

Proposal for a Regulation on Classification, Labelling and Packaging of substances and mixtures:

**Globally Harmonised System of Classification and Labelling of Chemicals (GHS)
and its incorporation into Community legislation**

Abstract:

On the 3rd of September a large majority of the European Parliament supported a text on which agreement had been reached between the Council and the European Parliament on the Commission's proposal for a Classification, Labelling and Packaging ("CLP") Regulation. The new Regulation will align EU legislation on classification, labelling and packaging of substances and mixtures to the United Nations Globally Harmonised System (GHS). This new system will ensure that the same hazards will be described and labelled in the same way all around the world. By using internationally agreed classification criteria and labelling elements, it is expected to facilitate trade and to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals. The new Regulation will complement the REACH Regulation on the registration, evaluation, authorisation and restriction of chemicals. The next step will be the final adoption in the Council, after which the act will be published later in the year, thereby making the EU one of the international leaders in the actual uptake of the UN system.

After a transitional period, the new Regulation will replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). The rules on harmonised classification and notification to the inventory will apply from entry into force. The deadline for substance classification according to the new rules will be 1 December 2010 and for mixtures 1 June 2015.

It is important to note that the current text of the new CLP Regulation must still be formally adopted by the Council and that the text is still undergoing legal-linguistic finalisation.

BACKGROUND

Global Context

Over the past 30 years or more, a number of different classification and labelling (C&L) systems for chemicals (substances and preparations/mixtures) have been developed by different jurisdictions in the world such as the European Union, Australia, Canada, Japan, the USA, China, Korea etc. This has led to divergent C&L systems providing different Health and Safety (H&S) information for the same goods originating in different countries, but which are traded internationally.

In 1992, the UN Conference on Environment and Development (UNCED) in Rio de Janeiro identified the harmonisation of classification and labelling systems for chemicals as one of its action programmes in Chapter 19 of UNCED Agenda 21.

The aim of this work was to bring together the major world classification and labelling systems. Three main elements were identified:

- a globally harmonised classification system for chemical substances;
- a globally harmonised classification system for mixtures/preparations;
- and a globally harmonised system for hazard communication for workers, consumers and in transport (which includes labelling and safety data sheets (SDS)).

The system has been developed in co-operation between various international organisations. EU Member States and the Commission were involved in this development work.

In December 2002, the GHS was agreed by the UN Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals (CETDG/GHS)¹. It was formally adopted by UN ECOSOC² in July 2003 and revised³ in 2005 and 2007.

In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the **World Summit on Sustainable Development** encouraged countries to implement the GHS as soon as possible, with a view to having the system operational by 2008.

Current EU System and GHS

The current EU classification and labelling system for chemicals is set out in the following key instruments:

- the Dangerous Substances Directive (67/548/EEC)⁴;
- the Dangerous Preparations Directive (1999/45/EC)⁵;
- Annex II to the REACH Regulation (EC) 1907/2006⁶; originally the Safety Data Sheet Directive (91/155/EEC)⁷
- Title XI of the REACH Regulation (EC) 1907/2006; the classification and labelling inventory.

These existing acts and the new Classification, Labelling and Packaging Regulation follow a similar logic. They have Internal Market (Article 95 of the EC Treaty) objectives (i.e. the approximation of

¹ An ECOSOC subsidiary body serviced by the UNECE secretariat.

² Economic and Social Committee of the UN

³ http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

⁴ Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended [OJ 196, 16.8.1967, p. 1]

⁵ Council Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparation, as amended [OJ L200, 30.7.1999, p.1]

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European chemicals agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [OJ L 396, 30.12.2006, p. 1, as corrected by OJ L 136, 29.5.2007]

⁷ Council Directive 91/155/EEC relating to defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations and dangerous substances, as amended [OJ L 076, 22.03.1991, p. 35], repealed and replaced by Regulation (EC) No 1907/2006 as of 1 June 2007.

laws aiming at the establishment of an Internal Market, in this case in the trade of chemicals, in the EU), taking as a basis a high level of protection of human health and the environment.

The first two Directives set out rules on the classification, packaging and labelling of dangerous substances and preparations. Annex II to the REACH Regulation, which replaces the Safety Data Sheet Directive, ensures that suppliers of substances and preparations provide information about the hazards of their chemicals and guidance on safe use to professional customers. Title XI of the REACH Regulation requires that substances placed on the market are notified to the classification and labelling inventory of the European Chemicals Agency ("ECHA"). The Title contains the provisions for establishing a list of harmonised classification and labelling of substances as carcinogenic, mutagenic, toxic for reproduction or as respiratory sensitiser. Harmonised classification for other effects may be done on a case-by-case basis.

The current EU system and the GHS are conceptually similar. Both cover classification and hazard communication through labelling and safety data sheets. The GHS is a common approach that provides criteria for harmonised classification and hazard communication for different target audiences, including consumers, workers and emergency responders, and in transport. Therefore, it includes a "building block" approach to enable countries to adopt the system having regard to the various target audiences in different regulatory areas.

