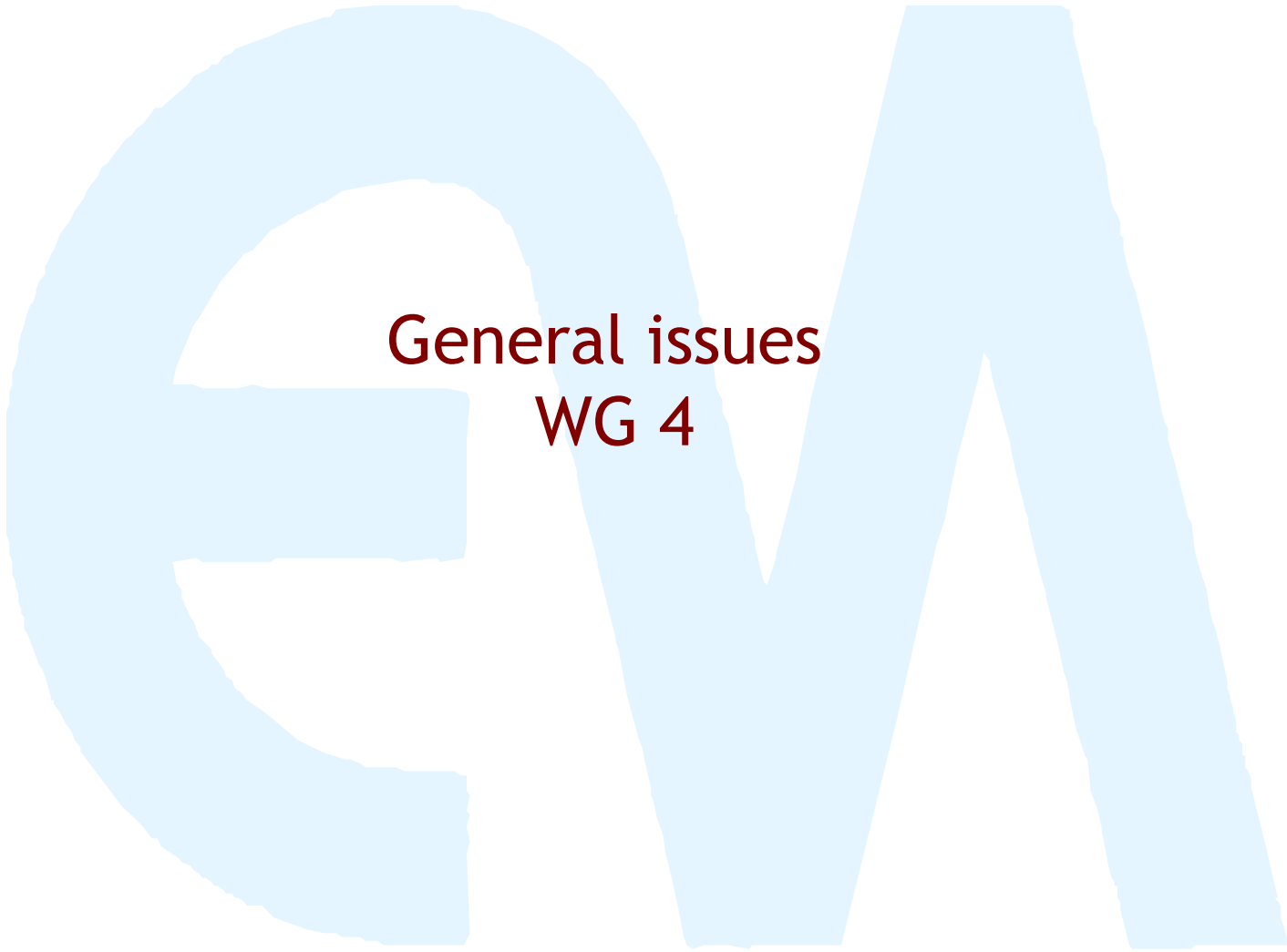
→ Are cut-offs too low?

