

Globally Harmonised System (GHS) to merge with EU Directive and become a Regulation

New classifications with GHS

The GHS (United Nations Global Harmonization of Systems for classification of chemicals) will replace the current substance directive and the current preparation directive in the EU. The new classification and labelling system will in many ways be similar to EU's current system. Principles for classification and labelling of mixtures of several substances (preparations) have been determined. However, since the criteria for classification vary from those of the EU in several areas, this will mean that many substances and preparations will be classified differently under GHS compared to the EU rules. Furthermore, substances and preparations not classified under the current system may be classified according to GHS. These differences will be negotiated during the coming year.

New hazard symbols

The current hazard symbols are replaced by new pictograms for physical-chemical hazards, health hazards and environmental hazards respectively. Instead of the current hazard terms the concept of signal words is introduced. Finally, the R- and S-phrases as we know them today within EU will be replaced with new hazard phrases and phrases describing relevant safety precautions.

Background

The aim with GHS is to create a harmonized system for classification and labeling of substances, with Safety Data Sheets and easily understandable pictograms and signal words. The GHS system includes substances and preparations and covers biocides and pesticides. GHS is a hazard based system with four classes: consumers; transportation; emergency; and workplace. Within the four classes hazard categories are established. The GHS system intends to harmonize existing classification systems in different countries.

The aim of the European Commission is to let the GHS system enter into force parallel to the implementation of the REACH regulation. Directorate-General Enterprise and Industry (DG Ent) is responsible for GHS mixtures work but DG Environment (DG Env) is responsible for co-ordination of the GHS program.

The proposed Regulation is discussed by the European Parliament and the Council under the co-decision procedure. An optimistic time perspective for the European parliament's possible decision is mid 2008 and more realistically at the end of the year or first quarter of 2009.

After entry into force the deadline for substance reclassification is proposed to be 1 December 2010 and for mixtures 1 June 2015. The GHS system has already been ratified by the UN and implemented in a number of developing countries.

Controversial Points that Needs Attention

The Building Block Approach is Challenged by ChemSec

"countries are free to determine which of the building blocks will be applied in different parts of their systems...the elements of the GHS may thus be seen as a collection of building blocks from which to form a regulatory approach..."

The idea with the building block approach is that individual countries should be able to adjust GHS components appropriate to their legislation. As an example the European Commission wants to keep its four classes instead of embarking on GHS five categories for acute toxicity for consumers' articles. Both hazard classes and hazard categories may be interpreted as building blocks. The text may also be interpreted vertically: each country or (or the EU) may decide to adopt hazard pictograms without the linkage to a particular safety phrase or a certain hazard statement.

The EU Commission's wish is not to include any new categories into the new regulation on classification and labeling of substances, but ChemSec emphasize that all countries must embrace the whole GHS.

The Lack of Acute Toxicity Category 5 in the EU Proposal is Challenged

One main issue with the building block approach in the EU is the classification of acute toxicity. The GHS system has five categories versus the EU's four. Category 5 would contain chemicals of relative low acute toxicity but which may present a danger to vulnerable parts of the population such as children, elderly, and sick. The current EU classification does not cover all chemicals that would be classified under GHS category 5, this is in particular relevant for mixtures. Without category 5, thousands of products presently classified in the EU system will be excluded during the new classification regime. The Swedish Chemical Agency estimates that almost one third or more of the currently harmful products no longer will be classified! The agency argues that category 5 must be introduced for consumer products. To highlight one example; propanol used for cleaning car windows is highly toxic for children, but would not be labeled as toxic. The chemical industry, the Directorate-General for Enterprise and Industry and many member states oppose category 5.

ChemSec is of the opinion that Acute Toxicity Category 5 must be a part of the new EU regulation.

