Chemicals: classification, labelling and packaging of substances and mixtures

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The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Amalia **SARTORI** (EPP-ED, IT) and made some amendments to 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 committee attempted, where possible, to align the text with GHS texts.

The main amendments are as follows :

Scope: the Regulation will not apply to substances and mixtures for scientific research and development or for process oriented research and development, which are not placed on the market or are placed on the market at an annual volume below 1 tonne per supplier. The Commission had excluded from the scope substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under such controlled conditions minimising exposure as if they were classified as carcinogenic, germ cell mutagenic or toxic to reproduction (CMR) category 1A or 1B according to Annex I, but the Committee did not accept this. The latter added that the list of the substances with their harmonised classifications and labelling should be available for the public.

Definition: preparation means a mixture or solution composed of two or more substances; mixture and preparation are synonyms.

Minimum threshold value for notification to the Agency: Members stated that the obligation, starting from 1 December 2010, to notify the Agency for the purposes of the classification inventory should not apply to every case in which a substance subject to registration is to be placed on the market, but only to substances classified as hazardous, including where REACH is concerned. For a substance classified as hazardous on its own or in a mixture, a threshold of 1 tonne a year is laid down.

PBT labelling: the Agency shall, in accordance with Article 123 of Regulation (EC) No 1907/2006, provide as a matter of high priority, and in consultation with the Commission, competent authorities and stakeholders, guidance and/or recommendations for any supplemental information on the label that is considered necessary for the protection of human health or the environment when a mixture contains substances with persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties in excess of 0.1%. In addition, Members stipulated that the Commission shall promote the harmonisation of the labelling of PBT and vPvB at the level of the United Nations and shall, as appropriate, subsequently adjust and adapt sections 1.1 and 1.2 of Annex II and part 2 of Annex III referred to in Article 27(1) and/or part 2 of Annex II and part 3 of Annex III referred to in Article 24.

Labelling: in the case of natural materials, a designation such as 'essential oil from ...' or ' ... extract' may be used instead of the names of the components of this essential oil or extract.

Deadline for labelling update: the supplier of a substance or a mixture shall take all appropriate measures to update the label following any change to the classification and labelling of the substance or mixture, without delay and in any case not later than twelve months after the change of classification.

Tests on humans: tests on humans for the sole purpose of this Regulation are generally not acceptable and shall only be undertaken when no other alternatives are possible to ensure the best protection of

human health and the classification of a substance or mixture according to its actual effects on human health. Tests on non-human primates shall not be performed for the purposes of this Regulation. The Commission proposal contained a prohibition on testing on humans and animals.

Animal testing: where new tests are carried out for the purposes of this Regulation, tests on animals shall be undertaken only where no other alternatives, which provide the same level of reliability and quality of data, are possible. Testing methods shall be regularly reviewed with a view to reducing testing on vertebrate animals and the number of animals involved. The committee added that validation studies to assess non-animal tests, or methods that reduce the number of animals used or the suffering experienced by test animals, shall be designed to ensure that new test methods take account of the requirements of the Regulation and similar legislation implementing the Globally Harmonised System of Classification and Labelling of Chemicals in other jurisdictions so that classification and labelling requirements do not become a barrier to the replacement, reduction and refinement of animal testing.

Evaluation of data: when evaluating the data the manufacturer or importer shall consider additional information such as the form and/or physical state in which the substance or mixture is used after it is placed on the market and may refine the classification accordingly. Normal handling and use should be taken into consideration in the classification of a substance or mixture. Where a specific product sector group has established a Hazard and Classification Centre, which brings together expertise in the evaluation of information, test data, weight of evidence determinations, and bridging principles, any supplier within the product sector may rely on an evaluation from that centre for the establishment of the hazards associated with, and the corresponding classification of, the mixture.

Packaging: the committee added several clauses amending the provisions on packaging relating to, inter alia, packaging containing 125 ml or less, if the substance or mixture is classified as Chronically Aquatic Hazardous of category 3 or 4; hazard and precautionary statements regarding substances or mixtures in small or unsuitable packaging; packaging for single use; packaging of substances and mixtures destined for the general public and fulfilling the criteria for Hazard Class 2.16. An additional Article was added on the labelling of detergents.

Guidance by the Agency: the supplier of a substance or a mixture intended for use by the general public shall label the product in accordance with the guidance provided by the Agency for the communication of information to the general public on the risks and safe use of chemical substances and mixtures, as provided for in Regulation (EC) No 1907/2006.

New Article 40(a): a new article entitled classification and labelling of hazardous substances under Directive 67/548/EEC for hazard categories other than those specified in Article 38(1) is inserted. It states that the classifications and forms of labelling set out in the new part 4 of Annex VI may be applied by suppliers. Where a supplier decides not to apply those classifications and forms of labelling, he shall be required to re-evaluate the substance in question on the basis of the criteria laid down in parts 2 to 5 of Annex I.

The committee noted that in the Commission proposal, Annex VI, part 3, has binding force. It proposed adding a part 4 setting out classifications and forms of labelling for hazardous substances which have already been the subject of Community harmonisation under Directive 67/548/EEC in connection with hazard categories other than those specified in Article 38. Part 4 on Annex VI is to be considered a non-binding reference tool for the use of the authorities and industry.

Accidents: every year Member States shall submit to the European accident database set up under the EHLASS programme (European Home and Leisure Accident Surveillance System) data detailing the number of accidents, and the mixtures involved, in respect of which appointed bodies have received requests for medical information concerning treatment and curative measures.

Comitology: the Commission must adopt Annex VIIa and may adjust and adapt Annexes I to VIIa to technical and scientific progress in accordance with the regulatory procedure with scrutiny. The Commission shall take due account of the further development of the GHS within the United Nations, developments in international chemical programmes and conventions, data from accident databases, such as poison information units and the European Home and Leisure Accident Surveillance System (EHLASS), and the validation of alternative tests by ECVAM.