

Rio Tinto

How does Industry Prepare for CLP and the Global Implementation of the GHS?

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Conference on EU and World-wide Rules for Classification, Labelling and Packaging of Chemicals - 17th June 2009

Rio Tinto

Representing Industry (CEFIC, Eurometaux, ICMM)

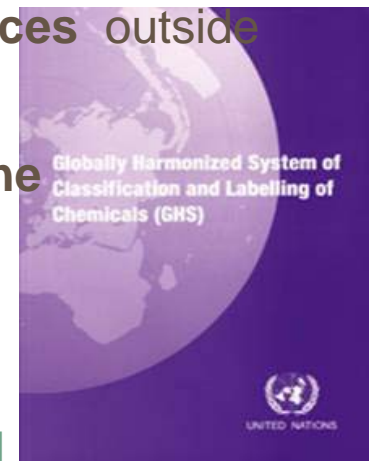


Introduction – What are the Issues?

- Not Straightforward
- Overload of Chemical Legislation e.g. REACH in the EU
 - implementing REACH and CLP/GHS at the same time - complex operation with significant implications
 - GHS Global Implementation in parallel
- Substances more severely classified and more classified mixtures
- Downstream consequences different in EU from rest of the world
- Safety Data Sheet formats changing; New Labels significant changes
- Estimated 30,000 substances subject to REACH + other **substances** outside of REACH to enter the Inventory
- Estimated approximately 2,000,000 mixtures **marketed in EU alone**


NEED GOOD PREPARATION!

http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html



Why GHS Necessary?

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

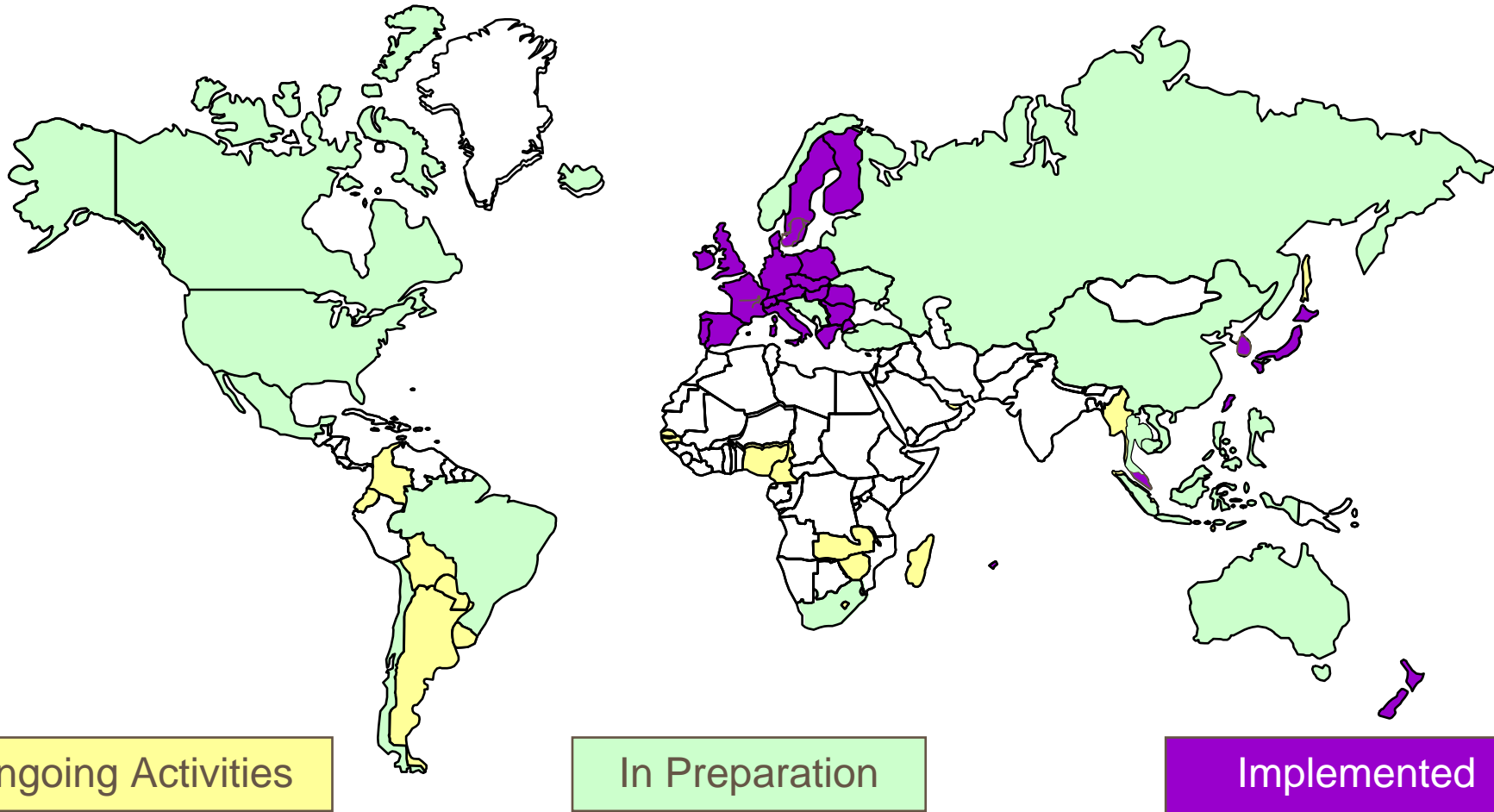
EU	Harmful (St Andrew's Cross)
US	Toxic
CAN	Toxic
Australia	Harmful
India	Non-toxic
Japan	Toxic
Malaysia	Harmful
Thailand	Harmful
New Zealand	Hazardous
China	Not Dangerous
Korea	Toxic
GHS....	Danger (Skull & Cross Bones) 