			Cat 1 90-day	Cat 1 28-day	Cat 2 90-day	Cat 2 28-day
Inhalation, vapor	Rat	<b>mg/l/6 h/d</b>	≤ 0.2	≤ 0.6	≤ 1	1 ≤ 3
Inhalation, dust/mist/fume	Rat	<b>mg/l/6 h/d</b>	≤ 0.02	≤ 0.06	≤ 0.2	≤ 0.6



Timing:

- ✓ Drafts fibrosis, bioavailability and read-across to send to ECB and WG2 < June 27
- ✓ Request for an additional meeting
- ✓ SEG meeting: June 4



**General issues  
WG 4**

# Key issues

- Correct interpretation of the Articles in the CLP Regulation
- General issues in Annex I
- Classification of Mixtures for health and environment (e.g. application of bridging principles, mixtures in mixtures etc.)
- Setting of specific concentration limits (also the use of general SCLs)
- Read across, grouping and categorisation - **ISSUE**
- Biological availability - **ISSUE**
- Form or physical state (aerosols) - **ISSUE**
- Use of Precautionary statements in Annex IV
- Foreword to Annex VI (e.g. application of Notes) - **ISSUE**
- Labelling (of substances and mixtures)
- Links with REACH (where not covered by Module 1)
- Re-classification of substances and mixtures and use of tables in Annex VII **ISSUE**



Timing:

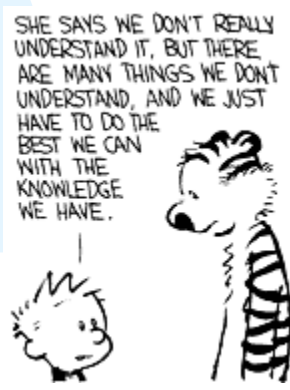
✓ Followed up via CEFIC

✓ SEG meeting: June 4



# ENM

## Joint GHS Project



## Joint GHS Project

**International Council on Mining and Metals (ICMM)**  
**EUROFER**  
**EUROMETAUX**  
**Cobalt Development Institute (CDI)**  
**European Copper Institute (ECI)**  
**European Nickel Industry Association (ENIA)**  
**European Powder Metallurgy Association (EPMA)**  
**International Cadmium (ICdA)**  
**International Copper Association (ICA)**  
**International Lead Zinc Research Organization, Inc. (ILZRO)**  
**International Molybdenum (IMoA)**  
**Lead Development Association International**  
**NiPERA**  
**CEMBUREAU**  
**Rio Tinto Minerals**  
**EBRC Consulting GmbH**  
**EUROMINES**  
**Keller and Heckman LLP**

**Patricia Koundakjian**  
**Treibacher IND AG**  
**UMICORE AG & Co. KG**  
**UMICORE**  
**Wirtschaftsvereinigung Metalle**  
**Environment**  
**ARCELOR**  
**Galvanizers Association**  
**ThyssenKrupp Steel AG**  
**Teamleiterin Nachhaltigkeit**  
**OMG Finland OY**  
**IZA-Europe**  
**KV Consulting Services**  
**Chamber of Mines of South Africa**  
**EURAS**  
**EUROALLIAGES**  
**BBL Sciences/ ARCADIS**

# GHS Joint Project Team (1)

Purpose: GHS review, guidance and interpretation for substances and mixtures in the metals and mining industries

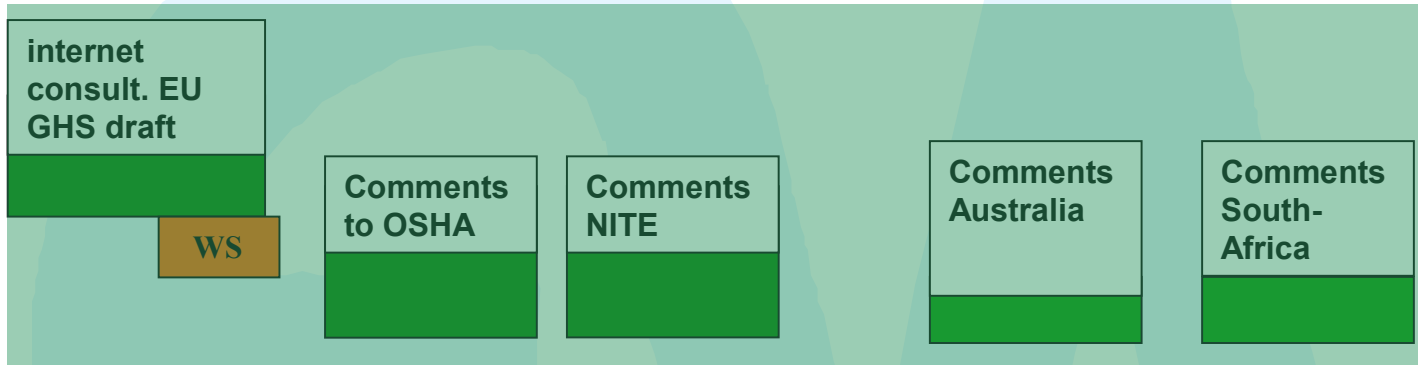
## Objectives:

