

# 1. History of the GHS and its implementation at international level

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# Background

- Chemical products have the potential for adverse effects to people or the environment. As a result, a number of countries or organizations have developed laws or regulations that require information to be prepared and transmitted to those using chemicals, through labels or Safety Data Sheets (SDS)
- While these existing laws or regulations are similar in many respects, their differences are significant enough to result in different labels or SDS for the same product in different countries



# Origins of GHS

In 1992, the UN Conference on the Environment and Development (UNCED) established 6 programme areas to strengthen national and international efforts related to the environmentally sound management of chemicals, as follows:

- a) Expanding and accelerating international assessment of chemical risks;
- b) Harmonization of classification and labelling of chemicals.
- c) Information exchange on toxic chemicals and chemical risks;
- d) Establishment of risk reduction programmes;
- e) Strengthening of national capabilities and capacities for management of chemicals;
- f) Prevention of illegal international traffic in toxic and dangerous products.

(Agenda 21, Chapter 19: Programme Areas)

# GHS Released in 2005

- Common and coherent global approach to:
  - defining and classifying hazards of chemicals
  - communicating such hazards via labels and safety data sheets.
- Encourages all countries (Competent Authorities) to implement GHS ASAP (By end of 2008)
- “The purple book” sets out the approach but allows for flexibility



# Purpose

United Nations (UN), Organization of Economic Cooperation and Development (OECD), International Labour Organization (ILO)

- Enhanced protection of the environment and human health through an internationally comprehensible system for hazard communication
- Provide a recognized framework for those countries without an existing system;
- Reduce the need for testing and evaluation of chemicals; and
- Facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis.

# General Principles

- Focus on intrinsic hazards (not exposure or risk)
- Self-classification (not by regulatory authorities)
- Best scientific practice and judgment applied to existing data
- “Building block” approach to facilitate implementation
- Not intended to reduce current level of control in any country - Competent Authorities decide which elements to implement
- However...

**flexibility = non-uniform implementation  
around the world!**

# GHS Scope

## In-Scope

- All hazardous chemicals
- Substances and Mixtures in all types of use situations\*
- R&D
- Production
- Storage
- Transportation
- Workplace Use
- Consumer Use
- Presence in the Environment

## Out-of-Scope

- Pharmaceuticals (human and animal)
- Foods and food additives
- Cosmetics
- Pesticide residues in food
- Setting uniform test methods
- Promoting further testing
- Risk assessment procedures or risk management decisions

\* Articles excluded from scope unless they emit a hazardous substance

# Why is the GHS Necessary?

## Current Global Disharmony in Classification and Labelling

**Example: Different risk phrases used for a substance with an Acute Oral Toxicity  $LD_{50} = 257$  mg/kg/day**

<b>EU</b>	<b>Harmful (St Andrew's Cross)</b>
<b>US</b>	<b>Toxic</b>
<b>CAN</b>	<b>Toxic</b>
<b>Australia</b>	<b>Harmful</b>
<b>India</b>	<b>Non-toxic</b>
<b>Japan</b>	<b>Toxic</b>
<b>Malaysia</b>	<b>Harmful</b>
<b>Thailand</b>	<b>Harmful</b>
<b>New Zealand</b>	<b>Hazardous</b>
<b>China</b>	<b>Not Dangerous</b>
<b>Korea</b>	<b>Toxic</b>
<b>GHS....</b>	<b>Danger (Skull &amp; Cross Bones)</b>



# The GHS includes:

## Classification of hazardous substances and mixtures

- × Physical-Chemical Hazards
- × Human-Health Hazards
- × Environmental Hazards

## Hazard Communication

- × Labelling
- × Safety Data Sheets

# Health Hazard Classification

## Health Hazard Classes

- Acute Toxicity, Oral
- Acute Toxicity, Dermal
- Acute Toxicity, Inhalation
- Skin Corrosion/Irritation
- Eye Damage/Irritation
- Respiratory Sensitisation
- Skin Sensitisation
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicity
- Target Organ ST – Single Dose
- Target Organ ST – Repeat Dose
- Aspiration Hazard

## Hazard Category

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	1A/B/C	2	3	
1	2	2A/B		
1				
1				
1	1A/B	2		
1	1A/B	2		
1	1A/B	2	Lactation	
1	2	3		
1	2			
1	2			

Optional Sub Categories  
 Optional Categories  
 Separate Classifications

(1 is more severe than 5...)