The EU Context

All EU Member States signed up to the recommendation of the World Summit on Sustainable Development and in several instances called upon the Commission to take up the GHS. Accordingly, the Commission services have indicated in various fora that the GHS would be incorporated into Community legislation.

Commission proposal

On 27th of June 2007, the European Commission adopted the "Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006" ("CLP proposal") (COM(2007) 355 final). The proposed act aligns the EU system of classification, labelling and packaging of substances and mixtures to the United Nations Globally Harmonised System (GHS).

The GHS was developed by international organisations, with participation of various stakeholders. Similarly, in the EU there have been continuous technical discussions with Member States and other stakeholders over the past years regarding supply and use.

As we are striving for harmonisation, a Regulation was chosen as the regulatory instrument, which will lead to the direct application of the legislation throughout the European Community and thus ease the application in an enlarged Community of 27 Member States. The proposed Regulation is based on Article 95 of the EC Treaty to ensure a level playing field for all suppliers of chemical substances and mixtures in the internal market, while at the same time ensuring a high level of protection of human health and the environment.

As to scope, the CLP proposal, which covers supply and use, contains provisions for the classification and labelling of substances and mixtures including Plant Protection Products and Biocides consistent with the current EU system.

During the drafting stage, the Commission services applied the general principles as laid out in the UN GHS document.

The criteria for the classification of substances and mixtures as hazardous, including the building block approach that enables the legislator to choose the appropriate hazard classes and categories, were developed at international level. To ensure proportionality, the Commission services selected those hazard classes and categories which are comparable with existing legislation, thereby maintaining the current high level of protection of health and environment and not increasing the burden on industry.

Therefore, firstly, the CLP proposal does not include the following categories, as they are not part of current EU legislation and are not needed for consistency with transport legislation: “flammable liquids category 4”, “acute toxicity category 5”, “skin corrosion/irritation category 3”, “aspiration hazard category 2” and “acute aquatic toxicity category 2 and 3”.

Secondly, those elements which are part of current EU legislation, but which have not yet been included in the GHS are also part of the CLP proposal, e.g. “ozone depletion”.

To be consistent with the GHS, those elements which have only led to additional labelling requirements under current EU legislation but which are now part of the GHS classification system have been included in the CLP proposal, e.g. “effects on or via lactation” and “narcotic effects”. For consistency with transport legislation, the CLP proposal incorporates some hazard classes or categories which are not included in current EU legislation for supply and use, but are part of the existing EU transport system or will be implemented in transport legislation. These are “gases under pressure”, “self-reactive substances and mixtures, Type C to G”; “self-heating substances and mixtures”; “oxidising liquids category 3”; oxidising solids category 3”; and “corrosive to metals”.

As safety data sheets are the main tool for communication under the REACH Regulation, the provisions on safety data sheets remain in the REACH Regulation.

The CLP proposal also takes over the provisions of the REACH Regulation (Title XI) regarding the notification of classification and labelling, the establishment of a list of harmonised classifications and the creation of a classification and labelling inventory.⁸

Classification of substances and mixtures triggers **obligations in other EU legislation**, referred to as "downstream legislation" (apart from REACH). The Commission, after having assessed the potential effects of the implementation of the GHS criteria on downstream legislation, concluded that effects are either minimal or can be minimized by appropriate changes to particular downstream acts. On this basis, the Commission adopted two additional proposals in October 2007 aiming to make such changes to six downstream Directives and one downstream Regulation, through amendments which take account of the effects of the CLP proposal, but without changing the scope or content of the downstream acts.

Therefore, where relevant, for hazard classes or categories which were added in order to be consistent with current EU legislation, such as “gases under pressure”, “corrosive to metals” or “narcotic effects”, the Regulation and the two additional proposals ensure that they do not trigger obligations under REACH or other downstream legislation.

As to implications for other EU downstream acts, such as the Seveso Directive and the legislation on occupational health and safety, these are addressed through ongoing reviews of the acts in question. With regard to the review of the Seveso Directive, please consult the following website: <http://ec.europa.eu/environment/seveso/index.htm>, with regard to occupational health and safety, please refer to http://ec.europa.eu/employment_social/health_safety/legislation_en.htm.

⁸ The relevant provisions of REACH will be deleted upon entry into force of the new Regulation.

State of Play

Since the Commission's proposal was published, it has been subject to the legislative co-decision procedure. Both the Council and the European Parliament considered the Regulation implementing the GHS as a high priority, and worked to a tight time schedule to secure final adoption by the end of 2008. A first milestone on the way to adoption was reached on the 27th of June 2008 under the Slovenian Presidency, when the Permanent Representatives Committee of the Council unanimously approved the current text of the CLP Regulation. A second milestone was reached by the vote of the European Parliament, on 3rd September 2008, where it was supported by an overwhelming majority.

