Developing a better understanding of the EU’s implementation of GHS and how it links into REACH

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• GHS was adopted in the EU on December 16th, 2008 and came into force January 5th, 2009
• Implemented (transposed) via a Regulation
  – In force in each Member State immediately and only for the enforcement part, national laws will be required – like for REACH.
• Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
  – Applies to
  • Companies placing chemicals on the market and
  • Other companies with registration requirements under REACH

EU CLP

1272/2008
• Replaces the Substance Directive (67/548/EEC) and the Preparations Directive (1999/45/EC)
  – Both directives will be fully replaced by June 1, 2015
• Will also take over Title XI from the REACH Regulation (the Classification and Labeling Inventory)
• Maintains the same level of protection as the current system
  – By leaving out some GHS elements and by keeping some of the existing (old) classification and labelling elements
• Number of classified substances expected to stay the same - Classification, however, may differ
• More mixtures may also be classified due to changes in concentration limits and calculation methods

EU CLP

• Harmonise the criteria for classification as well as for packaging and labeling of chemical products (including plant protection products and biocides);
• Require manufacturers, importers and downstream users to classify chemicals;
• Require suppliers of chemicals to label and package the products before placing them on the EU market;
• Require manufacturers and importers to notify the Chemical Agency of the classification and labeling of substances;
• Establish (keep) a list of substances with harmonized classification and labeling;
• Establish the Classification and Labeling Inventory

Classification

• Title II – Hazard Classification
  – Applies to substances Dec 1, 2010 and to mixtures Jun 1, 2015
• The EU CLP Regulation does not implement the UN GHS system in its entirety.
  – The GHS building block approach allows that only the appropriate hazard classes and categories are chosen.
• The following GHS categories are not included in the EU CLP Regulation:
  – Flammable liquids cat. 4
  – Skin corrosion/irritation cat. 3
  – Acute toxicity cat 5
  – Aspiration hazards cat 2
  – Acute aquatic toxicity cat. 2 and cat. 3
• These hazard categories are not covered under the current EU system and are not needed for consistency with the transport legislation.
• The additional EU hazard class “Hazardous to the ozone layer” is kept.
**Classification (cont’d)**

- Harmonised classification is kept:
  - The old "Annex 1" has been converted into Annex VI Table 3.1
  - More substances with harmonised C&L will be added
    - respiratory sensitization category 1, category 1A, 1B and 2
carcinogens, germ cell mutagens, and reprotoxic substances, substances in plant protection products and in biocides, others
- Substances on Annex VI Table 3.1 must be assessed for other hazard classes and differentiations (Art 4 item 3)
- Some substances on Table 3.1 has an "***" indicating minimum classification for a category

- Other substances must be classified according to Title II (Hazard Classification)
- Use conversion table for substances and mixtures to help ease transition
  - Annex VII to the EU CLP Regulation
  - Only for substances and mixtures that have been classified under the old system

**C&L Inventory**

- Title V, chapter 2 C&L inventory
  - Applies to substances subject to registration under REACH and to substances placed on the market (as pure substances or in a mixture)
- Notification to ECHA
  - From December 1, 2010 and then latest 1 month after placing on the market
  - Each notifier shall only notify a certain substance once
  - Substances that have been registered under REACH by that notifier need not be notified
- Substance information (C&L, etc) will be published in a database by ECHA
  - Certain information will be public available (coordinated with Art 119(1) of REACH)

**EU CLP & REACH**

- The EU CLP Regulation does not change the scope of REACH.
- Article 14.4 of REACH (exposure assessment and risk characterisation) is changed and the following hazards are exempt:
  - Gases under pressure
  - Self reactive substances and mixtures type C, D, E, F and G
  - Self heating substances and mixtures
  - Oxidising liquids category 3
  - Oxidising solids category 3
  - Organic peroxides type G
  - Corrosive to metals
  - Adverse effects on or via lactation
  - Specific target organ toxicity – single exposure, narcotic effects (part of category 3, H336)

