



EU implementation of GHS (CLP) *Effects on REACH*

STEPTOE & JOHNSON ^{LLP}

BRUSSELS ■ LONDON ■ WASHINGTON ■ NEW YORK
CHICAGO ■ PHOENIX ■ LOS ANGELES ■ CENTURY CITY

GHS: Global Overview

- Globally Harmonised System for Classification and Labelling ('GHS')
- UN Conference on Environmental and Development (UNCED) in Rio de Janeiro identified an action programme for GHS in 1992.
- Basic text agreed in December 2000.
- UN Economic and Social Council (ECOSOC) formally adopted the text in July 2003.
- Several UN member countries are in the process of implementing GHS (Brazil, South Korea, EU) in the near future.
- So far only Japan and New Zealand have implemented GHS.

GHS: EU Action

- June 2007 adoption of proposal for Regulation on Classification, Labelling and Packaging of Substances and Mixtures, and amending Directive 67/548/EC and Regulation (EC) No. 1907/2006 ('CLP')
- March 2008 submission of European Parliament comments to the Council and Commission.
- Council and Parliament anticipate agreement with other EU institutions at first reading (i.e. in 2008), giving industry time to re-classify its substances before the first REACH registration deadline (i.e. 1 December 2010).
- Latest amendment agreed by EU institutions published in 15 September 2008 (COD 2007/0121 Rev.1).
- Anticipated final adoption by Council and Parliament in October/November 2008.

GHS: Similarities with current EU system

- Similar in concept (hazard communication, labelling/packaging, Safety Data Sheets).
- Covers many hazards currently covered with similar criteria.
- Similar 'preparations' or 'mixtures' classification methods
(e.g., testing of mixtures, read-across between mixtures, calculation methods based on the components of the preparation).
- EU Risk and Safety phrases structurally maintained through the so-called Hazard and precautionary Statements.

GHS: Differences from current EU system

- Hazard Class System with 1-8 Hazard Categories (hazard severity).
- Test methods and criteria for phys./chem. hazards based on: *'UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria'*. → Major changes to the phys./chem. hazards classification.
- No comparable classification for certain EU R-phrases:
 - ✓ *R37(respiratory sensitisation), R65 (aspiration hazard), and other toxicological properties, except R64 (May cause harm to breast fed babies).*
- Separates acute toxic effects and systemic toxicity and introduces two new Hazard Classes (Target Organ Systemic Toxicity: single and repeated dose).
- Clear division of the Aquatic toxicity. Introduces Acute Aquatic Hazard and Chronic Aquatic Hazard.
- New hazard symbols (pictograms) and other graphic elements including signal words ('Warning' and 'Danger').

EU objectives on GHS

- Maintain (enhance) existing level of protection for the health and the environment.
- Closely align with Directives 67/548/EEC and 99/45/EC.
- Ensure all elements of current Directive 67/548/EEC and 99/45/EC on hazard communication are included.
- Minimise impact on REACH and other downstream use legislation (e.g. BPD, PPP, toys etc.).
- Minimise impact on industry concerning reclassification, re-labelling and re-packaging.
- Simplify harmonised classification and labelling.

Scope and Definitions under CLP

- The term '*mixture*' is introduced for '*preparation*'. (potential conflict over substances which are mixtures under the current regime)
- '*Scientific Research and Development*' under one tonne subject to classification while REACH still exempts such substances from its registration, authorisation and restrictions provisions.
- '*Supplier*' does not include suppliers of an article.
- '*Alloys*' are clarified by stating they are to be viewed as a mixtures.
- Exemptions are aligned with REACH, but do not match the exemptions under Directive 67/548/EEC. (*e.g.*, pesticides)
- Excludes from its scope transportation of dangerous goods, but packaging is subject to both supply and transport labelling.
- Explicit exemption for certain substances and mixtures used by the military.

Obligations under CLP

- Manufacturers, importers, and downstream users must classify any substance or mixture before placing on the market, and label and package it appropriately.

- However,
 - ‘Manufacturers, producers of articles and importers shall classify those substances **not placed on the market** where REACH provides for registration or notification.’ (Article 4(2) CLP)

- Other obligations:
 - ✓ Explosive articles must also be classified, labelled and packaged appropriately.

 - ✓ Distributors label and package only if they change the received labels or packages, or ensure that received classifications, labels or packages are correct.

 - ✓ Under specific circumstances non-classified mixtures must be ‘specially’ labelled and packaged if they contain hazardous substances.

 - ✓ If a hazard class is not covered by the harmonised classification then the supplier must cover the missing classification.