The current text of the CLP Regulation:

In the view of the Commission, the compromise agreed is a balanced one. The changes introduced by the co-legislators are quite significant in number. They contribute to the legal certainty and workability of the CLP Regulation but they alter neither the philosophy nor the structure of the original Commission CLP proposal.

On the main issues, the compromise was concluded as follows:

- Clarification of obligations in the supply chain; *in Article 4, the roles of the different actors in the supply chain (manufacturers, importer, downstream users and distributors) were specified.*
- Clarification of the concept "hazardous" vs "dangerous"; *Article 3(2) of the Commission proposal was deleted, because not all EU languages allow the differentiation of "hazardous" and "dangerous", therefore the use of the term "dangerous" was avoided and the applicable scope defined for REACH in Article 56 of the CLP Regulation and for the downstream acts in the amendments to the acts themselves.*
- Clarification of the "read across" and "expert judgement" concept; *in Article 9(4) and Annex I Part 1 the use of "expert judgement" was further specified.*
- Use of human data obtained from other sources; *Article 7 of the Commission CLP proposal did not allow testing on humans and non-human primates. Both the EP and some Member States (MS) were concerned that this would mean that certain necessary (but very limited) tests would no longer be allowed ("patch testing"). The compromise allows now the use of human data obtained from other sources, such as clinical studies, for the purpose of classification.*
- Confidentiality, use of an alternative name; *Article 26 was aligned closer to the provisions in Directive 1999/45/EC and under REACH.*
- Labelling of small packaging and of outer, inner, single packaging; *the labelling exemptions for small packages (Article 31) were further developed and the provisions for outer, inner and single packaging (Article 36) clarified by the co-legislator.*
- Deadlines for labelling up-date; *Article 33, also here the provisions were further specified.*
- Harmonisation of information to poison centres; *Article 45 requires the Commission to carry out a review to assess the possibility of harmonising the information, including the format, that suppliers need to submit to poison centres and to make a proposal, if appropriate.*
- Scope of child resistant fastening (CRF), tactile warning (TW); *in Annex II, the provisions were fully aligned with the provision of the current legislation.*
- Possibility to establish networks for specific product sector; *Annex I Part 1 allows suppliers in an industry sector to cooperate through formation of a network to share data and expertise when classifying substances and mixtures. However, each supplier remains fully responsible for any requirement under the Regulation.*
- Promote C &L development for PBT/vPvB at the UN; *in Article 53, MS and the Commission are required to promote the harmonisation of the criteria for classification and labelling of PBTs or vPvBs at the level of the United Nations.*

Next steps

Formal adoption by the Council in the autumn would allow publication and entry into force of the Regulation by end of 2008, allowing the European Union to honour its international commitments to have the system in place by 2008.

After a transitional period, the new regulation will replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). The rules on harmonised classification and notification to the inventory will apply from entry into force. The deadline for substance classification according to the new rules will be 1 December 2010 and for mixtures 1 June 2015.

Guidance documents

Guidance on how to apply the provisions of the proposed Regulation on classification, labelling and packaging is currently being developed by the Consumer Products Safety and Quality (CPS&Q) unit of the European Commission's Joint Research Centre (the former European Chemicals Bureau (ECB)). The work is being done within the so-called REACH Implementation Project 3.6 (RIP 3.6), cf. also <http://ecb.jrc.it/reach/rip/>. Four working groups have been established, dealing with general aspects, physical, health and environmental hazards. They consist largely of Member State and stakeholder experts. Finalisation of the RIP 3.6 guidance document is planned for the first half of 2009.

In addition to specific guidance, general guidance is also being developed, focussing on basic features and procedures related to classification and labelling in the EU context. The guidance is addressed to those who want to have a quick overview of the new legal requirements for classification and labelling in the EU. This guidance document will be made available by the time the Regulation enters into force.

Transport

For international transport purposes, classification and labelling systems mirror the international transport regulations for all modes of transport. The Commission Services responsible for implementation in transport have introduced GHS, in the framework of the Directives on Transport of Dangerous Goods, based on the "Recommendations on the Transport of Dangerous Goods, Model Regulations".

- ADR/RID 2005: directives 94/55 (road) and 96/49 (rail) (amendments 2004/111 and 2004/110) included most elements;
- ADR/RID 2007: directives 94/55 (road) and 96/49 (rail) (amendments 2006/89 and 2006/90) added some further categories;
- The new Directive 2008/68 was published on 30 September 2008, implementation by MS by 30 June 2009.

LINKS TO THE LEGISLATIVE PROPOSAL

Supply and use

The Commission proposal as well as **a link** to the Council web-site where the latest text of the Regulation, including the “compromise package” agreed by the Slovenian Presidency and the European Parliament’s rapporteur are available via the following web-site:

http://ec.europa.eu/enterprise/reach/ghs_more_on_com_proposal_en.htm

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Transport

Further information about transport is available via the following web-site:

http://ec.europa.eu/dgs/energy_transport/security/goods/index_en.htm