

EU Regulatory Compliance: Challenges and Solutions, EU CLP Regulation Overview.

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Presentation Overview



- Background to CLP regulations
 - UN GHS
- Implementation of CLP in Europe
 - Transition periods
- C&L notification requirements
 - What?
 - When?
 - How?
- Impact on MSDS
 - REACH Annex II regulation changes

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.

Global GHS Development



- GHS legislation or standards have been passed in:
 - Asia Pacific:
 - New Zealand (2001)
 - Korea (2008)
 - Singapore (2008)
 - China (2009)
 - Japan (2006)
 - Taiwan (2008)
 - Vietnam (2008)
 - Indonesia (2009)
 - Europe
 - EU (2008)
 - Serbia (2009)
 - Russia (2009)
 - Middle East & Africa
 - South Africa (2008)
 - Abu Dhabi (2009)
 - Americas
 - Brazil (2009)
 - Uruguay (2009)
 - Transportation - SOLAS (International Convention for the Safety of Life at Sea) (2009)
- But there will always be transition periods from the old system



Global GHS Development/cont



- Draft regulations on GHS published:
 - USA
 - Australia
 - Malaysia
 - India
- 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
 - Philippines
 - Thailand
 - UNITAR/ILO Global GHS Capacity Building Programme: 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
- Retains consistency with existing EU classification systems

Comparison of CLP Classification to GHS



- GHS also allows for national cut off levels 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?
 - Substances subject to registration under REACH (both hazardous and non-hazardous)
 - All substances that are considered hazardous according to CLP regulation
 - Note: no tonnage threshold!
 - Hazardous polymers
 - Certain product types covered in other regulations eg. cosmetics, medicines fall out of scope of CLP regulations
 - Notification not required if REACH registration completed

C&L Notification Scope



- **Who has to register?**
 - Manufacturer
 - Importer
 - Group of manufacturers or importers
 - Consortia
 - SIEF's
 - No impact on downstream users, distributors.
 - Articles not included

C&L Notification Scope



- What information has to be registered?
 - Identification of the notifier
 - Identification of the substance
 - 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 factors
 - Label information

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 whenever there is a change to C&L

Notification Process



- Notification made to European Chemicals Agency (ECHA) through their REACH IT website
- Tools for preparing data for submission
 - IUCLID 5.2
 - 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
 - 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
- New Annex II describes process
- Different timelines for substances and mixtures
- 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

SDS – Major changes (1)



- Section 1:
 - Supplier, national supplier, non-Community manufacturer
 - Registration number for pure substance
 - Identified uses and uses advised against
 - Operating hours for emergency call centers
- Section 2:
 - Label elements
 - Result of classification also if not classified
 - Result of PBT and vPvB assessment

SDS – Major changes (2)



- Section 3:
 - Different structure for substances and mixture
 - Declaration of PBT and vPvB substances
 - Indication of OEL, PBT, vPvB substance if substance is not classified
 - New thresholds limits for declaration for certain substances
- Section 4, 6, 8, 14:
 - New sub-headings
 - New contents for some sub-headings

SDS – Major changes (3)



- Section 15:
 - No label elements
 - Reference to the Community legislation (restrictions, authorization)
 - Reference to national legislation specified
 - Reference to Chemical Safety Assessment
- Section 16:
 - Indication of changes made if it is a revision
 - Abbreviations used through SDS, including wording of R-phrases and H-statements
 - Indication of classification method for mixture –calculation or testing
 - References

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 > 10Te 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

Thank you for your attention!
Any questions?

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