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to :	Permanent representatives Committee (Part 1)
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No. Cion prop. :	11497/07 COMPET 213 ENV 382 CHIMIE 17 MI 177 ENT 85 CODEC 759
Subject :	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 Annex to this Note sets out the draft compromise text resulting from the informal trialogue on 19 June 2008. It is intended for presentation to the Permanent Representatives Committee at its meeting on 27 June 2008.

This Annex contains a clean text. In document DS 655/08, which is the same text, the changes to the Commission proposal are indicated.

ANNEX

2007/0121 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on classification, labelling and packaging of substances and mixtures, and amending Directives 67/548/EEC and 1999/45/EC and Regulation (EC) No 1907/2006

(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[1]

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

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 from Member State to Member State.

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(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 not only an issue of the internal market, but also of 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 "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 is without prejudice to the full and complete application of the Community competition rules.

(10) The objective of this Regulation is 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 identif**ied** and communicated. Such properties should include physical hazards as well as hazards to human health and to the environment, including hazards for 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 Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[4], Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[5], 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[6], Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption[7], 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[8], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[9], Directive 98/79 of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[10], 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 of 28 October 1996[11], Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary

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4 OJ L 262, 27.9.1976. Directive as last amended by Commission Directive 2005/80/EC (OJ L 303, 22.11.2005, p. 32).

5 OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

6 OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003.

7 OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.

8 OJ L 189, 20.7.1990, p. 17.

9 OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

10 OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

11 OJ L 84, 27.3.1999, p. 1. Decision as last amended by Commission Decision 2006/22/EC (OJ L 91, 29.3.2006, p. 48).

medicinal products[12], 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[13], 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[14] 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[15] or where substances and mixtures are transported by air, sea, road, rail or inland waterways.

(12) [Deleted]

(13) 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[16], 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.

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12 OJ L 311, 28.11.2001, p. 1.
13 OJ L 311, 28.11.2001, p. 67.
14 OJ L 31, 1.2.2002, p. 1.
15 OJ L 268, 18.10.2003, p. 29. Regulation as last amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
16 OJ L 396, 30.12.2006, p. 1.

(13a) The term mixture as defined in this Regulation should have the same meaning as the term preparation previously used in Community legislation.

(14) 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.

(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[17] 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[18]. 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.

[17] OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

[18] OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).

(16) Responsibility for the identification of hazards of substances and mixtures and for deciding on their classification should mainly lie with the 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 for 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 the hazards suppliers of substances and mixtures should ensure that substances or mixtures are labelled and packaged in accordance with the provisions of this Regulation before placing them on the market, according to the classification derived. In fulfilling their responsibilities hereto downstream users should be allowed to use the classification for 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 for 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 him 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 according to 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 and 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, 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 assessed sufficiently 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.

(23a) Specific product 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 that product sector, and in particular SMEs in the fulfilment of their obligations under this Regulation. The network 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.

(24) 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[19] is of high priority. Accordingly, where the manufacturer, importer and downstream user chooses to generate information for the purposes of this Regulation, he 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.

[19] OJ L 358, 18.12.1986, p.1. Directive as last amended by Directive 2003/65/EC (OJ L 230, 16.9.2003, p. 32).

(24a) The test methods in Commission Regulation No.440/2008[20] 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 European Commission's Joint Research Centre plays an important role in the scientific assessment and validation of alternative test methods.

(24b) The classification and labelling criteria of this Regulation should take the utmost account of promoting alternative methods for the assessment of hazards of substances and mixtures and of the obligation to generate information on intrinsic properties by means other than tests on animals within the meaning of Directive 86/609/EEC as laid down in Regulation No. 1907/2006. Future criteria should not become a barrier to this aim and the corresponding obligations under that Regulation, and should under no circumstances lead to the use of animal tests where alternative tests are adequate for the purposes of classification and labelling.

(25) [Deleted]

(26) For the purposes of classification, data should not be generated by means of testing on humans. Available, reliable epidemiological data and experience with regard to the effects of substances and mixtures on humans (e.g. occupational data and data from accident databases) should be taken into account and may be given priority over data derived from animal studies when they demonstrate hazards not identified from those studies. Results of animal studies should be weighed against results of data from humans and expert judgement should be used to ensure the best protection of human health when evaluating both the animal and human data.

(26a) New information as regards physical hazards should always be necessary, except if the data are already available or if a derogation is foreseen in part 2 of Annex 1 of this Regulation.

[20] OJ L 142, 31.5.2008, p.1.

(27) Testing that is carried out for the sole purpose of this Regulation should be carried out on the substance or mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably **be expected to be used**. It should, however, be possible to use, for the purpose of this Regulation, the results of tests that are carried out to comply with other regulatory requirements, including those laid down by third countries, even if the tests were not carried out on the substance or mixture in the form in which it is placed on the market and in which it can reasonably be expected to be used.

(27a) If tests are performed, they should comply where appropriate with the relevant requirements of protection of laboratory animals, set out in Directive 86/609/EEC, and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances[21].

(28) The criteria for classification in different hazard classes and differentiations are set forth in Annex I, which also contains additional provisions as to how the criteria may be met.

(29) Recognising that the application of the criteria for the different hazard classes to information is not always straightforward and simple, manufacturers, importers and downstream users should apply weight of evidence determinations involving expert judgment to arrive at adequate results.

[21] OJ L 50, 20.02.2004, p. 44.

(30) Specific concentration limits for substances should be assigned to a substance by a manufacturer, importer or downstream user in accordance with the criteria referred to in this Regulation, provided the manufacturer, importer or downstream user is able to justify the limits and informs the European Chemicals Agency, hereinafter “the Agency”, accordingly. However, specific concentration limits should not be set for harmonised hazard classes or differentiations for substances included in part 3 of Annex VI of this Regulation. Guidance should be provided by the Agency for the purpose of setting the specific concentration limits. In order to ensure uniformity, specific concentration limits should also be included, where appropriate, in cases of harmonised classifications. Specific concentration limits should take precedence over any other concentration limit for the purpose of classification.

(30a) Multiplying factors ("M-factors") for substances classified as hazardous for the aquatic environment, acute category 1 or chronic category 1, should be assigned to a substance by a manufacturer, importer or downstream user in accordance with the criteria referred to in this Regulation. Guidance should be provided by the Agency for the purpose of setting the multiplying factors.

(31) For reasons of proportionality and workability, generic cut-off values should be defined, both for identified impurities, additives and individual constituents of substances and for substances in mixtures, specifying when information on these should be taken into account in determining the hazard classification of substances and mixtures.

(32) To ensure adequate classification of mixtures, available information on synergistic and antagonistic effects should be taken into account for the classification of mixtures.

(33) Manufacturers, importers and downstream users should re-evaluate the classifications of substances or mixtures they place on the market if they become aware of new adequate and reliable scientific or technical information that may affect the classification or if they change the composition of their mixtures to ensure that the classification is based on up-to-date information, unless there is sufficient evidence that the classification would not change. Suppliers should update the labels accordingly.

(34) Substances and mixtures classified as hazardous should be labelled and packaged according to their classification, so as to ensure appropriate protection and to provide essential information to their recipients, by drawing their attention to the hazards of the substance or mixture.

(35) The two instruments foreseen by this Regulation to be used to communicate the hazards of substances and mixtures are labels and the safety data sheets provided for in Regulation (EC) No 1907/2006. Of these two, the label is the only tool for communication to consumers, but it may also serve to draw the attention of workers to the more comprehensive information on substances or mixtures provided in safety data sheets. Since the provisions on safety data sheets are included in Regulation (EC) No 1907/2006 which uses the safety data sheet as the main communication tool within the supply chain of substances, it is appropriate not to duplicate the same provisions in this Regulation.