# Four GHS Harmonised Labelling Elements

1. Hazard Symbols or “Pictograms”

2. Signal Words

“Danger”, “Warning”

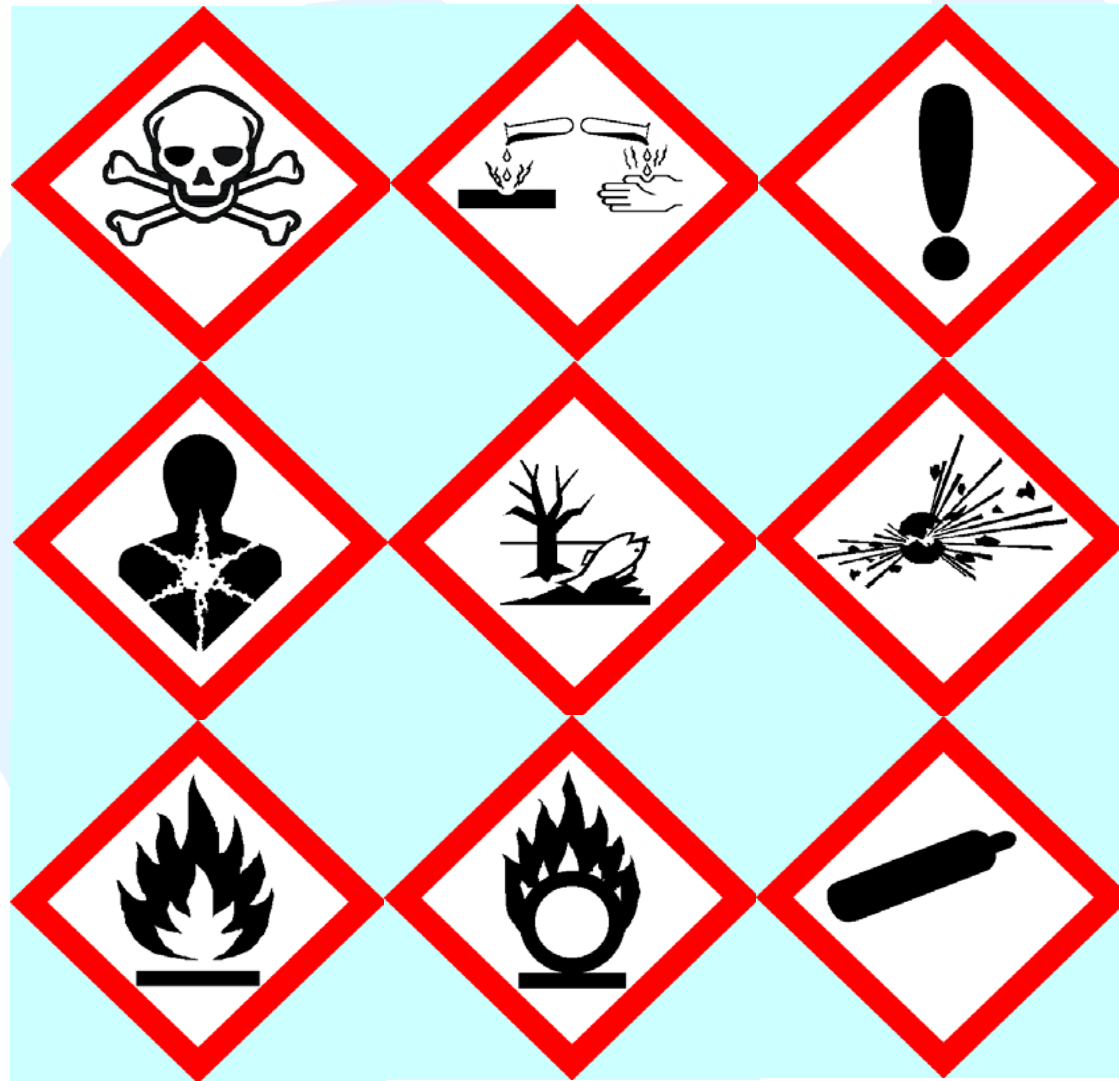
3. Hazard Statements

“Fatal if swallowed”, “Harmful to aquatic life”

