Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation.

(2) The efficient functioning of the internal market for substances, mixtures and those articles can be achieved only if the requirements applicable to them do not differ significantly between Member States.

(3) A high level of human health and environmental protection should be ensured in the approximation of legislation on the criteria for classification and labelling of substances and mixtures, with the goal of achieving sustainable development.

(4) Trade in substances and mixtures is an issue relating not only to the internal market, but also to the global market. Enterprises should therefore benefit from the global harmonisation of rules for classification and labelling and from consistency between, on the one hand, the rules for classification and labelling for supply and use and, on the other hand, those for transport.

(5) With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling have been carefully developed over a period of 12 years within the United Nations (UN) structure, resulting

in the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as 'the GHS').

(6) This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law.

(7) The benefits for enterprises will increase as more countries in the world adopt the GHS criteria in their legislation. The Community should be at the forefront of this process to encourage other countries to follow and with the aim of providing a competitive advantage to industry in the Community.

(8) Therefore it is essential to harmonise the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the GHS, but also by building on the 40 years of experience obtained through implementation of existing Community chemicals legislation and maintaining the level of protection achieved through the system of harmonisation of classification and labelling, through Community hazard classes not yet part of the GHS as well as through current labelling and packaging rules.

(9) This Regulation should be without prejudice to the full and complete application of Community competition rules.

(10) The objective of this Regulation should be to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated. Such properties should include physical hazards as well as hazards to human health and to the environment, including hazards to the ozone layer.

(11) This Regulation should, as a general principle, apply to all substances and mixtures supplied in the Community, except where other Community legislation lays down more specific rules on classification and labelling, such as Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[(3)], Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[(4)], Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production[(5)], Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[(6)], Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[(7)], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(8)], Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(9)], Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council[(10)], Directive 2001/82/EC of the European Parliament and of the Council of 6 November

2001 on the Community code relating to veterinary medicinal products[11], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[12], Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[13] and Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[14] or except where substances and mixtures are transported by air, sea, road, rail or inland waterways.

(12) The terms and definitions used in this Regulation should be consistent with those set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[15], with those set out in the rules governing transport and with the definitions specified at UN level in the GHS, in order to ensure maximum consistency in the application of chemicals legislation within the Community in the context of global trade. The hazard classes specified in the GHS should be set out in this Regulation for the same reason.

(13) It is especially appropriate to include those hazard classes defined in the GHS which specifically take account of the fact that the physical hazards which may be exhibited by substances and mixtures are to some extent influenced by the way in which they are released.

(14) The term ‘mixture’ as defined in this Regulation should have the same meaning as the term ‘preparation’ previously used in Community legislation.

(15) This Regulation should replace Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[16] as well as Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[17]. It should maintain the overall current level of protection of human health and the environment provided by those Directives. Therefore, some hazard classes which are covered by those Directives but are not yet included in the GHS should be maintained in this Regulation.

(16) Responsibility for the identification of hazards of substances and mixtures and for deciding on their classification should mainly lie with manufacturers, importers and downstream users of those substances or mixtures, regardless of whether they are subject to the requirements of Regulation (EC) No 1907/2006. In fulfilling their responsibilities for classification, downstream users should be allowed to use the classification of a substance or mixture derived in accordance with this Regulation by an actor in the supply chain, provided that they do not change the composition of the substance or mixture. Responsibility for classification of substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006 should mainly lie with the manufacturers, producers of articles

and importers. However, there should be a possibility to provide for harmonised classifications of substances for hazard classes of highest concern and of other substances on a case-by-case basis which should be applied by all manufacturers, importers and downstream users of such substances and of mixtures containing such substances.

(17) Where a decision has been taken to harmonise the classification of a substance for a specific hazard class or differentiation within a hazard class by including or revising an entry for that purpose in Part 3 of Annex VI to this Regulation, the manufacturer, importer and downstream user should apply this harmonised classification, and only self-classify for the remaining, non-harmonised hazard classes or differentiations within the hazard class.