(35a) To ensure proper and comprehensive information provision to consumers on the hazards and safe use of chemicals and mixtures, the use and dissemination of Internet sites and freephone numbers should be promoted, particularly in connection with information provision on specific types of packaging.

(36) Workers and consumers worldwide would benefit from a globally harmonised hazard communication tool in the form of labelling. Therefore, the elements to be included in labels should be specified in accordance with the hazard pictograms, signal words, hazard statements and precautionary statements which form the core information of the GHS system. Other information included in labels should be limited to a minimum and should not call into question the main elements.

(37) It is essential that the substances and mixtures placed on the market are well identified. However, the Agency should allow enterprises, upon their request and where necessary, to describe the chemical identity of certain substances in a way that does not put the confidential nature of their businesses at risk. Where the Agency refuses such a request an appeal should be allowed in accordance with the provisions of this Regulation. The appeal should have a suspending effect, so that the confidential information with regard to which the request has been made, should not appear on the label while the appeal is pending.

(38) The International Union of Pure and Applied Chemistry (IUPAC) is a long standing global authority on chemical nomenclature and terminology. Identification of substances by their IUPAC name is widespread practice worldwide and provides the standard basis for identifying substances in an international and multilingual context. It is therefore appropriate to use these names for the purposes of this Regulation.

(39) The Chemical Abstracts Service (CAS) provides a system whereby substances are added to the CAS Registry and are assigned a unique CAS Registry Number. Those CAS numbers are used in reference works, databases, and regulatory compliance documents throughout the world to identify substances without the ambiguity of chemical nomenclature. It is therefore appropriate to use the CAS numbers for the purposes of this Regulation.

(40) To limit the information on the label to the most essential information, principles of precedence should determine the most appropriate label elements for cases in which substances or mixtures possess several hazardous properties.

(41) The provisions of Council Directive 91/414/EEC concerning the placing of plant protection products on the market[22] and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market[23]should remain fully applicable to any product within their scope.

(41a) 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 the classification should not appear on the labels or packaging of hazardous substances or mixtures.

(41b) In general, substances and mixtures, especially those supplied to the general public, should be supplied in packaging together with the necessary labelling information. The supply of appropriate information between professionals, including for unpackaged substances and mixtures, is ensured through the provisions of Regulation (EC) 1907/2006.

However, in exceptional circumstances substances and mixtures may also be supplied to the general public unpackaged. Where appropriate, relevant labelling information should be supplied to the general public by other means, such as an invoice or bill.

(42) Rules for the application of labels and the location of information on labels are necessary to ensure that the information on labels can be easily understood.

(42a) The Agency should study the possibilities for further simplification of the notification procedure in particular taking the needs of Small and Medium-sized Enterprises (SMEs) into account.

(43) This Regulation should set general packaging standards, in order to ensure the safe supply of hazardous substances and mixtures.

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22 OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/6/EC (OJ L 43, 15.2.2007, p. 13).

23 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/140/EC (OJ L 414, 30.12.2006, p. 78).

(44) Resources of the authorities should be focused on substances of the highest concern with regard to health and to the environment. Provision should therefore be made to enable competent authorities or manufacturers, importers and downstream users to submit proposals to the Agency for a harmonised classification and labelling of substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity categories 1A, 1B or 2, for respiratory sensitisation, or in respect of other effects on a case-by-case basis. The competent authorities of Member States should also be able to propose harmonized classification and labelling for active substances used in plant protection products and biocidal products. The Agency should give its opinion on the proposal while interested parties should have an opportunity to comment. The Commission should submit a draft decision on the final classification and labelling elements.

(45) In order to take full account of the work and experience accumulated under Directive 67/548/EEC, including the classification and labelling of specific substances listed in Annex I of Directive 67/548/EEC, all existing harmonised classifications should be converted into new harmonised classifications using the new criteria. Moreover, as the applicability of this Regulation is deferred and the harmonised classifications in accordance with the criteria of Directive 67/548/EEC are relevant for the classification of substances and mixtures during the ensuing transition period, all existing harmonised classifications should also be placed unchanged in an Annex to this Regulation. By subjecting all future harmonisations of classifications to the provisions of this Regulation, inconsistencies in harmonised classifications of the same substance under the existing and the new criteria should be avoided.

(46) In order to achieve the functioning of the internal market for substances and mixtures, while at the same time ensuring a high level of protection for human health and the environment, rules should be established for a classification and labelling inventory. The classification and labelling for any registered or hazardous substance placed on the market should therefore be notified to the Agency to be included in the inventory.

(47) Different manufacturers and importers of the same substance should make every effort to agree on a single classification for that substance except for hazard classes and differentiations subject to a harmonised classification for that substance.

(48) To ensure a harmonised protection for the general public, and, in particular, for persons who come into contact with certain substances, and the proper functioning of other Community legislation relying on classification and labelling, an inventory should record the classification in accordance with this Regulation agreed by manufacturers and importers of the same substance, if possible, as well as decisions taken at Community level to harmonise the classification and labelling of some substances.

(49) The information included in the classification and labelling inventory should benefit from the same degree of accessibility and protection as that afforded by Regulation (EC) No 1907/2006, especially with regard to information which, if disclosed, risks jeopardis**ing** the commercial interests of those concerned.

(50) Member States should appoint the competent authority or competent authorities responsible for proposals for harmonised classification and labelling and the authorities responsible for the enforcement of the obligations set out in this Regulation. Member States should put in place effective monitoring and control measures in order to ensure compliance with this Regulation.

(50a) It is important to provide advice to suppliers and any other interested parties, in particular small- and medium-sized enterprises (SMEs), on their respective responsibilities and obligations under this Regulation. The national helpdesks already established under Regulation (EC) No 1907/2006 may act as the national helpdesks provided for under Article 44a of this Regulation.

(51) In order for the system established by this Regulation to operate effectively, it is important that there should be good co-operation and co-ordination between the Member States, the Agency and the Commission.

(52) In order to provide focal points for information on hazardous substances and mixtures, Member States should appoint bodies responsible for receiving information relating to health and to the chemical identity, components and nature of substances, including those for which the use of an alternative chemical name has been allowed in accordance with this Regulation, in addition to the competent authorities for the application and the authorities responsible for the enforcement of this Regulation.

(52a) The responsible bodies, where requested by the Member State, may undertake statistical analysis to identify where improved risk management measures might be needed.

(53) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of chemicals legislation as well as trends in this field. Conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments.

(54) The Forum for the exchange of information on enforcement in the Agency, established by Regulation (EC) No 1907/2006, should also exchange information about the enforcement of this Regulation.

(55) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework with a view to imposing effective, proportionate and dissuasive penalties for non-compliance with this Regulation, as non-compliance can result in damage to human health and the environment.

(56) Rules should be laid down requiring advertisements for substances meeting the criteria for classification according to this Regulation to mention the associated hazards, in order to protect recipients of substances, including consumers. Advertisements for mixtures classified as hazardous that allow a member of the general public to conclude a contract for purchase without first having sight of the label should mention the type or types of hazard **indicated on the label**, for the same reason.

(57) A safeguard clause should be foreseen to address situations where a substance or a mixture constitutes a serious risk for human health or the environment, even if it, in compliance with this Regulation, is not classified as hazardous. Should such a situation occur, action at the UN level may be necessary, in view of the global nature of trade in substances and mixtures.

