

Classifications, Labeling & Packaging (CLP) Regulatory Compliance

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About the Speaker



- **Isaac Powell:**
- *3E Company – Carlsbad, CA*
- 14 years EH&S experience with implementing compliance management programs including regulatory reporting, emergency response, hazardous waste and dangerous goods management
- Currently Product Manager for 3E Technical Services including Emergency Response, Hazardous Waste Management, Transportation, Classification & Regulatory Reporting Services
- Member of the AHMP, AWMA, National Fire Protection Association & International Code Council
- BA in Economics from at the Univ. of Michigan, Ann Arbor

Presentation Overview



- Background to CLP regulations
 - UN GHS
- Implementation of CLP in Europe
 - What is required to do
 - Transition periods for phasing out existing Dangerous Substance/Preparations Directives
- C&L notification requirements
 - What?
 - When?
 - How?
- Impact on MSDS

Background to CLP



- European implementation of UN Globally Harmonized System of classification (GHS)
- Adopted in EU December 2008, came into force from January 2009
- Regulation EC1272(2008) on Classification, labelling and packaging of substances and mixtures (CLP)
 - Repeals directives 67/548/EEC (dangerous substances directive) and 1999/45/EC (dangerous preparations directive)
 - Some amendments to Regulation EC1907/2006 (REACH)

Basic CLP requirements



- Companies
 - Manufacturers, importers and downstream users to classify chemicals
 - Suppliers of chemicals to label and package products before placing them on the EU market
 - Manufacturers and importers to notify the European Chemicals Agency (ECHA) on the classification and labelling of each substance
- Regulator
 - Establish and maintain a list of substances with mandatory (harmonized) classification and labeling
 - Establish a classification and labeling inventory

Why Introduce GHS?



- Substance LD50
257mg/kg

Pre GHS	GHS
EU: Harmful	Acute toxicity
US: Toxic	Toxic
Canada: Toxic	Hazard class 3
Australia: Harmful	
New Zealand: Hazardous	
Japan: Toxic	
China: Not dangerous	

GHS Benefits



- Consistent underlying infrastructure which can be used to build national chemical safety programs
- One system worldwide, therefore consistent and clear information for all who need to use it
- Streamline the format of SDS and labels

Global GHS Development



- **Asia Pacific:**
 - New Zealand (2001) *
 - Korea (2008) * substances
 - Singapore (2008) * substances
 - China (2009) *
 - Japan (2006) *
 - Taiwan (2008) *
 - Vietnam (2008) *
 - Indonesia (2009) *
- **Europe**
 - EU (2008) * substances
 - Serbia (2009) * substances (2011)
 - Russia (2009/SDSs and 2011)*
 - Switzerland (2009)
- **Middle East & Africa**
 - Abu Dhabi (2009)
- **Americas**
 - Brazil (2009) * SDS format & substance classification (2011)
 - Uruguay (2009) *
 - Mexico (July 2011)
- **Transportation** - SOLAS (International Convention for the Safety of Life at Sea) *

* Indicates that GHS SDS and classifications are already required

GHS Regulations Drafted



- Draft regulations on GHS published:
 - United States (Final ruling expected September 2011)
 - Australia
 - Malaysia
 - Philippines
 - India (only transportation)
- Preparation activities
 - Canada – GHS compliant SDS accepted with reference to WHMIS
 - MERCOSUR countries (Argentina, Brazil, Paraguay, Uruguay)– SDS standards
 - ANDEAN Community (Bolivia, Colombia, Ecuador and Peru, Ecuador) – National Plan, capacity building
 - Croatia
 - Turkey
 - Thailand
 - UNITAR/ILO Global GHS Capacity Building Program: Cambodia, Gambia, Laos, Nigeria, Senegal, Zambia

Comparison of CLP Classification to GHS



- CLP adopts GHS format for data interpretation and labeling
- GHS building block approach allows for selection of appropriate hazard classes and categories only
- CLP has not included the GHS categories
 - Flammable liquids category 4
 - Skin corrosion irritation category 3
 - Acute toxicity category 5
 - Aspiration hazards category 2
 - Acute aquatic toxicity category 2 and 3
- CLP does include additional hazard class of “Hazard to the Ozone Layer” from previous rule
- Retains consistency with existing EU classification systems

