

# Global Regulatory Update

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AHMP - San Diego  
Sept. 2nd 2009

# Global Regulatory Update



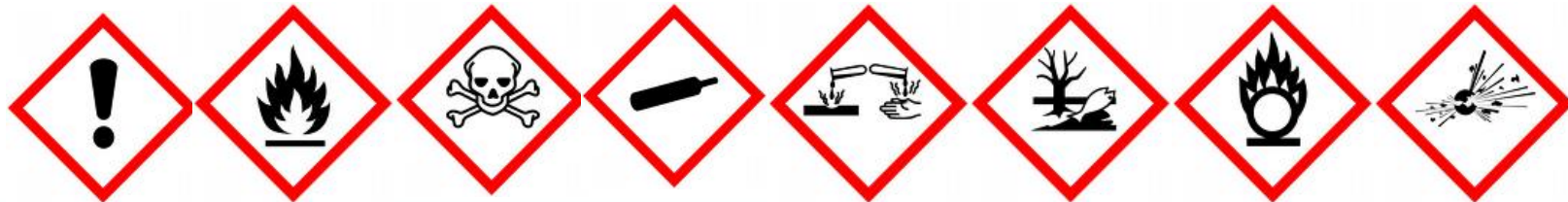
- Focus: Globally Harmonized System (GHS) for Classification and Labeling of Chemicals (GHS)
  - North America
  - Europe
  - Asia Pacific
  - Latin America and Africa



- .... the prevailing influence force on the regulatory framework for managing chemicals

# WHY GHS?

- To reconcile differences in hazardous substance regulations:
  - on the substances covered
  - on hazard definition
  - MSDS and label requirements
- To provide consistent way of classifying and labeling of chemicals:
  - Some times important information on the label might be lost due to inconsistency in presentation
- To simplify and decrease the burden of compliance:
  - Development of multiple MSDS and labels can be a major burden for companies



# Impact on Businesses

- Analyze existing formulations
- Source the capability to:
  - Re-classify substances and mixtures
    - Take into consideration country specific classifications and variations in GHS adoption
  - Develop new MSDS and labeling documentation
  - Evaluate compliance with new notification requirements



# GHS – United States

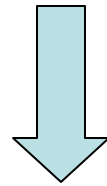


Four independent regulatory authorities formed the Interagency Working Group on Harmonization:

- Occupational Safety and Health Administration (OSHA)
- Department of Transportation (DOT)
- Environmental Protection Agency – Federal Insecticide Fungicide and Rodenticide Act (EPA FIFRA)
- Consumer Products Safety Commission (CPSC)

## What does GHS mean for OSHA?

- Modifying the Current Hazard Communication Standard (HCS)



### Resulting in:

- Consistent chemical hazard communication
  - Changed look of MSDS and labels
    - Example is the use of mandatory pictograms
  - Changed classifications

# United States – OSHA



- Proposed notice of rule making expected in October 2009
  - Final rule not expected for at least 180 days after that
  - Final rule lays down exact provisions OSHA will adopt

# United States – DOT



- DOT classifications
  - PHMSA adopted of several elements of GHS in rulemaking HM-115F
    - Directly affect the transport sector
    - Changes to the classification criteria for toxic materials and flammable liquids
  - Environmentally hazardous substances
    - Separate rule making



# Europe

- ✓  EU and EEC (Norway, Lichtenstein and Iceland)
- ✓  Russia



# EU - Regulation 1272/2008 (CLP)



- Formal adoption by European Parliament and EU Council - Dec. 2008
  - CLP entered into force on January 20, 2009
  - Scope – substances and mixtures including plant protection products and biocides
    - Adopts the UN Purple Book building blocks for classification and labeling of chemicals
  - Replaces Directive 67/548/EEC (DSD) & Directive 1999/45/EC (DPD)
- Aims to maintain same level of protection as pre-existing system for classification and labeling:
  - Expected is that similar number of substances will be classified, though some of the classifications may differ
  - Provides a list of harmonized GHS classifications replacing the current Annex I to 67/548
    - Expecting ATP 1 to CLP (ATP 30 and 31 to Annex I under DSD)
  - Takes over Title IX (Classification and Labelling Inventory) from the REACH Regulation