(58) While many of the obligations on enterprises established by Regulation (EC) No 1907/2006 are triggered by classification, this Regulation should not alter the scope and impact of that Regulation, except for its provisions on safety data sheets. To ensure this, this Regulation should make appropriate amendments to Regulation (EC) 1907/2006.

(59) The entry into force of this Regulation should be staggered to allow all parties involved, authorities, enterprises as well as stakeholders, to focus resources in preparing for new duties at the right times. Therefore, and because the classification of mixtures depends on the classification of substances, the provisions for the classification of mixtures should only be applied after the reclassification of all substances. If operators choose to apply the classification criteria contained in this Regulation earlier on a voluntary basis, this should be allowed, but to avoid confusion the labelling and packaging should in that case comply with the provisions of this Regulation instead of the provisions of Directives 67/548/EEC or 1999/45/EC.

(60) To avoid unnecessary burdens on enterprises, substances and mixtures which are already in the supply chain when the labelling provisions of this Regulation become applicable to them, may continue to be placed on the market without relabelling for a certain period of time.

(61) Since the objectives of this Regulation, namely harmonising the classification, labelling and packaging rules, providing an obligation to classify and establishing a harmonised list of substances classified at Community level as well as a classification and labelling inventory cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(62) The Regulation observes the fundamental rights and principles which are acknowledged in particular in the Charter of Fundamental Rights of the European Union[24].

(62a) This Regulation should contribute to the fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.

[24] OJ C 364, 18.12.2000, p. 1.

(63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[25].

(64) In particular, the Commission should be empowered to adapt this Regulation to technical and scientific progress, including incorporating amendments made at UN level to the GHS, in particular any such UN amendments relating to the use of information on similar mixtures . In carrying out such adaptations to technical and scientific progress the biannual working rhythm at UN level should be considered. Furthermore, powers should be conferred on the Commission for the purpose of deciding on the harmonised classification and labelling of specific substances. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(64a) Subject to developments at UN level, the classification and labelling of PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances should be included later in this Regulation.

(65) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a (6) of Decision 1999/468/EC for the adoption of adaptations to technical progress.

(66) The Commission should also for the purposes of this Regulation be assisted by the Committee established by Regulation (EC) No 1907/2006, with a view to ensuring a consistent approach to the updating of chemicals legislation,

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[25] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL ISSUES

Article 1

Aim and Scope

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in article 4(5a) of this Regulation by:

   (a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

   (b) providing an obligation for:

      (i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;

      (ii) suppliers of a substance or a mixture to label and package substances and mixtures placed on the market;

      (iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;

(c) 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 Agency as part of a registration under Regulation (EC) No 1907/2006;

(d) establishing a list of substances with their harmonised classifications and labelling elements at Community level in part 3 of Annex VI;

(e) establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).

2. This Regulation shall not apply to the following:

(a) radioactive substances and mixtures within the scope of Council Directive 96/29/Euratom[26];

(b) substances and mixtures which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;

(c) non-isolated intermediates;

(d) 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.

3. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council[27] is not a substance, mixture or article within the meaning of Article 2.

[26] OJ L 159, 29.6.1996, p. 1.
[27] OJ L 114, 27.4.2006, p. 9.

3a Member States may allow for exemptions from this Regulation in specific cases for certain substances or mixtures, where necessary in the interests of defence.

4. This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

(a) medicinal products as defined in Directive 2001/83/EC;

(b) veterinary medicinal products as defined in Directive 2001/82/EC;

(c) cosmetic products as defined in Directive 76/768/EEC;

(d) medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;

(e) food or feeding stuffs as defined in Regulation (EC) No 178/2002 including when they are used:

(i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;

(ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;

(iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003;

(iv) in animal nutrition within the scope of Directive 82/471/EEC.

5. Save where Article 36 applies this Regulation shall not apply to the transport of dangerous goods by air, sea, road, rail or inland waterways.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) *hazard class* means the nature of the physical, health or environmental hazard;

(2) *hazard category* means the division of criteria within each hazard class, specifying hazard severity;

(3) [Deleted]

(4) [Deleted]

(5) *hazard pictogram* means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information on the hazard concerned;

(6) *Signal word* means a word that indicates the relative level of severity of hazards to alert the reader to a potential hazard; the following two levels are distinguished:

(a) *Danger* means a signal word indicating the more severe hazard categories;

(b) *Warning* means a signal word indicating the less severe hazard categories;

(7) *Hazard statement* means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard;

(8) *Precautionary statement* means a phrase that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal;

(9) *Competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

(10) *The Agency* means the European Chemicals Agency established by Regulation (EC) No 1907/2006;

(11) *UN RTDG* means the United Nations Recommendations on the transport of dangerous goods;

(12) *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(13) *Mixture* means a mixture or solution composed of two or more substances;

(14) *Alloy* means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means; alloys are considered to be mixtures for the purposes of this Regulation;

(15) *Article* means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

(16) *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;

(17) *Monomer* means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

(18) *Registrant* means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance under Regulation (EC) No 1907/2006;

(19) *Notifier* means the manufacturer or the importer, or group of manufacturers or importers notifying to the Agency;

(20) *Intermediate* means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis");

(21) *Non-isolated intermediate* means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

(22) *Scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions;

(23) *Supplier* means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture;

(24) *Manufacturer* means any natural or legal person established within the Community who manufactures a substance within the Community;

(25) *Manufacturing* means production or extraction of substances in the natural state;

(26) *Importer* means any natural or legal person established within the Community who is responsible for import;

(27) *Import* means the physical introduction into the customs territory of the Community;

(28) *Downstream user* means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) of Regulation (EC) No 1907/2006 shall be regarded as a downstream user;

(29) *Use* means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

(30) *Producer of an article* means any natural or legal person who makes or assembles an article within the Community;

(31) *Distributor* means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties;

(32) *Placing on the market* means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

(33) *Cut-off value* means a threshold of any classified impurity, additive or individual constituent in a substance or in a mixture, above which threshold these shall be taken into account for determining if the substance or the mixture, respectively, shall be classified;

(34) *Concentration limit* means a threshold of any classified impurity, additive or individual constituent in a substance or in a mixture that may trigger classification of the substance or the mixture, respectively;

(35) *Differentiation* means distinction within hazard classes depending on the route of exposure or the nature of the effects;

(36) *M-factor* means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present;

(37) *Package* means the complete product of the packing operation, consisting of the packaging and its contents;

(38) *Packaging* means one or more receptacles and any other components or materials necessary for the receptacles to perform their containment and other safety functions;

(39) *Intermediate packaging* means packaging placed between inner packaging, or articles, and an outer packaging.

Article 3

Hazardous substances and mixtures and specification of hazard classes

A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.

Where, in Annex I hazard classes are differentiated on the basis of the route of exposure or the nature of the effects, the substance or mixture shall be classified in accordance with such differentiation.

2. [Deleted]

3. [Deleted]

Article 4

General obligations to classify, label and package

1. Manufacturers, importers and downstream users shall classify substances or mixtures in accordance with Title II before placing them on the market.

2. [Deleted]

3. Without prejudice to the requirements of paragraph 1, manufacturers, producers of articles and importers shall classify those substances not placed on the market in accordance with Title II where:

(a) Articles 6, 7 (1) or (5), 17 or 18 of Regulation (EC) No 1907/2006 provide for registration of a substance;

(b) Articles 7 (2) or 9 of Regulation (EC) No 1907/2006 provide for notification.

4. [Deleted]

4a If a substance is subject to harmonised classification and labelling in accordance with Title V through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes or differentiations covered by that entry.

However, where the substance also falls within one or more hazard classes or differentiations not covered by an entry in part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or differentiations.

