Chemicals: classification, labelling and packaging of substances and mixtures

2007/0121(COD) - 03/09/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted, by 604 votes to 9 with 13 abstentions, a legislative resolution amending 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. The report had been tabled for consideration in plenary by Amalia **SARTORI** (EPP-ED, IT) on behalf of the Committee on the Environment, Public Health and Food Safety. The amendments were the result of a compromise between Parliament and Council.

The main amendments were as follows :

Purpose of the Regulation: the Regulation aims to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures by:

- harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;
- providing an obligation for manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
- enabling suppliers to label and package substances and mixtures placed on the market;
- enabling manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under the REACH Regulation;
- providing an obligation for manufacturers and importers of substances to notify the Agency, of such classifications and labelling elements if these have not been submitted to the Agency as part of a registration under REACH;
- establishing a list of substances with their harmonised classifications and labelling elements at Community level;
- establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements.

Scope: Parliament did not accept the Environment Committee’s amendment relating to exclusion from the scope for substances and mixtures for scientific research which are placed on the market at an annual volume below 1 tonne per supplier. The text now states that the Regulation does not apply to substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under controlled conditions in accordance with Community workplace and environment legislation. Furthermore, Member States may allow for exemptions from this Regulation in specific cases for certain substances or mixtures, where necessary in the interests of defence.

Definitions: the term "mixture" as defined in this Regulation has the same meaning as the term "preparation" previously used in Community legislation. In addition, Parliament inserted several new terms into the text.

Labelling: the label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise. The product identifier for a mixture shall consist of both the trade name or the designation of the mixture and the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration

hazard. Statements such as “non-toxic”, “non-harmful”, “non-polluting”, “ecological” or other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with its classification should not appear on the labels or packaging of hazardous substances or mixtures.

Deadline for labelling update: the supplier must ensure that the label is updated, without undue delay, following any change to the classification and labelling of that substance or mixture, where the new hazard is more severe or where new supplemental labelling elements are required. Where labelling changes are required other than those referred to above, the supplier shall ensure that the label is updated within 18 months.

SMEs: when there is a request for use of an alternative chemical name, SMEs shall pay a reduced fee. The Agency should study the possibilities for further simplification of the notification procedure in particular taking the needs of SMEs into account.

Bodies responsible for information: Member States shall appoint a body or bodies responsible for receiving information for formulating preventative and curative measures, in particular in case of emergency health response. Three years after entry into force the Commission shall assess possibility to harmonise information.

Information to the public: within three years from the entry into force of the Regulation, the Agency shall carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels.

Animal and human testing: where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no other alternatives, which provide an adequate reliability and quality of data, are possible. Tests on non-human primates are prohibited. Tests on humans must not be performed. Data obtained from other sources, such as clinical studies, can however be used for the purposes of the Regulation.

PBT labelling: Member States and the Commission shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of PBT or vPvB at the level of the UN.

Lastly, it should be recalled that the reclassification and labelling of most substances must be completed by 1.12.2010 for substances and 1.6.2015 for mixtures. The current Directives on classification, labelling and packaging will be repealed on 1 June 2015. During a transitory period both systems will be applied.