(18) To ensure that customers receive information on hazards, suppliers of substances and mixtures should ensure that they are labelled and packaged in accordance with this Regulation before placing them on the market, according to the classification derived. In fulfilling their responsibilities downstream users should be allowed to use the classification of a substance or mixture derived in accordance with this Regulation by an actor in the supply chain, provided that they do not change the composition of the substance or mixture, and distributors should be allowed to use the classification of a substance or mixture derived in accordance with this Regulation by an actor in the supply chain.

(19) To ensure information on hazardous substances is available when they are included in mixtures containing at least one substance that is classified as hazardous, supplemental labelling information should be provided, where applicable.

(20) While a manufacturer, importer or downstream user of any substance or mixture should not be obliged to generate new toxicological or eco-toxicological data for the purpose of classification, he should identify all relevant information available to him on the hazards of the substance or mixture and evaluate its quality. The manufacturer, importer or downstream user should also take into account historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure and effect data, and clinical studies. That information should be compared with the criteria for the different hazard classes and differentiations in order for that manufacturer, importer or downstream user to arrive at a conclusion as to whether or not the substance or mixture should be classified as hazardous.

(21) While the classification of any substance or mixture may be carried out on the basis of available information, the available information to be used for the purposes of this Regulation should preferably have been generated in accordance with the test methods referred to in Regulation (EC) No 1907/2006, transport provisions or international principles or procedures for the validation of information, so as to ensure quality and comparability of the results and consistency with other requirements at international or Community level. The same test methods, provisions, principles and procedures should be followed where the manufacturer, importer or downstream user chooses to generate new information.

(22) To facilitate hazard identification for mixtures, manufacturers, importers and downstream users should base this identification on the data for the mixture itself, where available, except for mixtures with carcinogenic, germ cell mutagenic or reproductive toxic substances, or where the biodegradation or bioaccumulation properties in the hazard class hazardous to the aquatic environment are evaluated. In those cases, as the hazards of the mixture cannot be sufficiently assessed in a manner that is based on the mixture itself, the data for the individual substances of the mixture should normally be used as a basis for the hazard identification of the mixture.

(23) If sufficient information is available on similar tested mixtures, including relevant ingredients of the mixtures, it is possible to determine the hazardous properties of an untested mixture by applying certain rules known as 'bridging principles'. Those rules allow characterisation of the hazards of the mixture without performing tests on it, but rather by building on the available information on similar tested mixtures. Where no or inadequate test data are available for the mixture itself, manufacturers, importers and downstream users should therefore follow the bridging principles to ensure adequate comparability of results of the classification of such mixtures.

(24) Specific industry sectors may establish networks to facilitate exchange of data and bring together expertise in the evaluation of information, test data, weight of evidence determinations and bridging principles. Such networks may support manufacturers, importers and downstream users within those industry sectors, and in particular small and medium-sized enterprises (SMEs) in the fulfilment of their obligations under this Regulation. Those networks may also be used to exchange information and best practices with a view to simplifying fulfilment of the notification obligations. Suppliers making use of such support should remain fully responsible for the fulfilment of their classification, labelling and packaging responsibilities under this Regulation.

(25) The protection of animals falling within the scope of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[(18)] is of high priority. Accordingly, where the manufacturer, importer or downstream user chooses to generate information for the purposes of this Regulation, they should first consider means other than testing on animals within the scope of Directive 86/609/EEC. Tests on non-human primates should be prohibited for the purposes of this Regulation.

(26) The test methods in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[(19)] are regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The European Centre for the Validation of Alternative Methods (ECVAM) of the Commission's Joint Research Centre plays an important role in the scientific assessment and validation of alternative test methods.

(27) The classification and labelling criteria set out in this Regulation should take the utmost account of promoting alternative methods for the assessment of hazards of substances