4b. Where a substance or mixture is classified as hazardous, suppliers of a substance or a mixture shall ensure that the substance or mixture is labelled and packaged in accordance with Titles III and IV, before placing it on the market.

4c. In fulfilling their responsibilities under paragraph 4b, distributors may use the classification for a substance or mixture derived in accordance with Title II by an actor in the supply chain.

4d. In fulfilling their responsibilities under paragraphs 1 and 4b, downstream users may use the classification for a substance or mixture derived in accordance with Title II by an actor in the supply chain, provided that they do not change the composition of the substance or mixture.

5. A mixture referred to in part 2 of Annex II that contains any substance classified as hazardous, shall not be placed on the market, unless it is labelled in accordance with Title III.

5a. For the purposes of this Regulation, the articles referred to in section 2.1 of Annex I shall be classified, labelled and packaged in accordance with the rules for substances and mixtures before being placed on the market.

5b. Suppliers in a supply chain shall co-operate to meet the requirements for classification, labelling and packaging in this Regulation.

5c. Substances and mixtures shall not be placed on the market unless they comply with the provisions in this Regulation.

6. [Deleted]

TITLE II

HAZARD CLASSIFICATION

Chapter 1

Identification and examination of Information

Article 5

Identification and examination of available information on substances

1. Manufacturers, importers and downstream users of a substance shall identify the relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard as set out in Annex I, and, in particular, the following:

(a) data generated in accordance with any of the methods referred to in Article 8 (3);

(b) epidemiological data and experience on the effects on humans, such as occupational data and data from accident databases;

(c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006;

(ca) any new scientific information;

(cb) any other information generated under international chemical programmes**.**

The information shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used.

2. Manufacturers, importers and downstream users shall examine the information referred to in paragraph 1 to ascertain whether it is adequate, reliable and scientifically valid for the purpose of the evaluation pursuant to Chapter 2.

Article 6

Identification and examination of available information on mixtures

1. The **m**anufacturer, importer or downstream user of a mixture shall identify the relevant available information on the mixture itself or the substances contained in it for the purposes of determining whether the mixture entails a physical, health or environmental hazard as set out in Annex I, and, in particular, the following:

(a) data generated in accordance with any of the methods referred to in Article 8 (3) on the mixture itself or the substances contained in it;

(b) epidemiological data and experience on the effects on humans for the mixture itself or the substances contained in it, such as occupational data, data from accident databases;

(c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006 for the mixture itself or the substances contained in it;

(ca) any other information generated under internationally recognized chemical programmes for the mixture itself or the substances contained in it**.**

The information shall relate to the forms or physical states in which the mixture is placed on the market and, when relevant, in which it can reasonably be expected to be used**.**

2. Subject to paragraphs 3 and 4, where the information referred to in paragraph 1 is available for the mixture itself, and the manufacturer, importer or downstream user has ascertained that information to be adequate and reliable and where applicable, scientifically valid, he shall use that information for the purposes of the evaluation pursuant to Chapter 2.

3. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity' and 'reproductive toxicity' hazard classes referred to in sections 3.5.3.1, 3.6.3.1 and 3.7.3.1 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.

   Further, in cases where the available test data on the mixture itself demonstrate germ cell mutagenic, carcinogenic or toxic to reproduction effects which have not been identified from the information on the individual substances, those data shall also be taken into account.

4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation and bioaccumulation' properties within the 'hazardous to the aquatic environment' hazard class referred to in section 4.1.2.8 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.

5. Where no or inadequate test data on the mixture itself of the kind referred to in paragraph 1 are available, the manufacturer, importer or downstream user shall use other available information on individual substances and similar tested mixtures which may also be considered relevant for the purposes of determining whether the mixture is hazardous, provided that he has ascertained that information to be adequate and reliable for the purpose of the evaluation pursuant to Article 9(4).

Article 7

Animal and human testing

1. 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.

1a. Tests on non-human primates shall be prohibited for the purposes of this Regulation.

2. Tests on humans shall not be performed for the purposes of this Regulation. Data obtained from other sources, such as clinical studies, can however be used for the purposes of this Regulation.

Article 8

Generating new information for substances and mixtures

1. For the purposes of determining whether a substance or a mixture entails a health or environmental hazard as set out in Annex I, the manufacturer, importer and downstream user may, provided that he has exhausted all other means of generating information including by applying the rules provided for in section 1 of Annex XI to Regulation (EC) No 1907/2006, perform new tests.

2. For the purposes of determining whether a substance or a mixture entails any of the physical hazards referred to in part 2 of Annex I, the manufacturer, importer and downstream user shall perform the tests required in that part, unless there is adequate and reliable information already available.

3. The tests referred to in paragraph 1 shall be conducted in accordance with one of the following methods:

(a) [Deleted]

(b) the test methods referred to in Article 13 (3) of Regulation (EC) No 1907/2006;

or

(c) sound scientific principles that are internationally recognized or methods validated according to international procedures.

3a. Where the manufacturer, importer or downstream user carries out new ecotoxicological or toxicological tests and analyses, they shall be carried out in compliance with Article 13(4) of Regulation (EC) No 1907/2006.

3b. Where new tests for physical hazards are carried out for the purposes of this Regulation, they shall be carried out, at the latest from 1 January 2014, in compliance with a relevant recognised quality system or by laboratories complying with a relevant recognised standard.

4. Tests that are carried out for the purposes of this Regulation, shall be carried out on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.

Chapter 2

Evaluation of Hazard Information and Decision on Classification

Article 9

Evaluation of hazard information for substances and mixtures

1. **M**anufacturers, importers and downstream users of a substance or a mixture shall evaluate the information identified in accordance with Chapter 1 by applying to it the criteria for classification for each hazard class or differentiation in parts 2 to 5 of Annex I, so as to ascertain the hazards associated with the substance or mixture.

2. In evaluating available test data for a substance or a mixture which have been obtained from test methods other than those referred to in Article 8 (3), manufacturers, importers and downstream users shall compare the test methods employed with those indicated in that Article in order to determine whether the use of those test methods affects the evaluation referred to in paragraph 1.

3. Where the criteria cannot be applied directly to available identified information**,** manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI of Regulation (EC) No 1907/2006.

4. Where only the information referred to in Article 6(5) is available, manufacturers, importers and downstream users shall apply the bridging principles referred to in section 1.1.3 and in each section of parts 3 and 4 of Annex I for the purposes of the evaluation.

However, where that information does not permit the application of the bridging principles and the principles for using expert judgement and weight of evidence determination as described in Part 1 of Annex I of this Regulation, manufacturers, importers and downstream users shall evaluate the information by applying the other method or methods described in each section of parts 3 and 4 of Annex I.

4a. When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.

Article 10

Concentration limits and M-factors for classification of substances and mixtures

1. **Specific concentration limits** and generic concentration limits are limits assigned to a substance indicating **a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.**

Subject to paragraph 3:

(a) specific concentration limits shall be set by the **manufacturer, importer and downstream user where** adequate and reliable scientific **information shows that the hazard of a substance is evident when** the substance **is present at a level below the concentrations set for any hazard class in part 2 of Annex I or below the generic concentration limits set for any hazard class in parts 3 to 5 of Annex I;**

(b) **in exceptional** circumstances specific concentration limits may be set by the **manufacturer, importer and downstream user where** he has adequate, reliable and conclusive scientific **information that** a hazard of **a substance classified as hazardous is** not evident **at a level above the concentrations set for the relevant hazard class in part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in parts 3 to 5 of that Annex.**

2. Subject to paragraph 3, M-factors for substances classified as hazardous for the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.