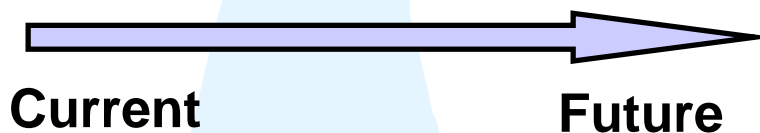
4. Precautionary Statements












Regarding prevention, response, storage or disposal

# GHS Supply Pictograms

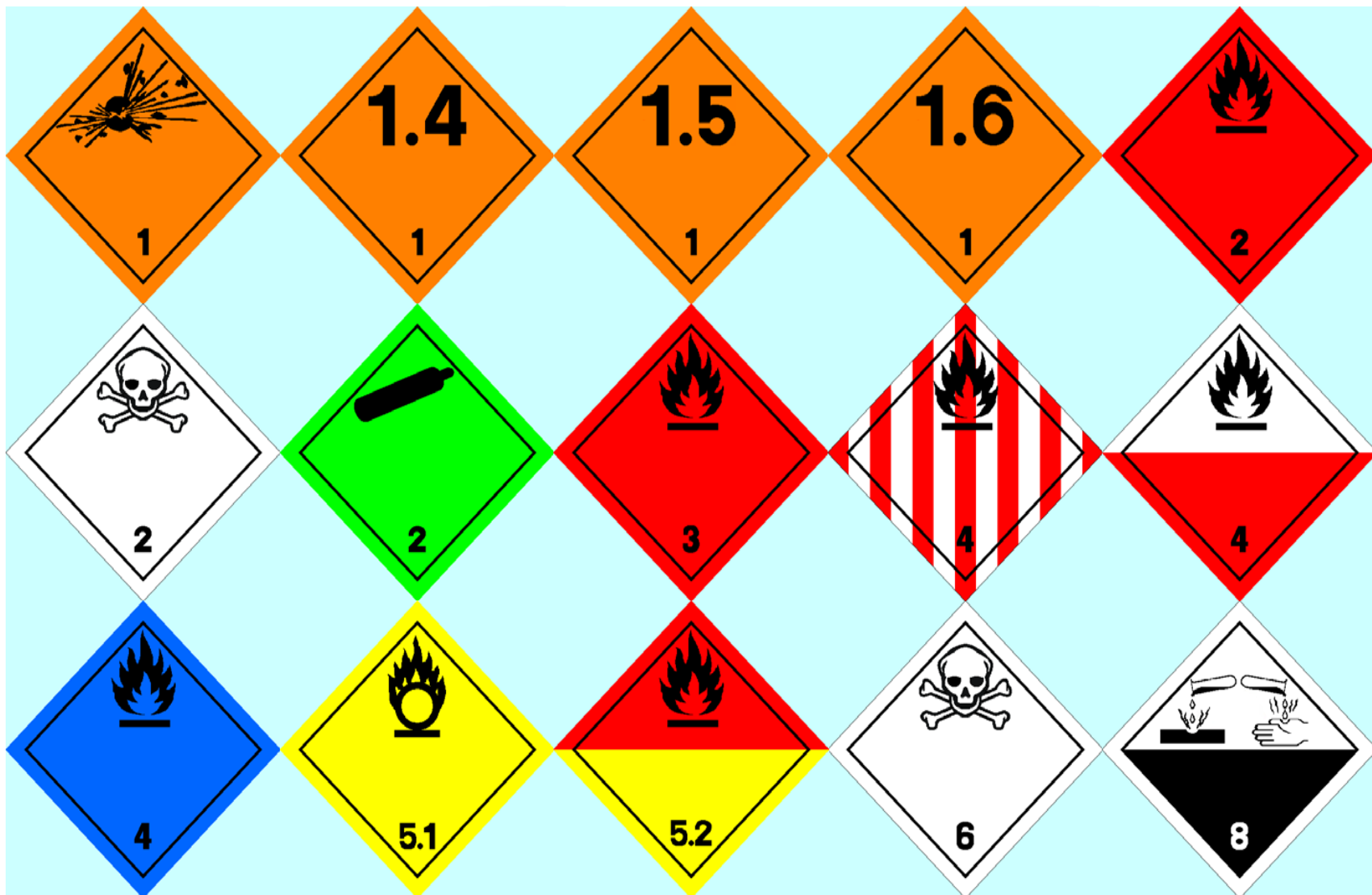


# Selected Examples of Labelling Changes for GHS



Category	EU	Canada	U.S.	GHS
Flammable			None	
Toxicity/ Health Hazard Danger			None	
Environmental Toxicity		None	None	
Chronic Health Hazard (e.g. Respiratory Sensitiser, Carcinogen)	Various  	None	None	

