

Classification and labelling of chemicals

What the Globally Harmonised System means for workers

In late June 2007, the European Commission adopted a proposal for a Regulation on classification, labelling and packaging of hazardous substances and mixtures intended to implement in the EU the Globally Harmonised System of classification and labelling of chemicals adopted by the United Nations Economic and Social Committee. The changes to the Community rules on classification and labelling of chemical substances and preparations will impact the health and safety of workers who are exposed to hazardous chemicals. This article looks at the draft Regulation, which the European Parliament and Council will have to agree on through the co-decision procedure.

Chemicals are manufactured and marketed globally, and present the same hazards everywhere¹, but different countries use different systems to classify and label them. The same substance, for instance, may be classified as “toxic” in the United States, “harmful” in the EU and “not dangerous” in China (see table below). Using different criteria to evaluate the hazards of the same chemical inevitably results in different health and safety information being supplied to professional users and consumers. It also complicates the job of firms that sell their products globally, and so have to change their labels to meet the criteria used in different jurisdictions.

Hazard classification and communication for a chemical with LD₅₀ = 257 mg/kg * (oral route) in different jurisdictions

Jurisdiction / System	Hazard Classification / Communication
GHS	Signal word: Danger Pictogram: Skull and crossbones
EU	Hazard statement: Harmful Pictogram: St Andrew's Cross
USA	Toxic
Canada	Toxic
Australia	Harmful
India	Non toxic
Japan	Toxic
Malaysia	Harmful
Thailand	Harmful
New Zealand	Hazardous
China	Not dangerous
Korea	Toxic

It was decided to address these issues and improve protection for people and the environment in all countries by developing a globally harmonised classification and labelling system under the aegis of the United Nations. The Globally Harmonised System (GHS) of Classification and Labelling of Chemicals was formally adopted in 2002 by the United Nations Economic and Social Committee (UN ECOSOC).

It aims to harmonise the different classification and labelling (C&L) systems used throughout the world for:

- chemicals;
- preparations (= mixtures of chemicals);
- communication of hazards for workers, consumers and the environment from the handling, transport and use of these products via labels and safety data sheets.

The benefit of a harmonised system is to provide a single benchmark for producers, importers and users in all countries, including those with no chemicals classification system or legislation. It should also promote global trade and movement of chemical substances and preparations.

Implementing the GHS in the EU

The Member States at the World Summit on Sustainable Development in Johannesburg in 2002 adopted a Plan of Implementation of the new system aimed at having the GHS up and running by 2008. The new system is an opt-in one, but most countries are keen to legislate for a mandatory one.

In Europe, the Commission has always favoured bringing the new system into Community law through a regulation to be adopted at the same time as that of the REACH reform. The REACH regulation was adopted in December 2006 and came into effect in the 27 Member States in June 2007, but the Commission was unable to keep to its initial timetable for the GHS.

¹ The hazards a chemical presents to humans or the environment come from its intrinsic properties, e.g., it may be explosive, very toxic, carcinogenic or environmentally hazardous.

Source: adapted from *Analysis of the potential effects of the proposed GHS regulation on its downstream legislation*, Commission Services, August 2006

* LD₅₀: the amount of a chemical administered in a single dose that kills 50% (half) a test group of animals. The lethal dose is expressed as mg of substance tested per kg of body weight.

Public consultation on the draft proposal for a Regulation

The Internet consultation ran for 2 months from 21 August 2006 to 21 October 2006*, during which time all the stakeholders concerned were invited to consult and comment on the Commission's draft text and impact assessment studies. The Commission slightly revamped its draft text in light of the responses received, and adopted the proposal (COM (2007) 355 final) which will become the Community GHS Regulation after scrutiny by the European Parliament and Council.

Around 370 replies were received, most (254) from industry. Comments were also received from European national governments and/or national public authorities (18 replies) as well as non-EU public authorities (4). Ten NGOs sent in replies. On the trade union side, the replies of member federations and confederations were collected and coordinated by the ETUC and its research institute (ETUI-REHS).

The draft regulation finally adopted by the Commission is almost identical in content to that put out to public consultation. There is no denying that the ultra-technicality of the subject and the protracted preliminary negotiations in the United Nations to get to a single, globally harmonised system left little "wiggle room". Unlike REACH, the impact assessment studies published by the Commission for the public consultation excited no controversy. The consensus was that the costs of implementing the GHS are relatively low compared to the costs of other chemicals legislation, and that even these will

be offset by the savings that the GHS will bring to companies that market these products.