- ✓ Identify relevant aspects of GHS
- ✓ Ensure key jurisdictions recognize issues relevant to the metals and mining industries
- ✓ Communicate information and provide guidance to ICMM, Eurometaux and Eurofer members

# GHS Joint Project Timescale

2006						2007								
July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	Apr	May	Jun	July	Aug	Sept

- Strategy note
- Identify consultant phase
- Set-up Project Team
- Preparatory work: identify issues of concern/UN GHS text



- Comparison GHS versus other systems (EU CI&L, Canadian, Australian, Japanese...): tables
- Selection of examples to visualise difference and stream (waste, minerals, metal +powder, metal compound)

**Outreach**

Communication, training

**World tour!**

# Deliverables Joint Project to date

Strategy note

Comments to different jurisdictions

Leaflet

Input RIP 3.6

Website: <https://project.bbl-inc.com/jointghs/index.cfm>



Comments on the European Commission's GHS Internet Consultation by Eurometaux, Eurofer and ICMM: <sup>1</sup>  
October 21, 2006

## Executive Summary

The European metals, alloys and minerals industry represented by Eurofer, Eurometaux and EIMAG, and the International Mining and Metals Industry (ICMM) (collectively, "the industry") welcome the opportunity to provide comments on the draft European Commission's proposed GHS regulation. The industry has proactively worked for years on the GHS scheme, in close cooperation with OECD and UN, resulting in the recognition of specific requirements for metals and alloys and detailed metal guidance in the UN-GHS text. Moreover, the industry is working to develop practical guidance for sound metal classifications through projects such as MERAG (Metal Risk Assessment Guidance Project) and HERAG (Human Health Risk Assessment


















GHS: Globally Harmonised System of Classification and Labelling of Chemicals

An Introduction



# ACUTE ORAL TOXICITY - Categories

GHS	Category 1	Category 2	Category 3	Category 4	Category 5
UN  Countries following UN GHS for this endpoint:  Japan and South Africa	$LD_{50} \leq 5 \text{ mg/kg}$    DANGER  Fatal if swallowed	$LD_{50} > 5 \leq 50 \text{ mg/kg}$    DANGER  Fatal if swallowed	$LD_{50} > 50 \leq 300 \text{ mg/kg}$    DANGER  Toxic if swallowed	$LD_{50} > 300 \leq 2000 \text{ mg/kg}$    WARNING  Harmful if swallowed	$LD_{50} > 2000 \leq 5000 \text{ mg/kg}$  No symbol  WARNING  May be harmful if swallowed
New Zealand GHS	6.1A	6.1B	6.1C	6.1D	6.1E
EU Current	Very Toxic $LD_{50} \leq 25 \text{ mg/kg}$   Very toxic if swallowed		Toxic $LD_{50} > 25 \leq 200 \text{ mg/kg}$   Toxic if swallowed	Harmful $LD_{50} > 200 \leq 2,000 \text{ mg/kg}$   Harmful if swallowed (R22)	
EU and Australia GHS	Category 1	Category 2	Category 3	Category 4	
EU, Australia, and US Proposed	  DANGER  Fatal if swallowed	  DANGER  Fatal if swallowed	  DANGER  Toxic if swallowed	  WARNING  Harmful if swallowed	
Canada GHS	Category 1	Category 2	Category 3	Category 4	
Canada Proposed in position paper	  DANGER  Fatal if swallowed	  DANGER  Fatal if swallowed	  DANGER  Toxic if swallowed	  WARNING  Harmful if swallowed	
				May not include, still under discussion	

# Next Steps Joint Project

## Further tracking GHS implementation globally :

- ✓ Russia, China, Korea
- ✓ EU: work on the Commission proposal + RIP 3.6
  - Advocacy efforts
  - Technical Input , MERAG, HERAG....

## Guidance for implementation in mining/metals industry [underway]

- ✓ Aim: Develop explanatory materials on GHS and its application to metals/ metal compounds and metal containing materials under different regulatory jurisdictions, to be used for training member company representatives or to download from the ICMM/EM websites

# More information on the Joint Project...

ICMM: Ben Davies [Benjamin.Davies@ICMM.com](mailto:Benjamin.Davies@ICMM.com)

Eurometaux: Violaine Verougstraete [Verougstraete@eurometaux.be](mailto:Verougstraete@eurometaux.be)

THANKS!!!