Comparison of CLP Classification to GHS



- GHS also allows for national cut off levels for mixtures to be selected from 2 options for the following classifications
 - Respiratory or skin sensitiser
 - CLP selects 1% cut off – solid liquid, 0.2% gas - for classification
 - Carcinogenicity
 - Category 1, CLP selects 0.1% cut off
 - Category 2, CLP selects 1.0% cut off
 - Reproductive toxicity
 - Category 1, CLP selects 0.3% cut off
 - Category 2, CLP selects 3.0% cut off
 - Affects on or via lactation, CLP selects 0.3% cut off

Comparison of CLP Classification to GHS



- Specific target organ toxicity (Single exposure)
 - CLP selects 10% cut off option

- Specific target organ toxicity (Repeated exposure)
 - CLP selects 10% cut off option

Comparison of GHS label to CLP



- Label requirements follow those of UN GHS
- Supplemental Information
 - Annex II, 1.1 and 1.2 phrases eg. EUH014 “Reacts violently with water”, EUH201A “Warning! Contains lead”
 - Supplemental hazard statements assigned in AnnexVI
 - If classified for ozone depletion – Signal word, H and P statements
 - Biocidal products(91/414/EEC) – additional phrase required
 - Label info required by other regulations
 - Other relevant information from the supplier

CLP Implementation - Timings



- Regulation came into force January 2009, including transition periods for implementation
- Separate timelines for substances and mixtures
- **Substances**
 - **Classification:** Must be classified according to CLP by December 1st 2010
 - **Labelling:** Labels to reflect CLP classification by December 1st 2010
 - Existing product eg. already in a distribution warehouse, have an additional 2 years before CLP labels must be used
 - **Safety Data Sheet:** Must use CLP classification from December 1st 2010
 - Until June 1st 2015 sections 2 and 3 to show both old and new classifications

CLP Implementation - Timings



- **Mixtures**

- **Classification:** Must be classified according to CLP by June 1st 2015
- **Labelling:** Labels to reflect CLP classification by June 1st 2015
 - Again existing products have additional 2 years before CLP labels must be present
- **SDS:** Must show CLP information from June 1st 2015
 - If product classified and labelled according to CLP before June 1st 2015
 - Sections 2 and 3 must show classification from both systems (CLP and DPD)
 - CLP classification can be shown on the SDS before 2015 even if label reflects old (DPD) classification

Notification of CLP Classification



- Where does the requirement come from?
 - CLP Title V “Harmonisation of classification and labelling of substances and the classification and labelling inventory”
 - Chapter 2, Articles 39 – 42
- Which substances have to be notified?
 1. Substances subject to registration under REACH (both hazardous and non-hazardous)
 2. All substances that are considered hazardous according to CLP regulation
 - Note: no tonnage threshold!
 - Hazardous polymers
 - Certain product types covered in other European regulations eg. cosmetics, medicines fall out of scope of CLP regulations
 - Notification not required if REACH registration completed

Notification Examples



1. Non-hazardous substance imported to the EU at >1 Tonne per year

- Notification required - Substance within scope of REACH registration (Notification may have already occurred in REACH registration process)

2. Corrosive substance imported at 300kg per year

- Notification required - substance within scope of CLP regulations although falls below 1 Tonne REACH registration requirement

3. Non-hazardous substance imported at 100kg per year

- No notification required – outside of REACH registration requirement and not hazardous under CLP

C&L Notification Scope



- **Who has to register?**
 - Manufacturer
 - Importer
 - Group of manufacturers or importers
 - Consortia
 - SIEF's (Substance Information Exchange Forum)
 - ✓ Make sure all companies that are involved in the group are involved in that notification process
 - No impact on downstream users, distributors.
 - Articles not included