# GHS Transport Pictograms



# Implications

- **Potential Changes/Implications:**
  - (M)SDS changes
  - Reformulation of products to eliminate certain ingredients/impurities
  - Warning labels for currently exempt products
  - More stringent shipment labelling and transport precautions
  - More stringent chemical storage, handling and disposal
  - New guidance regarding Hazard Communication within the workplace

# Intended GHS Benefits

## Regulators

- A single system should improve accurate information flow

## Manufacturers

- Facilitation of International Trade
- A single internal group can classify for global supply
- Less manpower required to track national legislation
- Greater likelihood of providing correct information globally

## Users

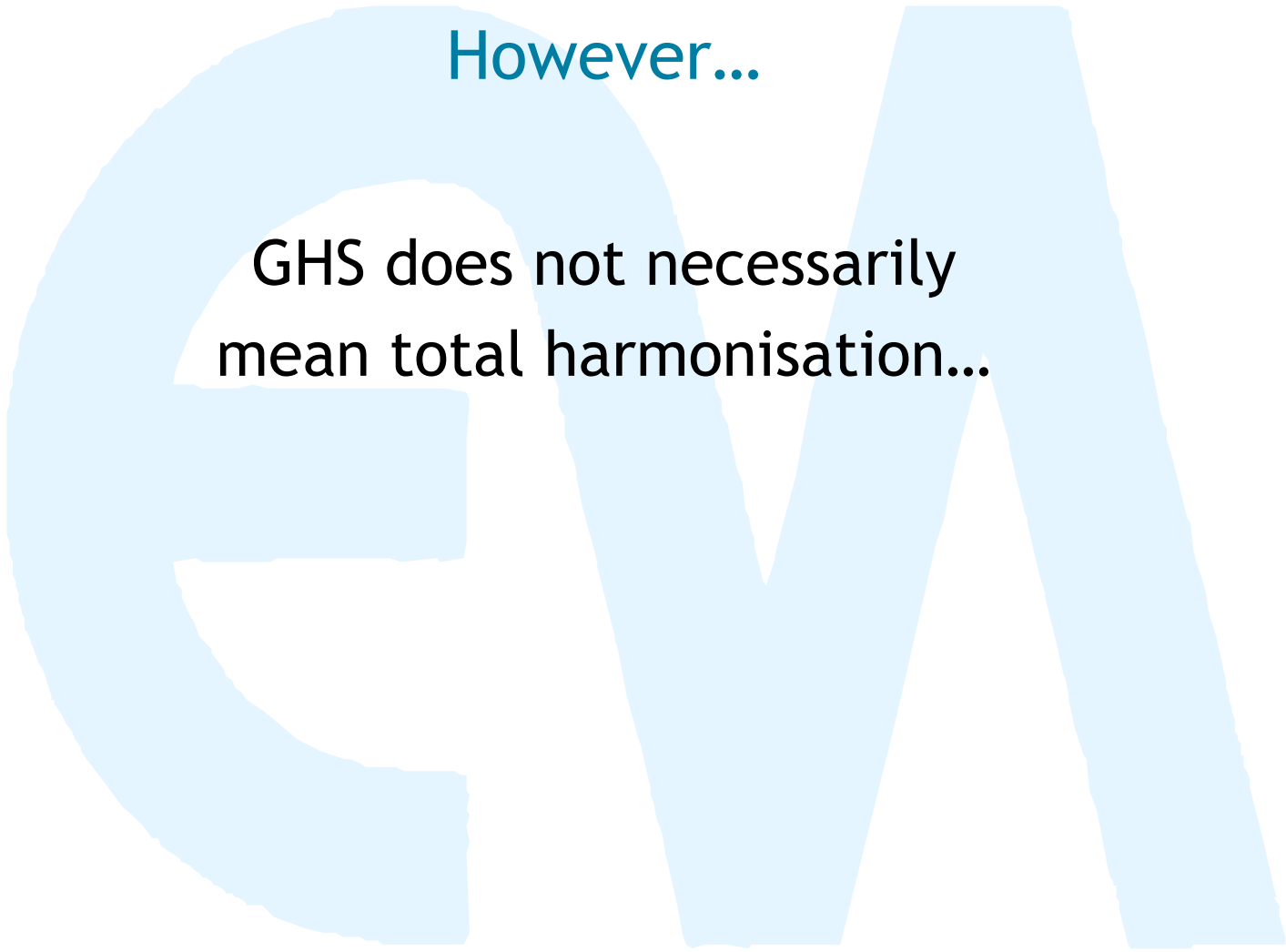
- Users should receive information on chemicals communicated on a consistent global basis which should lead to improvements and benefits in consumer and worker protection
- Less confusion when using global suppliers
- Improvement in worker risk assessment before use





However...