One of the key consultation issues was stakeholders' opinions on the length of the inevitable transitional period in which the old and new classification and labelling systems would run together. The Commission suggested three years for substances and a further four or five years for mixtures. This is because the classification of mixtures depends on the classification of substances, so the new criteria will have to be applied first to substances, and then to mixtures.

The Commission has finally gone with a first transitional period running from the entry into force of the GHS up to 1 December 2010, during which firms will be able to use either classification system for substances and mixtures. Then, a second, four-and-a-half year transitional period (up to 1 June 2015) will kick in, when the GHS system will be compulsory for the labelling of substances. Substance safety data sheets will have to show both the old EU classification and the new GHS classification. Firms will be able to continue using either system for mixtures during this second period. From 1 June 2015, the old EU system will no longer be legal, and the GHS system will be the rule for both substances and mixtures.

* http://ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

In August 2006, the Commission departments sponsoring the GHS (DG Enterprise and DG Environment) put up a draft proposal for a Regulation to introduce the GHS into Community law² on the legal basis of article 95 of the European Treaty (harmonization of the internal market). As with REACH, the Commission issued a two-month Internet public consultation on its draft proposal before it is formally adopted by the Commissioners as a body (see box).

The proposal for a Regulation on classification, labelling and packaging of hazardous substances and mixtures was finally adopted by the Commission on 27 June 2007³. It has since gone forward to the Parliament and Council, which will have to agree on the final wording of the regulation via a co-decision procedure.

How will the GHS change the current system?

The current EU classification and labelling system for chemicals is set out in three key directives:

- the Dangerous Substances Directive: 67/548/EEC
- the Dangerous Preparations Directive: 1999/45/EC
- the Safety Data Sheet Directive: 91/155/EEC

The first two lay down the rules on classification, packaging and labelling of dangerous substances and dangerous preparations placed on the Community market. In practical terms, that means that a hazard assessment must be done in line with the rules set out in these two directives on any substance or preparation manufactured or imported in the EU. If the substance or preparation meets the specified danger criteria in terms of its physicochemical properties, or its impacts on human or environmental health, these hazards must be marked on the label.

All the dangerous substances and preparations marketed in Europe must be classified and labelled whatever the quantity placed on the market.

Annex I of Directive 67/548/EEC contains the list of dangerous substances whose classification is harmonised in the EU. It currently contains some 8000 substances and is periodically updated in response to proposals from a Commission technical committee⁴ to take account of scientific and technical progress.

If a dangerous substance not included in Annex I is placed on the market (as it is, or as an ingredient in a

² http://ec.europa.eu/enterprise/reach/ghs_consultation_en.htm.

³ 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, 27 June 2007, COM (2007) 355 final.

⁴ Technical Committee on Classification and Labelling of Dangerous Substances (TC C&L).

preparation), the manufacturer, importer or distributor must classify it (or the preparation) themselves in line with the criteria set out in Annex VI of Directive 67/548/EEC.

The final piece of the jigsaw – the Safety Data Sheet Directive – ensures that suppliers of dangerous substances and preparations supply information on the hazards of their chemicals and guidance on safe use to professional customers. These provisions on safety data sheets were incorporated in the REACH Regulation that has recently come into effect.

After a transitional period in which the old and new systems will run in tandem, the GHS Regulation will replace Directive 67/548/EEC and Directive 1999/45/EEC in the Community legal set-up. Manufacturers, importers and distributors will still have the same obligations on classification and labelling of their own substances and mixtures, but will have to apply the newly-defined globally harmonised criteria as taken over into the EU's GHS Regulation.

The scope of the GHS

The Commission proposal for a GHS Regulation applies to substances and mixtures. Aerosols are also included in a specific hazard class. Radioactive substances are excluded from the scope, as they are covered by other rules. Substances and mixtures not placed on the Community market are also excluded. These would include non-isolated intermediates, and substances and mixtures for scientific research and development, for example. Nor does

the proposal for a Regulation apply to substances and mixtures intended for the final user in the form of medicines, cosmetics and foodstuffs (covered by specific rules). Biocides and pesticides, by contrast, are firmly within its scope.

Key changes made by the GHS

The key changes lie in adjustments to the classification criteria, assigning danger symbols (pictograms) and risk phrases (now "hazard statements" in the GHS). Detailing all the changes would make for a laborious read; these are best found in the proposal for a Regulation itself. A brief outline of the changes is given in the box below, however.