# Adoption of GHS Principles



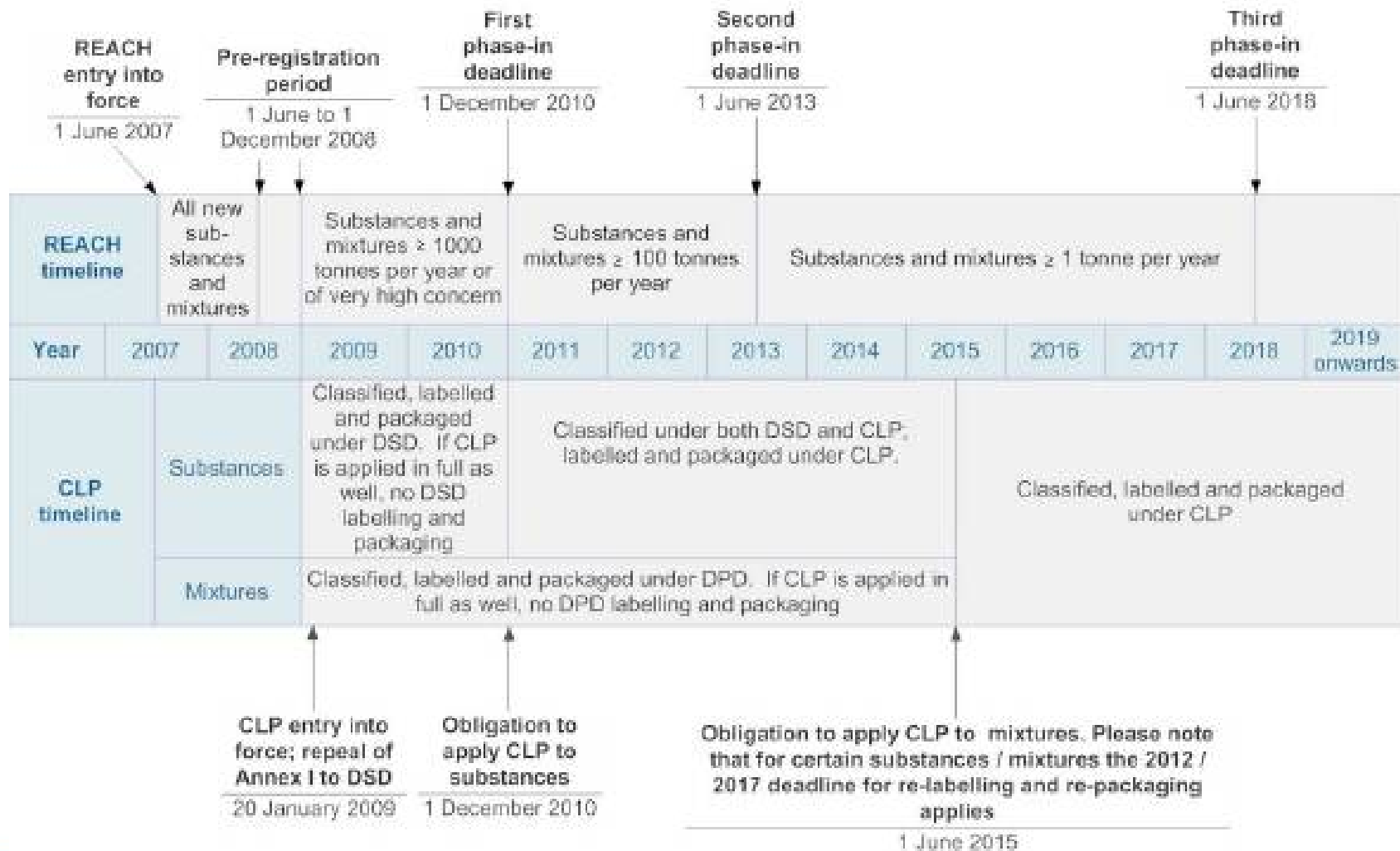
- Takes up all GHS Hazard Classes
- Does not include categories not part of old EU system
  - Flammable Liquids Category 4
  - Acute Toxicity Category 5
  - Skin Corrosion/Irritation Category 5
  - Aspiration Hazard Category 2
  - Acute Aquatic Toxicity Category 2&3
- Maintains current level of protection by including EU specific elements:
  - Additional labeling requirements – Annex II, i.e. EUH014, EUH066