GHS does not necessarily  
mean total harmonisation...



# Building Block Approach

## Building Block Approach Example Application

### Hazard Classes

Aquatic Environment

Physico-Chemical Hazards

Acute Toxicity

Corrosion - Skin and Eyes

Irritation - Skin and Eyes

Sensitisation

CMRs

Target Organ Toxicity

### Supply

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

### Transport

Yes

Yes

Yes

Yes (skin)

No

No










No

No

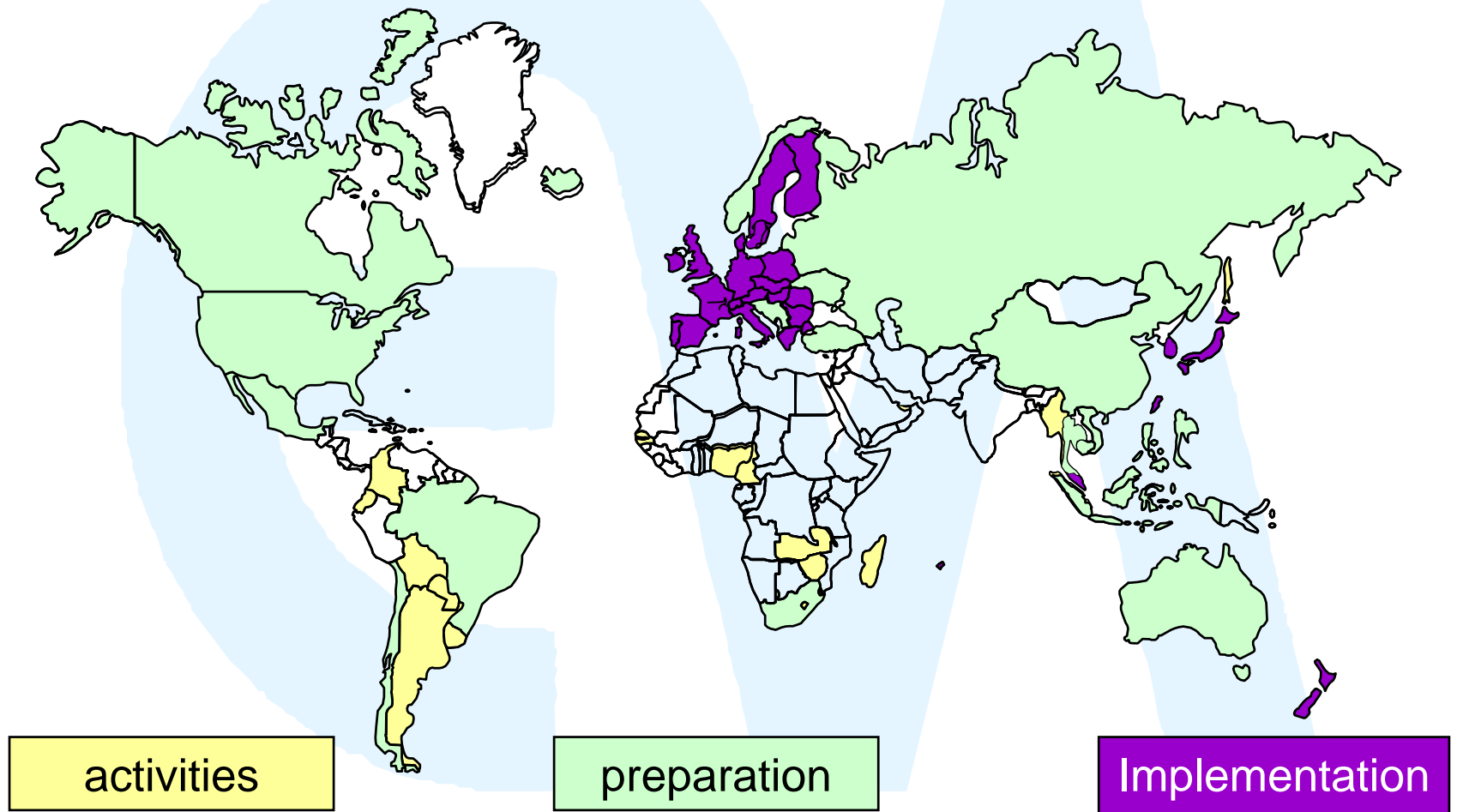
# Some key issues for minerals and metals