If EU, a region with an elaborate hazard classification system, does not accept the GHS fully, it will send strange signals to the developing countries, which will or has already adopted the complete GHS. Both South Africa and Brazil have for instance reached far in the implementation of the entire GHS classification and labeling of substances. Russia is struggling with a new chemical legislation and wants one single global system with all the classification categories, and if EU does not; what impact will it have on the Russian legislation?

What will happen with the trade which GHS is supposed to facilitate? In the export/import scenario when a commodity labeled in a particular way chosen by a country arrives at a port in another country which does not have the same labeling and classification – nothing will be gained and confusion will prevail.

ChemSec is of the opinion that the GHS version must be entirely adopted and reinforced where the EU directives are more rigors.

Germ Cell Mutagenicity Category 2 must be kept

The current EU wording is more stringent than the wording in the GHS system. GHS requires that it must be proven that a substance interact with the gem cells, while current EU wording states that it has to be shown that the substance reach the gem cells. I.e. the EU wording is more precautionary than the GHS. ChemSec is of the opinion that the EU version must prevail.

List of Classified Substances

The current EU directives include an inventory of classified substances in the EU. In the proposed new EU Regulation Annex VI will have a list of harmonized classification and labelling for certain hazardous substances. It will be possible for suppliers to reclassify existing products, but it may lead to a weaker classification than the present. For some hazards the criteria in the two systems are similar and easily transferred into GHS. For others, as for acute toxicity, the classifications in EU and GHS are not coherent and equivalences are needed to transfer the classifications from EU to GHS system.

It is ChemSec's opinion that reclassification of substances and articles to a lesser hazard category under the new regulation must not be possible.

The present EU list in Annex I in Directive 67/548/EEC is the most elaborate and widely used reference source for substances in the world. It is therefore essential that the EU persuades parties to the GHS to amend this list to the GHS. Germany and Sweden have encouraged the EU to take this approach, and the final report from Milieu 2005, launched by the EU Commission, made the same conclusion.

Interpretation of test results

Test results are the basis for hazardous classification. But the results could very well be interpreted differently within the EU as compared to the countries in America, Japan or elsewhere. It needs to be clarified how this should be dealt with at a global level.

ChemSec is of the opinion that ambiguous interpretation of test results must be avoided, and that a coherent guidance document is established under GHS to avoid misinterpretation.

GHS vs current EU Classification and Labelling of substances and preparations

Similarities

- One single system for hazard classification and labelling covers approximately the same hazards
- Uses often similar or equal classification criteria
- Equivalent system of hazard communication

Differences

- GHS sets criteria for both transport and supply/use
- GHS defines further hazard classes and categories
- GHS uses partly other criteria cut-offs
- GHS uses a different approach for mixtures
- GHS changes some labelling elements

Elements currently not in GHS but part of the EU system with risk phrases (R)

Health properties

- R66 Repeated exposure may cause skin dryness or cracking
- R67 Vapours may cause drowsiness and dizziness (included in 3.8, STOT- single exposure)
- R29 Contact with water liberates toxic gas
- R31 Contact with acids liberates toxic gas
- R32 Contact with acids liberates very toxic gas
- R33 Danger of cumulative effects (replaced by 3.9, STOT-repeated exposure)

The proposed regulation requires companies to classify, label and package their substances and mixtures before placing them on the market. It aims to protect workers, consumers and the environment by labelling which should reflect possible hazards of a particular chemical.

The proposed regulation also takes over provisions of the REACH Regulation regarding the notification of classifications, the establishment of a list of harmonised classifications and the creation of a classification and labelling inventory.

GHS will be implemented together with REACH

GHS will be implemented in the EU at the same time as implementation of REACH, as the two systems are closely connected, but REACH does not cover classification and labeling of substances which will be incorporated in a new regulation replacing directive 67/548/EEG (substances) directive 1999/45/EG (preparations).

The International Chemical Secretariat will follow the implementation process in the EU and the rest of the world. Although it is called a "globally harmonized system", there is still room for a number of regional and national differences when the regulation is implemented.