3. Specific concentration limits shall not be set in accordance with paragraph 1 for harmonised hazard classes or differentiations for substances included in part 3 of Annex VI.

3a. M-factors shall not be set in accordance with paragraph 2 for harmonised hazard classes or differentiations for substances included in part 3 of Annex VI for which an M-factor is given in that part.

However, where an M-factor is not given in part 3 of Annex VI for substances classified as hazardous for the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.

4. In setting the specific concentration limit or M-factor manufacturers, importers and downstream users shall take into account any specific concentration limits or M-factors for that substance which have been included in the classification and labelling inventory.

5. Specific concentration limits set in accordance with paragraph 1 shall take precedence over the concentrations in the relevant sections of part 2 of Annex I or the generic concentration limits for classification in the relevant sections of parts 3 to 5 of Annex I.

6. The Agency shall provide further guidance for the application of paragraphs 1 and 2.

Article 11

Cut-off values

1. Where a substance contains another substance, itself classified as hazardous, whether in the form of an identified impurity, additive or individual constituent, this shall be taken into account[28] for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than the applicable cut-off value according to paragraph 3.

2. Where a mixture contains a substance classified as hazardous, either as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value according to paragraph 3.

3. The cut-off value **referred to in paragraphs 1 and 2** shall be determined as set out in section 1.1.2.2. of Annex I.

[28] Linguistic Note: The English term ("account" or "consideration") should be linked to the concept of "Berücksichtigungsgrenze" in German.

Article 12

Specific cases requiring further evaluation

Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification:

(a) where adequate and reliable information demonstrates that in practice the physical hazards of a substance or a mixture differ from those shown by tests (in which they are not detected adequately);

(b) where conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable;

(c) where adequate and reliable scientific information demonstrates the potential occurrence of synergistic or antagonistic effects among the substances in a mixture for which the evaluation was decided on the basis of the information for the substances in the mixture.

Article 13

Decision to classify substances and mixtures

If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture in relation to the relevant hazard class or classes or differentiations by assigning the following:

(a) one or more hazard categories for each relevant hazard class or differentiation;

(b) subject to Article 21, one or more hazard statements corresponding to each hazard category assigned in accordance with (a).

Article 14

Specific rules for the classification of mixtures

1. The classification of a mixture shall not be affected where the evaluation of the information indicates any of the following:

   (a) that the substances in the mixture react slowly with atmospheric gases, in particular oxygen, carbon dioxide, water vapour, to form different substances at low concentration;

   (b) that the substances in the mixture react very slowly with other substances in the mixture to form different substances at low concentration;

   (c) that the substances in the mixture may self-polymerize to form oligomers or polymers, at low concentration.

2. A mixture need not be classified for explosive, oxidising, or flammable properties as referred to in part 2 of Annex I provided that any of the following requirements are met:

   (a) none of the substances in the mixture possesses any of these properties and, on the basis of the information available to the supplier, the mixture is unlikely to present hazards of this kind;

   (b) in the event of a change in the composition of a mixture, scientific evidence indicates that an evaluation of the information on the mixture will not lead to a change in classification;

   (c) where a mixture is placed on the market in the form of an aerosol dispenser, it satisfies the provisions of **Article** 8(1a) of Council Directive 75/324/EEC.[29].

[29] OJ L 147, 9.6.1975, p.40.

Article 15

Review of classification for substances and mixtures

1. **Manufacturers, importers and downstream users** shall take all reasonable steps available to them to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place on the market. When **a manufacturer, importer or downstream user** becomes aware of such information which he considers to be adequate and reliable he shall without undue delay carry out a new evaluation in accordance with this Chapter.

2. Where the **manufacturer, importer or downstream user** introduces a change to a mixture **that** has been classified as hazardous, he shall carry out a new evaluation in accordance with this Chapter where the change is either of the following:

   (a) a change in the composition of the initial concentration of one or more of the hazardous constituents in concentrations at or above the limits in Table 1.2 of part 1 of Annex I;

   (b) a change in the composition involving the substitution or addition of one or more constituents in concentrations at or above the cut-off value referred to in Article 11 (3).

3. A new evaluation in accordance with paragraphs 1 and 2 shall not be required if there is valid scientific justification that this will not result in a change of classification.

4. The **manufacturer, importer and downstream user** shall adapt the classification of the substance or the mixture in accordance with the results of the new evaluation except where there are harmonised hazard classes or differentiations for substances included in part 3 of Annex VI.

4a. For paragraphs 1 to 4, when the substance or mixture concerned is within the scope of Directive 91/414/EEC or Directive 98/8/EC, the requirements of those directives shall also apply.

Article 16

Classification of substances included in the classification and labelling inventory

1. Manufacturers and importers may classify a substance differently from the classification already included in the classification and labelling inventory, provided they submit the reasons for the classification to the Agency together with the notification in accordance with Article 41.

2. Paragraph 1 shall not apply if the classification included in the classification and labelling inventory is a harmonised classification included in part 3 of Annex VI.

TITLE III

HAZARD COMMUNICATION IN FORM OF LABELLING

Chapter 1

Content of the Label

Article 17

General rules

1. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements:

   (a) the name, address and telephone number of the supplier(s) of the substance or mixture;

   (b) the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;

   (c) product identifiers as specified in Article 18;

   (d) where applicable, hazard pictograms in accordance with Article 19;

   (e) where applicable, signal words in accordance with Article 20;

   (f) where applicable, hazard statements in accordance with Article 21;

   (g) where applicable, the appropriate precautionary statements in accordance with Article 22;

   (h) where applicable, a section for supplemental information in accordance with Article 27.

2. 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.

Suppliers of a substance or mixture may use more languages on their labels than those required by the Member States, provided that the same particulars appear in all languages used.

Article 18

Product identifiers

1. The label shall include details permitting the identification of the substance or mixture, hereinafter "product identifiers".

The term used for identification of the substance or mixture shall be the same as that used in the safety data sheet drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006 , hereinafter "safety data sheet".

2. The product identifier for a substance shall consist of at least the following:

(a) if the substance is included in part 3 of Annex VI, a name and an identification number as given therein or;

(b) if the substance is not included in part 3 of Annex VI, but appears in the classification and labelling inventory, a name and an identification number as given therein or;

(c) if the substance is not included in part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the Chemical Abstracts Service, hereinafter "the CAS number", together with the name set out in the nomenclature provided by the International Union of Pure and Applied Chemistry, hereinafter "the IUPAC Nomenclature", or the CAS number together with another international chemical name(s) or;

(d) if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s).

Where the name in the IUPAC nomenclature exceeds 100 characters, an other name (usual name, trade name, abbreviation) may be used provided that the notification in accordance with Article 41 includes both the name in the IUPAC Nomenclature and the other name used.

3. The product identifier for a mixture shall consist of both of the following:

(a) the trade name or the designation of the mixture;

(b) 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**.**

Where, in the case referred to in (b), that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless more than four names are needed to reflect the nature and the severity of the hazards.

The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements.

Article 19

Hazard pictograms

1. The label shall include the relevant hazard pictogram(s), intended to convey specific information on the hazard concerned.

2. Subject to Article 36, hazard pictograms shall fulfil the requirements laid down in section 1.2.1 of Annex I and in Annex V.

3. The hazard pictogram relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in Annex I.

4. [Deleted]

Article 20

Signal words

1. The label shall include the relevant signal word in accordance with the classification of the hazardous substance or mixture.
2. The signal word relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in parts 2 to 5 of Annex I.
3. Where the signal word 'Danger' is used on the label, the signal word 'Warning' shall not appear on the label.