Harmonised Classification and Labelling

- Title XI (Classification and labelling Inventory) of REACH is replaced.
- Substantial changes to Annex XV (Dossiers) of REACH.
- Changes in procedure for establishing a harmonised C&L inventory:
 - ✓ Under REACH, only Member State Competent Authorities may submit a proposal to the Agency for harmonised Classification and labelling including amendments.
 - ✓ Under CLP, this right has been extended to include industry under specific conditions:
 1. Member States may propose new entries as well as amend an existing entries in Annex VI.
 2. Manufacturers, importers, and downstream users may propose new entries or amend existing entries in Annex VI for new hazard classes or differentiation for that substance.

Labelling of packaging under CLP

- If a package consists of inner (incl. intermediate) and outer packaging where outer packaging must be labelled according to transport legislation then:
 - (1) inner packaging must be according to CLP, and
 - (2) outer packaging may be according to transport or CLP (do not have to repeat the pictograms).

- If a package consists of inner (incl. intermediate) and outer packaging where outer packaging does not need to be labelled according to transport legislation then:
 - (1) inner packaging must be according to CLP, and
 - (2) outer packaging may be according to CLP.

- Single packaging that meets the labelling requirements of transport legislation then the packaging must be labelled in accordance with both CLP and transport legislation (do not need to repeat the pictograms).

Timelines (substances)

- CLP enters into force 20 days after its publication in the *Official Journal* (anticipated date is end of 2008).
- **Until 1 December 2010**, substances must be classified, labelled and packaged according to Directive 67/548/EEC. Suppliers may chose to comply with the provisions of CLP, in which case they do not need to comply with Directive 67/548/EEC.
- **From 1 December 2010 until 1 June 2015**, substances must be classified in accordance with CLP and Directive 67/548/EEC. They must be labelled and packaged according to CLP.
- Derogation for labelling and packaging:
 - ✓ Substances placed on the market before 1 December 2010 and classified, labelled and packaged according to Directive 67/548/EEC do not need to be relabelled and repackaged according to CLP until 1 June 2012.
- **From 1 June 2015**, substances must be classified, labelled and packaged according to CLP. (Directive 67/548/EEC is repealed as of this date).

Timelines (mixtures)

- **Until 1 June 2015**, mixtures must be classified, labelled and packaged according to Directive 99/45/EC. Suppliers may chose to comply with the provisions of CLP, in which case they do not need to comply with Directive 99/45/EC.

- Derogation for labelling and packaging:
 - ✓ Mixtures placed on the market before 1 June 2015 and classified, labelled and packaged according to Directive 99/45/EC do not need to be relabelled and repackaged according to CLP until 1 June 2017.

- **From 1 June 2015**, substances must be classified, labelled and packaged according to CLP. (Directive 99/45/EC is repealed as of this date).

Timelines

Until 1 December 2011, Member States that have more stringent schemes for classification and labelling of substances (in Annex VI) may maintain them provided:

- ✓ The Member State notifies to the Commission (safeguard clause in Directive 67/548/EEC) before the entry into force of CLP, and
- ✓ The Member State submits a proposal for harmonised classification and labelling for the substance by 1 June 2009.

REACH elements affected by CLP

- Registration
- Hazard communication (Safety Data Sheets)
- Authorisation
- Restrictions
- Classification and labelling inventory
- Downstream use legislation (e.g. BPD, PPP, toys etc.)

Industry Concerns

- ✓ Deviation in the definitions between REACH and other legislation, and CLP.
- ✓ Distributor's duty to ensure correctness of package labels.
- ✓ Transitional periods are confusing and in some cases too short.
- ✓ Substances covered by REACH subject to classification and labelling notification even though not hazard classified.
- ✓ Some entries in Annex I of Directive 67/548/EEC are over 20 years old and should now be subject to review or stakeholder consultation,
- ✓ Lengthy Committee procedures,
- ✓ Concerns about the costs on industry such as new SDS and labels according to the new CLP (industry must update their SDS under REACH by 1 June 2007)
- ✓ Other issues such as risk communication to consumers on products they buy instead of just communicate hazards.

Final Thoughts

- Industry should:
 - ✓ Actively monitor CLP adoption to ensure understanding of last minute changes.
 - ✓ Ensure adequate infrastructure in place to deal with reclassification, re-labelling and re-packaging.
 - ✓ Prepare to update REACH dossiers.
 - ✓ Article suppliers must notify classification even for substances which **they** do not place on the EU market.
 - ✓ Ensure that labelling of packaging complies with both CLP and Transport of dangerous goods legislation.
 - ✓ Evaluate how obligations under CLP affect activities under REACH and other downstream use legislation.