- GHS introduces **NEW toxicity END-POINTS**
  - STOT : Systemic Target Organ Toxicity
- GHS **changes some END-POINTS** drastically
  - Environmental classification
    - Different Classification between massive and powder forms
    - Different Categories
    - Safety net (classification category when data is lacking)
  - CMR: category **1-2-3** under EU becomes **1A-1B** and 2
  - (1A & 1B are subject to Authorization under REACH)
- Not all jurisdictions adopt GHS as published by the UN resulting in different classification on some endpoints

# Classifications may vary by country

Jurisdiction/Regulation	Future Proposed GHS Classification	Pictograms	Notes
UN GHS Self-Classification	Serious Eye Damage/Eye Irritation: Category 2B Hazardous to the Aquatic Environment (Acute & Chronic): Category 1	 	Classification based on thorough review of available data
EU GHS Self-Classification*	Serious Eye Damage/Eye Irritation: Category 2B Hazardous to the Aquatic Environment (Acute & Chronic): Category 1	 	Watch for endpoint categories that have not been adopted
New Zealand	Eye Irritation: 6.4A, Aquatic Effects: 9.1A	 	<b>Terrestrial data needs to be evaluated to make classifications</b>
Australia GHS	Serious Eye Damage/Eye Irritation: Category 2B		Environmental classification not mandatory
Japan GHS	STOT Single Exposure: Category 3 (Lung); STOT Repeated Exposure: Category 1 (Liver); Chronic Hazards to the Environment (Category 4)	 	Japanese NITE Classification; followed UN approach, but used unreliable data.

# GHS Implementation - A World Tour



**Global Implementation expected by 2010!**

# GHS Implementation Around the World



**Brazil** (South American and MERCOSUR countries discussion ongoing)

- Draft Voluntary Standard by end 2008 Ministry of Labour Ordinance number 26 (Hazard Communication of Chemicals)
- Purple book translation to be completed by end Q1 2009
- Implementation by 2010; Transition by 2013 possibly



**USA**

- OSHA final regulation expected to be at least another year
- CPSC to do side by side comparison to be completed in 2009



**Canada**

- No final date for implementation
- Technical discussions; phase in options and category discussions ongoing

# GHS Implementation Around the World

## EU



- 1272/2008/EC CLP Regulation adopted 31.12.08 - in force in 20.01.09
- Reclassification (and notification to the EU) 01.12.2010 for substances and
- Reclassification mixtures 01.6.2015

## Russia



- SDS and CLP standard published in Russian, Implementation for 2010

## South Africa



- Regulation Planned for 2008/9 - no update
- National Standard (GHS) (SANS 10234) was published in 2007- essentially implementing the UN GHS
- Supplement with list reclassified substances due end 2008 - not yet aware of the list being published

# GHS Implementation Around the World

The 21 APEC economies agreed on a target date 2008 for implementation -NOT ACHIEVED

## New Zealand



- GHS in place since 2001
- Self-classification system, but there is a Government classification list
- Labels from US, AU, EU accepted; GHS labels accepted, but not mandatory until 2010
- GHS MSDS required June 2008
- Implementation Dec 2008

## Australia



- Legislation varies by State
- No agreed Australia wide position
- Transition likely to be for substances until 2012 and mixtures until 2015





# GHS Implementation Around the World

## Japan



- **3 Main Laws Impacted - Status of GHS**
  - Industrial Safety and Health Law (MHLW) requires GHS label and MSDS effective Dec. 1, 2006
  - Poisonous and Deleterious Substance Control Law (MHLW) encouraging industry to adopt GHS labelling and MSDS
  - PRTR Law (METI, MOE) recommend GHS MSDS
- **GHS Classifications published**
  - Non binding until 2010  
<http://www.safe.nite.go.jp/ghs/list.html>
  - Japanese manual published in Japanese