Article 21

Hazard statements

1. The label shall include the relevant hazard statements in accordance with the classification of the hazardous substance or mixture.

2. The hazard statements relevant for each classification are set out in the tables indicating the label elements required for each hazard class in parts 2 to 5 of Annex I.

2a. Where a substance is included in part 3 of Annex VI, the hazard statement relevant for each specific classification covered by the entry in that part shall be used on the label, together with the hazard statements referred to in paragraph 2 for any other classification not covered by that entry.

3. The hazard statements shall be worded in accordance with Annex III.

Article 22

Precautionary statements

1. The label shall include the relevant precautionary statements.

2. The precautionary statements shall be selected from those set out in the tables in parts 2 to 5 of Annex I indicating the label elements for each hazard class.

3. The precautionary statements shall be selected in accordance with the criteria laid down in part 1 of Annex IV taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture.

4. The precautionary statements shall be worded in accordance with part 2 of Annex IV.

Article 23 [Deleted]

Article 24 [Deleted]

Article 25

Derogations from labelling requirements for special cases

1. The specific provisions on labelling laid down in section 1.3 of Annex I shall apply in respect of the following:

   (a) transportable gas cylinders;

   (b) gas containers intended for propane, butane or liquefied petroleum gas;

   (c) aerosols and containers fitted with a sealed spray attachment and containing substances classified as presenting an aspiration hazard;

   (d) metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers;

   (e) explosives, as referred to in section 2.1 of Annex I, placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2. [Deleted]

Article 26

Request for use of an alternative chemical name

1. The manufacturer, importer or downstream user of a substance in a mixture may submit a request to the Agency to use an alternative chemical name which refers to that substance in a mixture either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation, where the substance meets the criteria in part 1 of Annex I and where he can demonstrate that disclosure on the label or in the safety data sheet of the chemical identity of that substance puts the confidential nature of his business, in particular his intellectual property rights, at risk.

2. Any request referred to in paragraph 1 shall be made in the format referred to in Article 111 of Regulation (EC) No 1907/2006 and shall be accompanied by a fee.

   The level of the fees shall be determined by the Commission in accordance with the procedure referred to in Article 54 (2).

   A reduced fee shall be set for small and medium-sized enterprises.

3. The Agency may require further information from the manufacturer, importer or downstream user making the request if such information is necessary to take a decision. If the Agency raises no objection within six weeks of the request or the receipt of further required information, the use of the requested name is deemed to be allowed.

3a. If the Agency does not accept the request, the practical arrangements referred to Article 118(3) of Regulation (EC) No 1907/2006 shall apply.

3b. The Agency shall inform Member State competent authorities of the outcome of the request according to paragraph 3 or 3a and provide them with the information submitted by the manufacturer, importer or downstream user.

3c. Where new information shows that an alternative chemical name used does not provide sufficient information for necessary health and safety precautions to be taken at the workplace and to ensure that risks from handling the mixture can be controlled, the Agency shall review its decision on the use of that alternative chemical name. The Agency may withdraw its decision or amend it by a decision specifying which alternative chemical name is allowed to be used. If the Agency withdraws or amends it decision, the practical arrangements referred to in Article 118(3) of Regulation (EC) No 1907/2006 shall apply.

3d. Where the use of an alternative chemical name has been allowed, but the classification of the substance in a mixture for which the alternative name is used no longer meets the criteria in Point 1.4 in Part 1 of Annex I, the supplier of that substance in a mixture shall use the product identifier for the substance in accordance with Article 18 on the label and in the safety data sheet, and not the alternative chemical name.

3e. For substances, whether on their own or in a mixture, where a justification in accordance with Article 10(a)(xi) of Regulation (EC) No 1907/2006 regarding information referred to in Article 119(2)(f) or (g) of Regulation (EC) No 1907/2006 has been accepted as valid by the Agency, the manufacturer, importer or downstream user may use on the label and in the safety data sheet a name that will be made publicly available over the Internet. For those substances in a mixture for which Article 119(2)(f) or (g) no longer applies, the manufacturer, importer or downstream user may request to the Agency to use an alternative chemical name as described in paragraph 1 above.

4. Where the supplier of a mixture, before 1 June 2015, has demonstrated under Article 15 of Directive 1999/45/EC that the disclosure of the chemical identity of a substance in a mixture puts the confidential nature of his business at risk, he can continue to use the agreed alternative name for the purposes of this Regulation.

Article 27

Supplemental information on the label

1. Statements shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous has the physical properties or health properties referred to in sections 1.1 and 1.2 of Annex II.

   The statements shall be worded in accordance with sections 1.1 and 1.2 of Annex II and part 2 of Annex III.

   Where a substance is included in part 3 of Annex VI, any supplemental hazard statements given therein for the substance shall be included in the supplemental information on the label.

2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of Directive 91/414/EEC.

   The statement shall be worded in accordance with part 4 of Annex II and part 3 of Annex III.

3. The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1 and 2, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.

3a. Statements such as “non-toxic”, " non-harmful", “non-polluting”, “ecological” or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification shall not appear on the label or packaging of any substance or mixture.

3b. Where a substance or mixture is classified in accordance with part 5 of Annex I,

(a) the hazard pictogram shall not be included on the label;

(b) the signal words, hazard statements and precautionary statements shall be placed in the supplemental information section of the label.

3c. Where a mixture contains any substance classified as hazardous, it shall be labelled in accordance with part 2 of Annex II.

The statements shall be worded in accordance with part 3 of Annex III and shall be placed in the supplemental information section of the label.

The label shall also include the product identifier referred to in Article 18 and the name, address and telephone number of the supplier of the mixture.

Article 28

Principles of precedence for hazard pictograms

1. Where the classification of a substance or mixture would result in more than one hazard pictogram on the label, the following rules of precedence shall apply to reduce the number of hazard pictograms required:

   (a) if the hazard pictogram "GHS01" applies, the use of the hazard pictograms "GHS02" and "GHS03" shall be optional, except in cases where more than one of these hazard pictograms are compulsory;

   (b) if the hazard pictogram "GHS06" applies, the hazard pictogram "GHS07" shall not appear;

   (c) if the hazard pictogram "GHS05" applies, the hazard pictogram "GHS07" shall not appear for skin or eye irritation;

   (d) if the hazard pictogram "GHS08" applies for respiratory sensitation, the hazard pictogram "GHS07" shall not appear for skin sensitisation or for skin and eye irritation.

2. Where the classification of a substance or mixture would result in more than one hazard pictogram for the same hazard class the label shall include the hazard pictogram corresponding to the most severe hazard category for each hazard class concerned.

For substances that are included in part 3 of Annex VI and are also subject to classification pursuant to Title II, the label shall include the hazard pictogram corresponding to the most severe hazard category for each relevant hazard class.

Article 29

Principles of precedence for hazard statements

If a substance or mixture is classified within several hazard classes or differentiations of a hazard class, all hazard statements resulting from the classification shall appear on the label, unless there is evident duplication or redundancy.

Article 30

Principles of precedence for precautionary statements

1. Where the selection of the precautionary statements results in certain precautionary statements being clearly redundant or unnecessary given the specific substance, mixture or packaging, such statements shall be omitted from the label.

2. Where the substance or mixture is supplied to the general public, one precautionary statement addressing the disposal of that substance or mixture as well as the disposal of packaging, shall appear on the label, unless not required under Article 22 of this Regulation.

In all other cases, a precautionary statement addressing disposal shall not be required, where it is clear that the disposal of the substance or mixture or the packaging does not present a hazard to human health or the environment.