C&L Notification Scope



- What information has to be registered?
 - Identification of the notifier or people involved in group notification (e.g. SIEF)
 - Identification of the substance (e.g. CAS)
 - CLP classification of the substance
 - Where substance is classified in some but not all hazard classes, an indication of why.
 - Lack of data, inconclusive data, data proves that no classification is required
 - Specific concentration limits or M (Mixture) factors
 - Label information
- (Approximately 200 data points per substance included in notification process)

C&L Notification Scope



- When does notification have to take place?
 - Substances placed on the market on or after December 1st 2010 shall be notified within one month
 - 1st notification deadline for substances on the market on December 1st was January 3rd 2011
 - 3.1 million notifications submitted covering 107,067 substances
 - Update notification information whenever there is a change to C&L of a substance

Notification Process



- Notification made to European Chemicals Agency (ECHA) through their REACH IT website
- Tools for preparing data for submission
 - IUCLID 5.2 Software
 - CLP C&L data can be entered into IUCLID 5.2 then submitted to ECHA
 - Information for each substance submitted separately
 - XML files
 - Enables “bulk” transfer of data (more than one substance)
 - On-line notification
 - Aimed at those notifying a small number of substances and not using IUCLID
 - Option for SME’s
- No charge from ECHA for C&L notification

C&L Inventory



- CLP regulation Article 42
- ECHA will produce a database of C&L information including:
 - Classification and label data
 - Indication whether classification is harmonised (e.g. set in the CLP regulations)
 - Indication when classification has been agreed by more than one supplier
- Database will be publically available
- Database will be updated when new C&L information is received

Amending the MSDS



- SDS need to adjust from showing DSD/DPD classifications to CLP Classification
- Different timelines for substances and mixtures
- New Annex II describes what information should be included under each of the 16 headings of a safety data sheet (SDS).
- Main challenge in sections 2 – Hazards Identification and 3 – Composition/Information on Ingredients

SDS - in transition (1)



- The SDS follows the label

Deadline - Additional 2 years if the product is already on the market	The Safety Data Sheet ...
until 1 December 2010	... shall contain the classification of a substance according to DSD. However, if a substance is already classified, labelled and packaged according to CLP, the Safety Data Sheet for the substance shall also contain the CLP classification of the substance.
until 1 June 2015	... shall contain the classification of a substance according to DSD. After 1 December 2010 the CLP classification shall also be provided.
until 1 June 2015	... shall contain the classification of a mixture according to DPD. However, if a mixture is already classified, labelled and packaged according to CLP, it shall also contain the CLP classification of the mixture.
from 1 June 2015	... shall contain substance and mixture classifications according to CLP.

SDS – in transition (2)



- Mixture: DPD label
 - Until 1 June 2015
 - Section 2: DPD classification -mandatory
 - Section 3: DSD classification for substances – mandatory
 - Also CLP if available
 - Section 16: CLP classification – optional
- Mixture: CLP label
 - Until 1 June 2015
 - Section 2: DPD and CLP classifications – mandatory
 - Section 3: DSD and CLP classification for substances – mandatory

Extended SDS



- The addition of Exposure Scenario (ES) information from the REACH registration dossier to the SDS
- Impacts substances that are REACH registered, supplied at > 10 tonnes per year and are hazardous
- For registering company, exposure scenarios must be included as an annex to the SDS
- Where exposure scenarios are received from suppliers for substances formulated into your own products these must either be annexed to the SDS, or the data be included in the standard 16 sections of the SDS

Extended SDS



- Exposure scenarios can be very long (over 80 pages per substance)
- Creates translation issues. Standard formats and phrasing has not been used in exposure scenarios
- Further guidance is expected imminently from ECHA / Industry Organizations. Many suppliers waiting for this before committing to process for dealing with ESDS

Conclusion



- Implementation of GHS/CLP is underway for substances in the EU and will soon impact mixtures
- GHS is also coming to the US SOON!
- Consider your position in the supply chain to understand how GHS/CLP affects you
- Understanding the implementation timelines is critical to ensure compliance
- Availability of expertise to classify to GHS/CLP regulations
- Tools available to maintain sustainable compliance with GHS/CLP requirements

Questions?

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