CLP Regulation: Implications of New Classification & Labeling Requirements in the European Union for U.S. Companies

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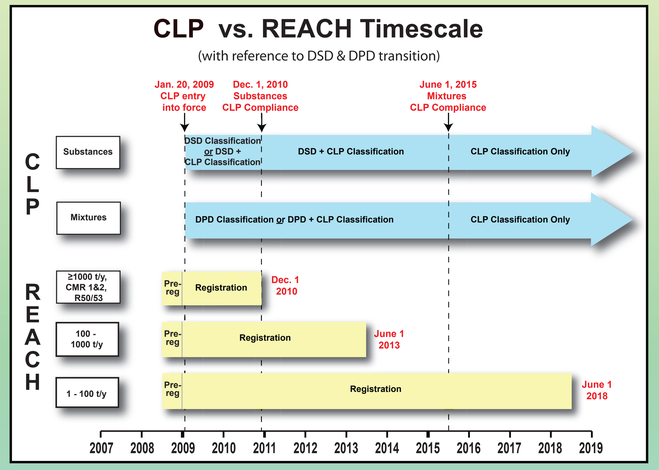
CLP Background

The European Union (EU) has implemented a major, innovative reform of legislation governing "Classification, Labeling and Packaging (CLP) of Substances and Mixtures", Regulation (EC) No 1272/2008. Entering into force on 20 January 2009, the principal aim of CLP is to protect workers, consumers and the environment by product labeling requirements reflecting possible hazardous effects. Intended to facilitate trade through harmonization, the new regulation requires manufacturers, importers, and formulators to appropriately classify, label and package their substances and mixtures before placing them on the EU market.

The CLP Regulation is essentially the EU's implementation of the classification and labeling rules set forth in the United Nations' "Globally Harmonized System" (GHS), and introduces new internationally agreed classification criteria, hazard symbols (pictograms) and labeling phrases. CLP complements the EU's chemical legislation for "Registration, Evaluation, Authorization, and Restriction of Chemicals" (REACH) and will gradually replace by 2015 the current classification and labeling systems set forth in the EU's "Dangerous Substances Directive" (DSD) and "Dangerous Preparations Directive" (DPD).



Rationale for GHS

- A United Nations' initiative to harmonize chemical classification and labeling by introducing consistent requirements at regional, national, and worldwide levels
- Provides a uniform basis for hazard communications of potential chemical effects on human health and the environment during handling, use, transport, and disposal
- Aims to lower import/export trade barriers caused by differing classification and labeling criteria – the intent is to facilitate international trade

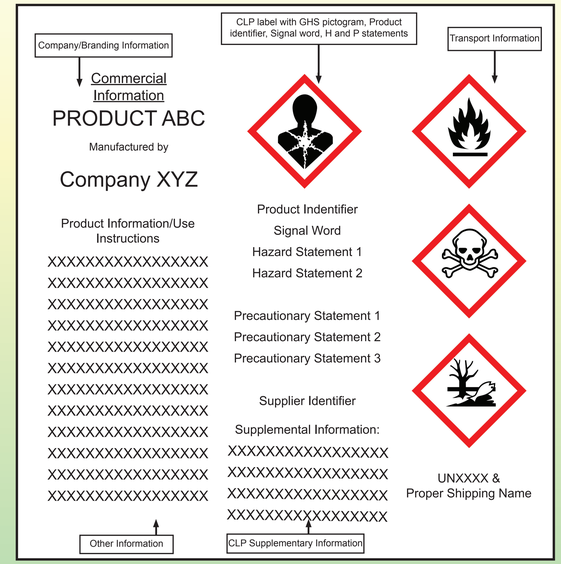
REACH Considerations

- CLP essentially implements GHS within REACH
- There is no tonnage threshold for classification and labeling under CLP
- All substances regulated by REACH must apply CLP criteria beginning 1 Dec. 2010
- All mixtures regulated by REACH must apply CLP criteria beginning 1 June 2015
- All substances registered under REACH (≥ 1 tonne/year) must be notified to the "Classification & Labeling (C&L) Inventory"
- All substances & mixtures classified as "hazardous" under CLP, regardless of tonnage, must be notified to the C&L Inventory
- REACH registration submissions before 1 December 2010 which do not already include CLP notification of substance classification must provide this information by 3 January 2011

DSD & DPD Transition

- CLP will repeal existing DSD & DPD Directives on 1 June 2015
- For substances:
  - DSD classification, labeling and packaging rules are binding until 1 December 2010; if CLP is applied in full before then, no DSD labeling and packaging is required
  - DSD + CLP classification until 1 June 2015, with labeling and packaging under CLP
  - Full compliance with CLP beginning 1 June 2015; DSD ends
  - DSD Annex I = CLP Annex VI
  - Substances already classified, labeled and packaged according to DSD and placed on the market before 1 December 2010 will only have to be re-labeled and re-packaged by 1 December 2012
- For mixtures:
  - DPD classification, labeling and packaging rules are binding until 1 June 2015; if CLP is applied in full before then, no DPD labeling and packaging is required
  - Full compliance with CLP beginning 1 June 2015; DPD ends
  - Mixtures already classified, labeled and packaged according to DPD and placed on the market before 1 June 2015 will only have to be re-labeled and re-packaged by 1 June 2017
- Users will start to see new pictograms, hazard & precautionary statements, and signal words on chemical labels as GHS guidance is implemented during this transition

Example CLP Label (single package, e.g., 200 L drum)



Reference: *"Guidance on the Application of the CLP*

Other Implications of the CLP Regulation

- Non-EU manufacturers technically have no direct obligation under CLP, but from a product stewardship stance will want to facilitate CLP compliance by their EU importers, and will also wish to increase their own preparedness for domestic implementation of GHS in their home markets
- More mixtures will be classified
- Many substances exempted from REACH must now meet CLP obligations
- Some substances with no or lower severity classifications under current legislation may be classified more severely under CLP
- Importers who place a hazardous substance on the EU market will also need to notify certain information into the C&L Inventory
- CLP compliance will necessitate review and updating of Safety Data Sheets (SDS)

What to do Next?

- Prior to classification: gather all available information, examine information to ensure it is adequate and reliable, evaluate available information against criteria, decide on appropriate classification
- Expert judgment should be used to evaluate data utilized to support health and environmental CLP classifications (existing and new data inventory, compliance with CLP-recommended methods and standards, non-GLP study data assessment, application of weight of evidence, (Q)SARs, read-across, etc.)
- Ensure that you understand your duties under CLP (whether you import, manufacture, formulate, distribute, or sell chemicals) - your substances must be correctly classified, with accurate labels reflecting the new scheme

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