3. Not more than six precautionary statements shall appear on the label, unless necessary to reflect the nature and the severity of the hazards.

Article 31

Exemptions from labelling and packaging requirements

1. [Deleted]

2. [Deleted]

2a. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements of Article 34 for a label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements in accordance with the first sentence of Article 17(2) shall be provided in accordance with Point 1.5.1 of Annex I.

2b. If the full label information cannot be provided in the way specified in paragraph 2a the label information may be reduced in accordance with Point 1.5.2 of Annex I.

2c. When a hazardous substance or mixture referred to in Part 5 of Annex II is supplied to the general public without packaging it shall be accompanied with a copy of the labelling elements in accordance with Article 17.

2d. For certain mixtures classified as hazardous to the environment, exemptions to certain provisions on environmental labelling or specific provisions in relation to environmental labelling may be determined in accordance with the procedure referred to in Article 53, where it can be demonstrated that there would be a reduction in the environmental impact. Such exemptions or specific provisions are defined in Part 2 of Annex II.

2e. The Commission may request the Agency to prepare and submit to it further draft exemptions from labelling and packaging requirements.

Article 32 [Deleted]

Article 33

Updating information on labels

1. The supplier of a substance or a mixture shall 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 under Article 27, taking into account the nature of the change as regards the protection of human health and the environment. Suppliers shall co-operate according to Article 4 (5b) to complete the changes to the labelling without undue delay.

2. Where labelling changes are required other than those referred to in paragraph 1, the supplier of a substance or mixture shall ensure that the label is updated within 18 months.

3. The supplier of a substance or a mixture within the scope of Directives 91/414/EEC or 98/8/EC shall update the label in accordance with the provisions of those Directives.

Chapter 2
Application of Labels

Article 34

General rules for the application of labels

1. Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally.

2. The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.

3. The label elements referred to in Article 17 (1) shall be clearly and indelibly marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.

4. The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I.

5. A label shall not be required when the label elements referred to in Article 17 (1) are shown clearly on the packaging itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the packaging.

Article 35

Location of information on the label

1. The hazard pictograms, signal word, hazard statements and precautionary statements shall be located together on the label.

2. The supplier may decide the order of the hazard statements on the label. However, subject to paragraph 3, all hazard statements shall be grouped together on the label by language.

   The supplier **of a substance or a mixture** may decide the order of the precautionary statements on the label. However, subject to paragraph 3, all precautionary statements shall be grouped together on the label by language.

2a. Groups of hazard statements and groups of precautionary statements referred to in paragraph 2 shall be located together on the label by language.

3. The supplemental information shall be placed in the supplemental information section referred to in Article 27, and shall be located with the other label elements specified in Article 17 (1) (a) to (g).

4. In addition to its use in hazard pictograms, colour may be used on other areas of the label to implement special labelling requirements.

5. Label elements resulting from the requirements provided for in other Community acts shall be placed in the section for supplemental label information referred to in Article 27.

6. [Deleted]

Article 36

Specific rules for labelling of outer packaging, inner packaging and single packaging

1. Where a package consists of outer and an inner packaging, together with any intermediate packaging, and the outer packaging meets labelling provisions in accordance with the rules on the transport of dangerous goods the inner and any intermediate packaging shall be labelled in accordance with this Regulation. The outer packaging may also be labelled in accordance with this Regulation. Where the hazard pictogram(s) required by this Regulation relate to the same hazard as in the rules for the transport of dangerous goods, the hazard pictogram(s) required by this Regulation need not appear on the outer packaging.

2. Where the outer packaging of a package is not required to meet labelling provisions in accordance with rules on the transport of dangerous goods, both the outer and any inner packaging, including any intermediate packaging, shall be labelled in accordance with this Regulation. However, if the outer packaging permits the inner or intermediate packaging labelling to be clearly seen, the outer packaging need not be labelled.

2a. In the case of single packages that meet the labelling provisions in accordance with the rules on the transport of dangerous goods, these shall be labelled both in accordance with this Regulation and the rules on the transport of dangerous goods. Where the hazard pictogram(s) required by this Regulation relate to the same hazard as in rules on the transport of dangerous goods, the hazard pictogram(s) required by this Regulation need not appear.

Article 36a

Report on communication on safe use of chemicals

1. By [3 years after the date of publication of this Regulation in the Official Journal], 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. This study shall be done in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice.

2. Without prejudice to the labelling rules provided for in this Title, the Commission shall, on the basis of the study referred to in paragraph 1, submit a report to the European Parliament and the Council and, if justified, present a legislative proposal to amend this Regulation.

TITLE IV

PACKAGING

Article 37

Packaging

1. Packaging containing hazardous substances or mixtures shall satisfy the following requirements:

   (a) the packaging shall be designed and constructed so that its contents cannot escape, except in cases where other more specific safety devices are prescribed;

   (b) the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form hazardous compounds with the contents;

   (c) the packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

   (d) packaging fitted with replaceable fastening devices shall be designed so that it can be refastened repeatedly without the contents escaping.

2. Packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children or to mislead consumers, or have a similar presentation or a design used for foodstuff or animal feeding stuff or medicinal or cosmetic products, which would mislead the consumers.

Where the packaging contains a substance or mixture which meets the requirements in section 3.1.1 of Annex II it shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II.

Where the packaging contains a substance or mixture which meets the requirements in section 3.2.1 of Annex II it shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II.

2a. The packaging of substances and mixtures shall be deemed to satisfy the requirements of paragraph 1 (a) to (c) if it complies with the requirements of the rules on the transport of dangerous goods by air, sea, road, rail or inland waterways.

TITLE V

HARMONISATION OF CLASSIFICATION AND LABELLING OF SUBSTANCES AND THE CLASSIFICATION AND LABELLING INVENTORY

Chapter 1

Establishing Harmonised Classification and Labelling of Substances

Article 38

Harmonisation of classification and labelling of substances

1. A substance that fulfils the criteria set out in Annex I for the following shall normally be subject to harmonised classification and labelling in accordance with Article 39:

   (a) respiratory sensitisation, category 1 (Annex I, Section 3.4);

   (b) germ cell mutagenicity, category 1A, 1B or 2 (Annex I, Section 3.5);

   (c) carcinogenicity, category 1A, 1B or 2 (Annex I, Section 3.6);

   (d) reproductive toxicity, category 1A, 1B or 2 (Annex I, Section 3.7).

1a. A substance that is an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC shall normally be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 39, Paragraphs 1, 4, 5 and 6 shall apply.

2. Where a substance fulfils the criteria for other hazard classes or differentiations than those referred to in paragraph 1 and the substance does not fall under paragraph 1a, a harmonised classification and labelling in accordance with Article 39 may also be added to Annex VI on a case-by-case basis, if justification is provided demonstrating the need for such action at Community level.

Article 39

Procedure for harmonisation of classification and labelling of substances

1. A competent authority of a Member State may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof.

   The proposal shall follow the format set out in part 2 of Annex VI and contain the relevant information provided for in part 1 of Annex VI.

2. A manufacturer, importer or downstream user of a substance may submit to the Agency a proposal for harmonised classification and labelling of that substance and, where appropriate, specific concentration limits or M -factors, provided that there is no entry in part 3 of Annex VI for such a substance in relation to the hazard class or differentiation covered by that proposal.

   The proposal shall be drawn up in accordance with the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 and it shall follow the format set out in part B of the Chemical Safety Report of section 7 of that Annex. It shall contain the relevant information provided for in part 1 of Annex VI to this Regulation. Article 111 of Regulation (EC) No 1907/2006 shall apply.

3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of a substance in accordance with Article 38 (2), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54 (2).

