

Chemicals: classification, labelling and packaging of substances and mixtures

2007/0121(COD) - 27/06/2007 - Legislative proposal

PURPOSE: to establish a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nations. **PROPOSED ACT:** Regulation of the European Parliament and of the Council.

CONTENT: Chemicals are manufactured and traded globally, and their hazards are the same around the world. Therefore the description of hazards should not differ between countries if the product is the same. If the same criteria are used to identify the hazards of chemicals and the same labelling is used to describe them, the level of protection of human health and the environment becomes more consistent, transparent and comparable throughout the world. Professional users of chemicals and consumers all over the world benefit from such a harmonisation. In addition, enterprises will save costs if they do not have to assess hazard information for their chemicals against different sets of criteria.

This proposal builds on existing chemicals legislation and establishes a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It addresses supply and use of chemicals and, therefore, the main target audience are workers and consumers, as is the case for the current EU system.

The aim is to ensure a level playing field for all suppliers of substances and mixtures in the internal market, as well as a high level of protection of health, safety, environment and consumers. The proposal aims to ensure that the requirements for substances and mixtures are harmonised and that substances and mixtures complying with them can move freely throughout the internal market. This rewards the efforts required from economic actors to reclassify substances and mixtures.

To this end, the proposed Regulation takes a fivefold approach based on the GHS:

- 1) it harmonises the classification, labelling and packaging rules for substances and mixtures;
- 2) it obliges enterprises to classify their substances and mixtures themselves;
- 3) it obliges enterprises to notify the classifications;
- 4) it establishes a harmonised list of substances classified at Community level in Annex VI;
- 5) it establishes a classification and labelling inventory, made up of all notifications and harmonised classifications referred to above.

The Regulation applies to substances and mixtures. However, since the physical hazards of substances or mixtures are to some extent influenced by the way in which they are released, the Regulation also covers release by aerosols through a specific hazard class. Radioactive substances are excluded from the scope, as they are covered by other rules. Substances and mixtures subject to customs supervision are also excluded, subject to certain conditions, as they are not supplied in the EU. Substances and mixtures for scientific research and development not placed on the market are also excluded when used under controlled conditions minimising exposure.

The essential terms are defined. Following the GHS, the term “preparation” is replaced by “mixture”.

Annex I lists the hazard classes of the GHS, as well as the relevant hazard categories and criteria. If a substance or a mixture fulfils the criteria for any hazard class, it is hazardous. The Commission is empowered to update Annex I and to include new hazard classes agreed at UN level. The concept of “dangerous” is also laid down, in order to allow minimising effects on downstream legislation.

The label elements from the GHS are specified, i.e. the name, address and telephone number of the supplier, product identifiers, hazard pictograms, signal words, hazard statements and precautionary statements. To maintain the level of protection of current EU law, supplemental information on hazards not yet included in the GHS must also be mentioned. Furthermore, the nominal quantity in the package, as placed on the market to the general public, has to be indicated. To protect confidential business information, it is possible to apply for permission to use a name that does not reveal the substance’s chemical identity. The Agency established by the REACH Regulation will decide on such applications. Principles of precedence for labelling are specified. The supplier has to update the label after changes to the classification, unless the labels are part of an approval decision concerning a biocide or a plant protection product. In the latter case, the applicable special legislation has to be complied with.

To ensure that customers notice hazard information, there are rules on the colours and format of labels and on the location of information on labels.

To reduce the burden on enterprises and to avoid the duplication of transport labels, there are provisions determining which labels to use in case of inner and outer packages.

Safety measures for containers and other packages are set out.

Certain provisions of the REACH Regulation are moved to this Regulation, with regard to the notification to the Agency and establishing the classification and labelling inventory.

Member States must to appoint the authorities for the application and enforcement of this Regulation. Good cooperation between all competent authorities is essential. To bundle information on human health, as under current legislation, one body per Member State is responsible for receiving health-related information. To enhance the exchange of practical experience, the Agency’s Forum established by the REACH Regulation shall also exchange enforcement information under this Regulation.

Lastly, Member States have to establish proportionate sanctions for non-compliance.