# GHS Implementation Around the World

Taiwan



The Taiwan EPA amended Regulation of Toxic Substance Labelling and Material Safety Data Sheet implementation - December 31st 2008 (EPA Public Notice 0960101710, 2007/12/31)

Taiwan Dept of Labour Safety & Health of Council of Labour Affairs (CLP) implementation of 31 Dec 2008 applies only to chemical substances (and mixtures containing them) Article 2 Paragraph 1 ( listed in Attachment 1 of the Regulations)

HOWEVER 03.02.09, the CLA granted a transitional period up to Dec. 31, 2009 for implementation

<http://ghs.cla.gov.tw/en/ghstaiwan.php?item=ghstaiwan&mode=action>  
[plan](#)

# GHS Implementation Around the World

Korea



GHS MSDS/ Labelling Regulation in Korea by the Ministry of Labour (MoL Public Notice No 2008-29) June 2008 changed the to enforcement dates

- Jul 1, 2008 New substances
- Jun 30, 2010 Single substances
- Jun 30, 2013 Mixtures
- Non Binding classification list

The Korean Ministry of Labour has provided classifications and labels for approximately 2,500 single-entity hazardous substances to chemical industry in Korea but self-classifications by industry will be accepted.

# GHS Implementation Around the World

## Thailand

Publication of the first revised edition of the GHS in Thai in 2008 Hazardous Substances Act The effective date is three years after the date of publishing in the Royal

Proposed transitional periods: 1 year for substances and 3 years for mixtures and products (by 2011). Not all endpoints included at this time

## Philippines

The Adoption and Implementation of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) December 2007

2 year transition from adoption of legislation - not finally adopted



Manila • PHILIPPINES

Davao •



# GHS Implementation Around the World

## Singapore



Singapore Standard SS 586:2008 Hazard Communication for Hazardous Chemicals and Dangerous Goods (23.10.08)

Part 1: Transport and Storage of Dangerous Goods

Part 2: Globally Harmonised System of Classification and Labelling of Chemicals (GHS) - Singapore's adaptations

Part 3: Preparation of Safety Data Sheets (SDS )

## Transition Periods

Manufacturers & Suppliers: 2 years for single substances till end 2010; 4 years for mixtures till end 2012

End users: 3 years for single substances till end 2011; 5 years for mixtures till end 2013

<http://app.mti.gov.sg>

# GHS Implementation Around the World

## Malaysia

The classification and communication of chemical hazard labelling will be implemented in the industrial and agriculture sectors apart from consumer products by 2010, Occupational Safety And Health (Chemicals Classification, Labelling And Safety Data Sheet) Regulations 20xx [Class]

## Vietnam

Decree No. 108/2008/ND-CP detailing and guiding the implementation of a number of articles of the chemical control related to GHS implementation (Published in Official Gazette on 21st October 2008) came into effect since 1 January 2009

# GHS Implementation Around the World

## China



- Decree No.344
- -GB/T 16483-2008 (SDS for Chemical Products Content and Order of Sections) - Issue Date: Jun 18, 2008, Effective Date: Feb 1, 2009
- - Standards for chemical caution label and cautionary description compilation - drafting
- - Hazard chemical list - drafting
- 26 Technical standards for chemical classification and label - issued date:2006-10-24, effective date: 2008-01-01
- In addition: Measures for testing and supervision of import and export chemicals - drafting by AQSIQ
- Conclusion: China will certainly implement GHS step by step, but there is no concrete timetable and there are still many questions to be discussed

# GHS Implementation Around the World

Indonesia



**Draft Presidential GHS Regulation published  
December 2007**

New labelling and MSDS must be GHS compliant to be implemented by December 2008

Status not currently known



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

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

# Conclusions

## Reality:

- GHS implementation around the world may result in differing classifications for identical substances; this is contrary to the intent of the UN

## Challenges:

- Acquiring the data necessary to assign appropriate classification
- Determining the correct classification for various jurisdictions
- Using the correct system within a jurisdiction to make the classification
- Maintaining consistent classifications within business units and across industry



# THANK YOU

For further information, please, consult the website:

[http://ec.europa.eu/environment/chemicals/ghs/index\\_en.htm](http://ec.europa.eu/environment/chemicals/ghs/index_en.htm)  
[http://www.unece.org/trans/danger/publi/ghs/implementation\\_e.html](http://www.unece.org/trans/danger/publi/ghs/implementation_e.html)