In line with the GHS, the Commission's draft Regulation also introduces a new terminology. What is now called a "preparation" will in future be a "mixture", while the description "dangerous" becomes "hazardous".

All the hazard classes defined in the GHS are taken over into the proposal for a Regulation but, not all the categories defined in the GHS are automatically included within each hazard class. For example, GHS category 5 is not included in the "acute toxicity" hazard class because it did not exist in the current Community system.

As well as having firms self-classify their substances and mixtures, the Commission proposal requires manufacturers or importers to "notify" all their classifications to the ECHA, the new European Chemicals Agency based in Helsinki. This is already

Comparison of categories for acute oral toxicity in current EU legislation and the GHS

EU	Very Toxic		Toxic		Harmful		
LD ₅₀ *	≤ 5	5-25	25-50	50-200	200-300	300-2000	2000-5000
GHS	Category 1	Category 2		Category 3		Category 4	Category 5

The concentration limits of the individual categories in the GHS system do not coincide with those of the categories in the European system for acute oral toxicity. This means, for example, that a substance classified as very toxic if swallowed in the current EU system (LD₅₀ < 25 mg/kg) will be classified in the GHS either as a category 1 substance (LD₅₀ < 5 mg/kg) or a category 2 substance (LD₅₀ between 5 and 25 mg/kg).

* See note of the table p. 8

Examples from the "translation" tables from the current EU system to the GHS system in Annex VII of the proposal for a Regulation

R Phrases (EU)	GHS hazard statement	GHS hazard classification
R42	H334	Respiratory sensitizer
R43	H317	Skin sensitizer
Carc. Cat.2; R45	H350	Carcinogen Cat. 1B
Repr. Cat.2; R60	H360	Reproductive toxicant Cat. 1B
Repr. Cat.2; R61	H360	("May damage fertility") ("May damage unborn child")

an obligation of the REACH regulation, and so is being carried over into the draft GHS Regulation. The idea is to establish a classification and labelling inventory made up of all the notifications and harmonised classifications received by the ECHA so as to be able to identify any differences in classification for the same substance manufactured by different producers, and force them to agree on the same classification.

The GHS' seven annexes

The draft Regulation proper sets out the principles and general rules on classification, packaging and labelling of hazardous substances and mixtures. The technical details are contained in seven Annexes.

- **Annex I** includes a general introduction (part 1), the hazard classes and criteria for physical, health and environmental hazards (parts 2, 3 and 4) replacing Annex VI of Directive 67/548/EEC, except for ozone depletion, which is placed in part 5.
- **Annex II** includes the extra labelling provisions from Annex VI to Directive 67/548/EEC not yet covered by the GHS.
- **Annex III** contains the list of hazard statements. It is similar to Annex III of Directive 67/548/EEC.
- **Annex IV** gives the rules for applying precautionary statements. The list of precautionary statements is similar to Annex IV of Directive 67/548/EEC.
- **Annex V** reproduces the GHS hazard pictograms and is similar to Annex II of Directive 67/548/EEC.
- **Annex VI** contains the list of substances with harmonised classifications. It includes the entries in Annex I of Directive 67/548/EEC, adapted where necessary to the GHS classification criteria.
- **Annex VII** includes "translation" tables for suppliers of substances and mixtures already evaluated under the current rules for those hazard categories where a simple equivalence exists. These tables provide an option for suppliers to fulfil their new obligations without having to reclassify their currently self-classified substances and mixtures from scratch. Should a supplier choose not to use the table, he must re-evaluate the substance or mixture using the criteria laid down in Annex I.

Issues for the various stakeholders

The future GHS Regulation is closely linked not only to REACH, but also to a raft of existing Community laws. This means it could play into all the laws that deal with classification and labelling rules for dangerous chemical substances or preparations, where classification lays various obligations on manufacturers ("downstream" legislation). Apart from REACH, this includes, for example, the Pesticides, Waste, Water and Air Quality Directives, but also the Seveso and Health and Safety at Work Directives (Chemicals Directive, Carcinogens Directive, Pregnant Workers Directive, etc.).

The Commission says that the new system was designed and negotiated to minimise the impact on existing legislation and keep up the levels of human and environmental protection provided by the current rules. But the changes to be made to the classification criteria will inevitably bring changes to the classification and labelling of some chemical substances and preparations.

Different scenarios could arise where chemical substances or preparations classified as hazardous could be re-categorized and classified as more or less so, while chemicals not currently classified as hazardous could be categorized as such.