General Principles of UN GHS

- 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 protection in any country
 - Competent Authorities decide which elements to implement
- However...

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

GHS Global Implementation Expected by 2010!



Global Implementation Summary - 1

Australia	Varies by State: Expected Implementation - 2010 for Substances, 2015 for Mixtures
China	Expected Implementation – March/April 2010 26 Classification standards published. Step By Step Implementation. Will have a mandatory List
Hong Kong	Expected Implementation - 2009. Expected Compliance - 2010
India	Expected Implementation - 2009. Expected Compliance - 2010
Indonesia	Implemented: Feb. 2008 for pure substances only. Compliance Deadline: end 2009 for pure substances only. Draft of Indonesian Presidential Regulation on GHS still pending for approval. Implementation date unknown
Japan	Implemented: Industrial Safety and Health Law (MHLW) implemented Dec. 1, 2006 GHS Classifications published - Non binding until 2010 http://www.safe.nite.go.jp/ghs/list.html
Korea	Implemented: Compliance deadline: June 30/2010-single substances (postponed from June 2008); June 30, 2014-mixture. Non Binding classification list for 2,500 substances
Malaysia	Implementation: Exact date not know but possibly Dec. 2010
New Zealand	Implementation: 2006, SDS compliance deadline: Jun 30/2008, but labels (full GHS compliance) is not required until Dec. 31/2010
Philippines	Expected Implementation - 2009. Expected Compliance - 2010
Singapore	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

Global Implementation Summary - 2

Taiwan	Implementation - Jan. 2007; Compliance deadline: Dec 31/2009-substances on CLA Dangerous Goods/EPA TCCL lists only.
Thailand	Implementation: Dec. 2008. Compliance Deadline: end 2009 for pure substances only. Expected compliance for mixtures - Dec. 2011 Not all endpoints included at this time
Vietnam	Implemented: January 2009 – transition to 1 July 2009 postponed – but final date unknown
EU	Implementation: 2009. Substance compliance - Dec 1, 2010, Mixture compliance - Jun 1, 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
Brazil	South American and MERCOSUR countries discussion ongoing Implementation expected by 2010; Transition by 2013 possibly
Mexico	Possible GHS implementation in Mexico Jan 1, 2010, but nothing confirmed yet
Canada	Expected implementation: 2009-date looks doubtful.
USA	DOT/IMDG/ICAO adopted GHS class 3 & 6 criteria for transport in 2007 and GHS class 9 criteria for aquatic toxicity in 2009. OSHA likely to be another year CPSC is just beginning to investigate GHS implications for consumer products. US implementation likely to be staggered across all 4 agencies ranging between 2007-2012

Global Implementation - Challenges for Companies

- How to keep up to date
 - UN website not current
 - Need Global Regulatory Information
 - SMEs disadvantaged
 - Industry is working together, but information is limited
- Biennium update of UN GHS – when can the new guidance be used
 - 3rd Edition – July 2009
 - Japan – Implemented 1st Ed; translated 2nd Ed, Industry can use 3rd Ed
 - Korea – Chemical Law to be amended before use 3rd Ed
 - South America – translated 1st Ed; GHS to be implemented with 1st Ed
 - EU updated by ATP to CLP Regulation; but when can new guidance actually be used for self-classification

Global Implementation - Challenges for Companies

- Building Block Approach
 - Varies by Country
 - Leads to different labels
 - Global IT (M)SDS systems need to be amended to handle this – do not underestimate the problems that this will cause