**Hazard Communication - Labels**

- Label requirements follow the UN purple book
- CPL labeling includes:
  - chemical names (max 4)
  - the hazard pictograms
  - signal word
  - hazard statements
  - precautionary statements (max 6)
  - Supplemental Information (Art 25 and 32)
    - Annex II, 1.1 and 1.2 phrases, e.g EUH14 "Reacts violently with water" or EUH201A "Contains lead"
    - Biocides (91/414/EEC – special phrase
    - If substance on Annex VI with supplemental hazard statements (e.g. acetone with EUH066 "Repeated exposure may cause skin dryness or cracking")
    - If classified for ozone depletion: signal word, H- and P statements
    - Label information required by other regulations

**Labels (cont’d)**

- Pure substances must be labelled according to 1272/2008 latest by Dec 1, 2010
- Mixtures must be labelled according to 1272/2008 latest by Jun 1, 2015
- Existing products have 2 more years to get re-labelled
- Packaging requirements – tactile warning and child resistant fastenings - are kept

**Hazard Communication - SDSs**

- Safety Data Sheets are still regulated by REACH
  - Art 31 is updated to include all chemicals classified under 1272/2008
- SDS for pure substances
  - Shall include the classification according to 1272/2008 from Dec 1, 2010
  - Until Jun 1, 2015 Sec 2 and Sec 3 shall show both old and new classification
- SDS for mixtures
  - Shall show the classification according to 1272/2008 from Jun 1, 2015 (Sec 2 and 3)
  - If classified under 1272/2008 before Jun 2015:
    - Sec 2 must show product classification from both systems (1272/2008 and 1999/45/EC)
    - Sec 3 must show substance classification from both systems (1272/2008 and 67/548/EEC)
- CLP classification (sec 2 and 3) includes:
  - Hazard statements, Hazard classes and categories
- Section 15 must show the "old" label (67/548/EEC and 1999/45/EC) as long as used and the CLP (GHS) label when used
Over 20 pieces of downstream legislation refer to classification either directly or indirectly.

Obligations in EU Community legislation referring to C&L include:
- Occupational Health and Safety
  - Chemical Agents Directive 98/24/EC
  - Carcinogens and Mutagens Directive 2004/37/EC
  - Safety Signs Directive 92/58/EEC
  - Pregnant Workers Directive 92/85/EEC
  - Young People at Work Directive 94/33/EEC
- Seveso II
- ELV, WEEE
- Consumer products,
  - Eco labels
  - Cosmetics
  - Toys
  - Etc.

New Zealand, Mauritius, Japan, Taiwan, Korea, China, Singapore have issued GHS legislation:
- New Zealand and Japanese GHS legislation have been in force for years
- Hazard classification data on chemicals, mixtures, kept on a database at ERMA New Zealand
- Japan has advisory list (NITE)
- In Taiwan, as of January 1st, chemical products have to be classified and labeled and MSDSs prepared according to the national implementation of GHS
- China is requiring GHS classification and labeling in the spring of 2009
  - Full UN GHS implementation
- Korea
  - MOL: Substances July 1, 2010; Mixtures July 1, 2013
  - MOE: Substances July 1, 2011; Mixtures July 1, 2013
  - Not all building blocks are implemented
- Singapore
  - Staggered implementation from end 2010 till end 2013
  - Not all building blocks are implemented
- Australia, Malaysia, Thailand, and Indonesia have issued draft legislation

GHS provides for a globally harmonised classification and hazard communication for chemical substances and mixtures. Companies with global supply and trade of their chemicals will benefit from the national implementations of the GHS system as the basic principles for classification of the chemicals will be harmonised.
- Some of the countries do a partial implementation of GHS
- Some have national lists of GHS classifications, some are mandatory to follow
- Some have kept part of their previous classification and labeling requirements
- Companies have to decide how to meet these different requirements where the GHS classification and the labeling of a chemical substance or mixture may vary from country to country

Thank you for your attention!
Any questions?