Labels will then have to be adapted, with very different consequences for producers, workers and consumers. Chemical substances or preparations that were not classified as hazardous and are now reclassified as such could suffer falling sales. On the other hand, workers and consumers will be informed about a hazard they were previously unaware of.

Conversely, downgrading dangerous substances or preparations to a lower category could benefit producers by relieving them of certain obligations linked to classification, such as the Chemicals Directive's requirement for employer to carry out a workplace risk assessment and take all the preventive measures necessary to eliminate or reduce these risks. Clearly, such a scenario would be a step backward for the health and safety of workers exposed to these chemicals.

The ETUC's position

The European Trade Union Confederation (ETUC) took a stance on the draft GHS Regulation in the EU⁵ for the public consultation issued by the Commission. In its response to the Commission, the ETUC welcomed the choice of a regulation to implement GHS in the EU, which would then make it directly applicable in the 27 Member States.

The ETUC also voiced concerns about some aspects of the proposal, especially the way in which the potential effects of the regulation on downstream legislations will be addressed. Some substances and preparations not classified in the current Community system will be classified in the new GHS. This could increase the number of substances and preparations that fall within the scope of downstream legislation.

The Commission proposes amending the classification criteria references in downstream legislation so as to minimise the GHS system's impacts on industry.

There have already been industry calls for the Commission to "uncouple" downstream legislation on dangerous substances and preparations classification before adopting the new GHS system. Any such levelling-down is not acceptable to workers.

⁵ <http://hesa.etui-rehs.org/uk/dossiers/files/ETUC-GHS-EN.pdf>.

Another issue of concern for the ETUC is that of taking manufacturers' obligations to supply the ECHA with an inventory of substances they have classified and labelled as hazardous out of the REACH regulation and putting it into the GHS Regulation. This could be an opportunity for industry to throw this gain into question to the disadvantage of workers, who will be better off with a harmonised classification for the same substance.

In its response to the Commission, the ETUC also argues that if a globally harmonized system is to be guaranteed, the EU needs to implement all the hazard categories specified in the GHS proposal. In cases where an existing category is not replaced, or where by replacing individual categories the GHS leads to a lowering of the current EU classification, the ETUC believes the latter should be kept.

Similarly, deleting substances currently classified in Annex I of Directive 67/548/EEC by the automatic application of the new GHS criteria is not acceptable. The ETUC does not want any individual chemical taken off the list of EU-classified hazardous substances until it has been further documented and re-assessed in terms of its (eco)-toxicological properties.

Next steps

The Commission believes that Parliament and Council could get to an agreement on the final text of the GHS Regulation towards the end of 2008 or early 2009. Only after this co-decision procedure will the regulation come into effect in the 27 EU countries. The transitional period during which the old and new systems will operate in tandem will be a testing time for manufacturers, importers and distributors of chemicals, as they have to phase in the new system. It will also be tough on the millions of European workers across all sectors who use chemicals and will have to get used to new labels, bearing in mind that they are often the only source of information available on the dangers of chemicals used in workplaces.

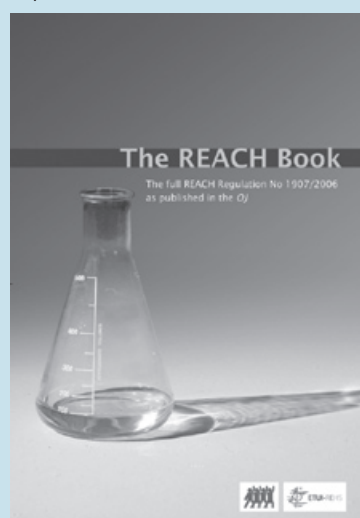
The Commission set up a working group in January 2007 to draw up guidance⁶ in order to help firms implement the GHS Regulation. It is also important for the trade unions to make an early start on informing and training workers in the future harmonised chemicals classification and labelling system. Workers' reps will also have to keep a particularly sharp watch on how existing worker protection laws are adapted to the new GHS Regulation. The European trade unions are clear on the fact that introducing the GHS system into Community law must not only preserve current levels of protection of human health and the environment, but also be an opportunity to raise them. ■

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⁶ RIP 3.6: *Guidance on Classification and Labelling under GHS* (Jan 2007).

The REACH Book

The full REACH Regulation No 1907/2006 as published in the *OJ*



The ETUI-REHS Health and Safety Department is publishing a softback version of the full text of the REACH Regulation (apart from Annex XVII) and Directive 2006/121/EC on the classification, packaging and labelling of dangerous substances.

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