Building Block Approach leads to Global Disharmony

Health and Environment

Japan/Taiwan/ South Africa	Human Health and Environmental follow criteria and endpoints outlined by UN.
China	Human Health: Aspiration hazard not adopted
Korea/ Singapore	Human Health: Acute Oral Cat 5 not adopted. Eye irritation – Cat. 2A only (MOL*); Cat 2 (2A&2B) (MOE*) so varies by Ministry Environment: Acute Cat. 2 – No (MOL); Yes (MOE);
EU	Human Health: Cat. 5 Acute Toxicity, Cat 3 Skin irritation, Cat 2b Eye Irritation, & Cat 2 Aspiration hazard are not adopted Environmental: Aquatic Acute 2 & 3 not adopted Hazardous for Ozone layer (R59) maintained

* MOL: Ministry of Labour; MOE: Ministry of Environment

Building Block Approach leads to Global Disharmony








Health and Environment

<p>New Zealand</p>	<p>Human Health: CMR Categories 1A & 1B and 2 are now Cat 1 and Cat 2 Environmental: 3 additional terrestrial endpoints (Categories have unique numbering scheme and a searchable database available for classifications) Note NZ only accepts GLP data!</p>
<p>Australia</p>	<p>Human Health: Cat. 5 Acute Toxicity not likely to be adopted Environmental: Not in scope</p>
<p>United States</p>	<p>Human Health: Will vary with Agency: CPSC will allow risk-based labeling Environmental: Unlikely to be required by OSHA but allowed, may be adopted by EPA</p>
<p>Canada</p>	<p>Human Health: Cat 4 and 5 Acute Toxicity, Aspiration Hazard and STOT under discussion Environmental: Under discussion</p>

GHS Implementation – Challenges for Companies

- GHS designed to permit self classification (UN GHS1.1.4.)
- Differences in knowledge and expertise in applying GHS criteria
 - Different regional interpretation of the guidelines
 - Different rules on data acceptance
- Difference between REACH and GHS data requirements for phys-chem hazards. The REACH methods (references test methods from Directive EC 440/2008) sometimes differ greatly from the test methods as required by GHS (which references the UN Manual of Tests and Criteria)

Classifications may vary by country (Example of a Metal Powder)

Jurisdiction	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	 Eye: Warning phrase only	Classification based on thorough review of available data
EU GHS Self-Classification*	Serious Eye Damage/Eye Irritation: Category 2 Hazardous to the Aquatic Environment (Acute & Chronic): Category 1	 	Not all endpoint categories have been adopted
New Zealand	Eye Irritation: 6.4A, Aquatic Effects: 9.1A	 	Terrestrial data needs to be evaluated to make classifications
Australia GHS	Serious Eye Damage/Eye Irritation: Category 2B	Eye: Warning phrase only	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 – Challenges for Companies

- Country Classification Lists
 - Not Mandatory (Japan (2010?), Korea, Taiwan etc)
 - Mandatory - China
 - Data sources can be limited (RTECS; MERC; SAX; online databases) or direct implementation of IARC classifications
 - Mandatory - EU CLP Annex VI – Industry may have newer data and therefore classify differently outside of EU –
 - Updating Annex VI has to go via Member States making a REACH Annex XV dossier – slow process!
 - EU CLP Inventory - Industry (agreed) Self-Classifications
- Use of GHS to harmonise various regulatory lists
 - OECD to review in PIC substances

GHS Implementation – Challenges for Companies

- EU Inventory issues – how to prepare
 - No detailed process
 - Needs to be simple (note recital 55 CLP requires the Agency to study the possibilities for further simplification of the notification procedure in particular taking into account the needs of SMEs), but need to allow several options
 - Maybe up to 5 million notifications
 - Propose to agree a limited exemption up to a 300 kg threshold for R&D substances
 - Propose to agree on a Small Volume Limit of 20 kg
 - No further burden on fees

What Should Industry Do?

- Get information sources and understand CLP/Global GHS and its implications for your business
 - Train staff
 - Note that change of classification in the EU can lead to a change of duties under REACH and impact other duties **under Downstream Legislation** under review : keep track...
- Develop inventory of substances (and/or as mixtures) regardless of volumes, and territory that require assessment for classification.
- Gather hazard data and assess substances
 - In EU those to be registered before 1 Dec 2010 and those subject to notification by 1 Dec 2010
 - Most regions working to 2010 deadline
 - In the EU plan for working towards an agreement of classification both under REACH and outside of scope of REACH

Conclusions

- **Reality**
 - GHS implementation around the world including the EU may result in differing classifications for identical substances - this is contrary to the intent of the UN
- **Challenges**
 - **Acquiring the good quality data** necessary to assign appropriate classification
 - Using the **correct system within a jurisdiction** to make the classification
 - Maintaining **consistent classifications** within business units and across industry
 - Agreeing industry classifications' for notification in the EU

THANK YOU & A FINAL NOTE

Are You Prepared? – the clock is ticking!



11 June 2009