# Transition Period



- Substances must be classified, labeled and packaged according to CLP from December 1, 2010.
- Mixtures: June 1, 2015.
- CLP can be used on labels and SDS now, provided that substances are also classified according to DSD until June 1, 2015

# Transition Period



Source: ECHA

# Transition Period (cont'd)



- Substances classified, labeled and packaged according to Directive 67/548/EEC & placed on the market before Dec. 1, 2010
  - Not required to be re-labeled and re-packaged according to this Regulation until Dec. 1, 2012
- Mixtures classified, labeled and packaged according to Directive 1999/45/EC & placed on the market before June 1, 2015
  - Not required to be re-labeled and re-packaged according to this Regulation until June 1, 2017

# What does this mean for you?



- **If you are a supplier:**

- Establish what your duties are
- Understand the transitional periods
- Check if you need to reclassify
- Evaluate your labels and SDSs
- Cooperate with others in the supply chain



- **If you use or employ users of chemicals:**

- Alert your employees to the changes and provide them adequate understanding and training
- Speak to your suppliers

# GHS Adoption in Europe



-  **Russia**

- The following seven GHS national standards have already been approved:
  - GOST 30333-2007 on Safety Data Sheets (in force since January 1, 2009);
  - GOST 31340-2007 on “Labelling of chemicals. General requirements” (in force since 1 January 2009);
  - Five standards on Classification (expected date of entry into force: July 1, 2010):
    - Classification of chemicals. General requirements.
    - Classification of chemicals for physical hazards. Testing substances.
    - Classification of chemicals for health hazards.
    - Classification of mixtures for environmental hazards.
    - Classification of chemicals for environmental hazards. Testing substances.

# GHS Adoption in Asia Pacific



## Asia Pacific

- GHS legislature has been passed in:
  - **New Zealand** (2001)
  - Mauritius (2004)
  - **Japan** (2006)
  - **Korea** (2008)
  - **Taiwan** (2008)
  - Singapore (2008)
  - Vietnam (2008)
  - **China** (2009)
- Draft regulations on GHS published:
  - **Australia**
  - **Malaysia**
  - **Indonesia**
  - Thailand



# New Zealand



- GHS classification criteria implemented by the Hazardous Substances & New Organisms Act in July 2001
- HSNO Approved Code of Practice for Preparation of Safety Data Sheets (HSNO CoP 8-1 09-06)
- HSNO Approved Code of Practice for Labeling of Hazardous Substances (HSNO CoP 10-1 08-07)
- NZ classifications have some additions to and deviations from UN GHS
- Correlation table between UN GHS to New Zealand GHS
- GHS labels
  - From July 2008 for chemicals that fall under a Group Standard
  - But labels in accordance with overseas jurisdictions (Europe, Australia, USA or Canada) are accepted until end of 2010

# Japan



- GHS label (article 57-1) and GHS MSDS (article 57-2) required by the Industrial Safety and Health law as of December 1, 2006
- Japan Industrial Standard (JIS) Z 7251:2006 - Labeling of Chemicals based on GHS
- Japan Industrial Standard (JIS) Z 7250:2005 – Material Safety Data Sheets for Chemical Products
  - All UN hazard categories are applied in Japan under ISHL
  - Under revision
- Applies to listed substances
  - 640 listed for MSDS (specific cut off values)
  - 99 listed for labels (specific cut off values)
- Advisory list with GHS classifications published by NITE (National Institute of Technology and Evaluation)
- GHS requirements not yet implemented by Regulations other than ISHL but GHS classification is recommended in general

# Korea



## Ministry of Labor:

- Industrial Safety and Health Law
- Pure substances: July 1, 2010; Mixtures: July 1, 2013
- KOSHA has published advisory list with GHS classifications

## Ministry of Environment:

- Ministerial Decree of Toxic Chemical Control Law
- The revision of the toxic chemicals classification list has not yet been published.
- Effective July 2008 with transitional period: Single toxic chemical (June 30, 2011); Mixtures of toxic chemicals (June 30, 2013)

The two ministries are working to better coordinate their implementations

- Different hazard categories adopted by each Ministry
- Different timelines for implementation

# Taiwan



- Two regulations:
  - Regulation of Labeling and Hazard Communication of Dangerous and Harmful Substances (effective on December 31, 2008) (“CLA Regulation”)
    - CLA Regulation does not have Environmental Hazard Categories
  - Management Measures on Toxic Substances Labeling and Material Safety Data Sheet (EPA No. 0960095329) (Effective Date: December 31, 2008) (“EPA Regulation”)
    - EPA Regulation has Environmental Hazard Categories
- Taiwan National Standard, CNS 15030: Classification and Labeling of Chemicals (based on GHS (Rev.1)(2005)).
- MSDSs and labels are required for (1<sup>st</sup> implementation phase)
  - the 1,062 substances specified by the CLA (Council of Labour Affairs) and for products containing these
  - the 258 toxic chemicals listed by EPA
  - Voluntary compliance is welcomed



- Standards on Safety Data Sheets and Labels came into effect on Feb 1, 2009
  - Both standards allow for no transitional period
- Standards issued June 21, 2009:
  - General Rule for Classification and Hazard Communication of Chemicals - GB13690-2009
    - Effective: May 1, 2010
  - General Rule for Preparation of Precautionary Label for Chemicals – GB15258
    - Effective: May 1, 2010

# Australia



- In July 2009, Safe Work Australia Council published two drafts:
  - National Code of Practice for the Labeling of Workplace Hazardous Chemicals [SWA:xxxx(20xx)]
  - National Code of Practice for the Preparation of Safety Data Sheets [SWA:20xx (2009)].
  - Both Codes are now available for public comments until September 18, 2009 before they are finalized.
  - These Codes are closely aligned with the GHS requirements for labeling of chemicals and Safety Data Sheet (SDS) (based on the GHS 3rd Revised Edition).
- Sustainable transition expected, with GHS coming into force in 2012

# Indonesia



- Draft Presidential Regulation on the Implementation of GHS and Labeling for Chemical Substances (3rd revision) – published/not yet finalized
- Regulation of the Minister of Trade of the Republic of Indonesia Number 04/MDAG/PER/2/2006 regarding the Distribution and Supervision of Dangerous Substances
  - Dangerous Substances must be labeled in accordance to Appendix III of the regulation (consistent with UN Purple Book)
- Regulation of the Minister of Industry of the Republic Indonesia regarding Control on Production and Usage of Dangerous Substances
  - Lists 6 substances which require labeling consistent with GHS

# Malaysia



- Department of Health and Safety (DOHS)
  - Draft regulation for the implementation of GHS to workplace chemicals
  - Date for entry into force still to be confirmed
  - Expected 2010 for substance and 2013 for mixtures
- Ministry of Environment (MOE)
  - EHS Notification and Registration Scheme (Voluntary in 2009)
    - Regulation not in place yet
      - 2010 – Program becomes mandatory
      - Intended to use GHS classifications
      - Reporting criteria defined by volume bands (except for CMRs and Aquatic toxicity cat. 1)
      - Environmental Quality Act (to be amended this year)

# GHS in Other Regions



- **Africa**

- South Africa - completed new regulation on Classification and Labeling of Chemical Substances
  - Regulation has been recommended for promulgation

- **Latin America**

- Argentina - identified as high priority and published SDS standard in line with GHS
- Brazil – released draft standards based on the GHS
  - Expected to come into force in 2009

# Conclusion



- GHS is a Global Standard
  - EU and most AP countries have either implemented or are in various stages of implementation of GHS into their respective regulatory frameworks
- Companies gain benefits from standardization, yet still need to consider how to account for national variations in implementation



Thank you for your attention!

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