4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76 (1) (c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission.

5. Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, without undue delay submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of part 3 of Annex VI and, where appropriate, the specific concentration limits or M-factors.

A corresponding entry shall be included in Table 3.2 of part 3 of Annex VI subject to the same conditions, until 31 May 2015.

That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 54 (4).

5a. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in part 3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 to the competent authority in one of the Member States in which the substance is placed on the market.

Article 40

Content of opinions and decisions for harmonised classification and labelling in part 3 of Annex VI; accessibility of information

1. Any opinion referred to in Article 39 (4) and any decision according to Article 39 (5) shall at least specify for each substance:

   (a) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI to Regulation (EC) No 1907/2006;

   (b) the classification of the substance referred to in Article 38, including a statement of reasons;

   (c) the specific concentration limits or M-factors, where applicable;

   (d) labelling elements specified in points (d) to (f) of Article 17(1) for the substance, together with any supplemental hazard information statements for the substance, determined in accordance with Article 27(1);

   (e) any other parameter enabling an assessment to be made of the health or environmental hazard of mixtures containing the hazardous substance in question or of substances containing such hazardous substances as identified impurities, additives and constituents, if relevant.

2. When making publicly available an opinion or a decision as **referred to** in Article 39(4) and (5) of this Regulation, **Article 118(2)** and **Article 119 of Regulation (EC) No 1907/2006 shall apply.**

Chapter 2
Classification and Labelling Inventory

Article 40a

Scope

This chapter shall apply to:

(a) substances subject to registration in accordance with Regulation (EC) No 1907/2006;

(b) substances within the scope of Article 1 which meet the criteria for classification as hazardous and are placed on the market either on their own or in a mixture above the concentration limits specified in this Regulation or Directive 1999/45/EC , where relevant, which results in the classification of the mixture as hazardous.

Article 41

Obligation to notify the Agency

1. Any manufacturer or importer , or group of manufacturers or importers, hereinafter "the notifiers", who places on the market a substance referred to in Article 40a, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 43:

   (a) the identity of the notifier or notifiers responsible for placing the substance or substances on the market as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006;

(b) the identity of the substance or substances as specified in section 2.1 to 2.3.4 to Annex VI of Regulation (EC) No 1907/2006;

(c) the classification of the substance or substances in accordance with Article 13;

(d) where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;

(e) specific concentration limits or M-factors, where applicable, in accordance with Article 10 of this Regulation together with a justification using the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;

(f) labelling elements specified in points (d) to (f) of Article 17(1) for the substance or substances together with any supplemental hazard information statements for the substance, determined in accordance with Article 27(1).

The information referred to in (a) to (f) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006, or if it has already been notified by that notifier.

The manufacturer or importer shall submit this information in the format specified pursuant to Article 111 of Regulation (EC) No 1907/2006.

2. The information listed in paragraph 1 shall be updated and notified to the Agency by the notifier or notifiers concerned when, pursuant to the review in Article 15(1), a decision to change the classification and labelling of the substance has been taken.

3. Substances placed on the market on or after 1 December 2010 shall be notified in accordance with paragraph 1 within one month after their placing on the market.

However, substances placed on the market before 1 December 2010can be notified in accordance with paragraph 1 before that date.

Article 42

Agreed entries

Where the notification in Article 41 (1) results in different entries on the inventory referred to in Article 43 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.

Article 43

The classification and labelling inventory

1. The Agency shall establish and maintain a classification and labelling inventory in the form of a database.

   The information notified pursuant to Article 41 (1) shall be included in the inventory, as well as information submitted as part of registrations under Regulation (EC) No 1907/2006.

   Information in the inventory which corresponds to the information referred to in Article 119 (1) of Regulation (EC) No 1907/2006 shall be publicly accessible. The Agency shall grant access to the other information on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance with Article 29(1) of Regulation (EC) No 1907/2006. It shall grant access to such information to other parties subject to Article 118 of that Regulation.

2. The Agency shall update the inventory when it receives updated information in accordance with Article 41 (2) or Article 42.

3. In addition to the information referred to in paragraph 1, the Agency shall, where applicable, include the following information in each entry:

(a) whether, in respect of the entry, there is a harmonised classification and labelling at Community level by inclusion in part 3 of Annex VI;

(b) whether, in respect of the entry, it is a joint entry between registrants of the same substance as referred to in Article 11 (1) of Regulation (EC) No 1907/2006;

(c) whether it is an agreed entry of two or more notifiers or registrants in accordance with Article 42;

(d) if the entry differs from another entry on the inventory for the same substance.

The information referred to in (a) shall be updated where a decision is taken in accordance with Article 39 (5).

TITLE VI

COMPETENT AUTHORITIES AND ENFORCEMENT

Article 44

Appointment of competent authorities and enforcement authorities and cooperation between authorities

Member States shall appoint the competent authority or competent authorities responsible for proposals for harmonised classification and labelling and the authorities responsible for the enforcement of the obligations set out in this Regulation.

The competent authorities and the authorities responsible for the enforcement shall cooperate with each other in the performance of their tasks under this Regulation and shall give the corresponding authorities of other Member States all the necessary and useful support to this end.

Article 44a

Helpdesk

Member States shall establish national helpdesks to provide advice to manufacturers, importers, distributors, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation.

Article 45

Appointment of bodies responsible for receiving information relating to emergency health response

1. Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in case of emergency health response, from importers and downstream users, placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, according to Article 26.

2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used:

   a) to meet medical demand by formulating preventative and curative measures, in particular in case of emergency;

   and

   b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

   The information shall not be used for other purposes.

3. The appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible.

3a. By …. [3 years after the entry-into-force], the Commission shall carry out a review to assess the possibility of harmonising the information referred to in paragraph 1, including establishing a format for the submission of information by importers and downstream users to appointed bodies. On the basis of this review, and following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), the Commission may adopt a Regulation adding an Annex to this Regulation.

Those measures, designed to amend non essential elements of this regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3).

Article 46

Enforcement and Reporting

1. Member States shall take all necessary measures, including maintaining a system of official controls, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation.

2. Member States shall submit a report to the Agency every 5 years by first July on the results of the official controls, and other enforcement measures taken. The first report shall be submitted by … [3 years after entry into force]. The Agency shall make those reports available to the Commission which shall take them into account for its report under Article 117 of Regulation (EC) No 1907/2006.

3. The Forum referred to in Article 76 (1) (f) of Regulation (EC) No 1907/2006 shall undertake the tasks specified in Article 77(4) (a) to (g) of Regulation (EC) No 1907/2006 concerning enforcement of this Regulation.

Article 47

Penalties for non-compliance

Member States shall introduce provisions for penalties for non-compliance with the provisions of this Regulation and shall take all measures necessary to ensure that the provisions of this Regulation are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall notify the Commission of the provisions for penalties no later than eighteen months after entry into force of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

TITLE VII

COMMON AND FINAL PROVISIONS

Article 48

Advertisement

1. Any advertisement for a substance classified as hazardous shall mention the hazard classes or hazard categories concerned.

2. Any advertisement for a mixture classified as hazardous or covered by Article 27(3c) which allows a member of the general public to conclude a contract for purchase without first having sight of the label shall mention the type or types of hazard indicated on the label.

   The first subparagraph shall be without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts.

Article 49

Obligation to maintain information and requests for information

1. The supplier of a substance or mixture is required to assemble and keep available all the information used by that supplier for the purposes of classification and labelling under this Regulation for a period of at least 10 years after the substance or the mixture was last supplied by that supplier.

   The supplier of a substance or a mixture shall keep this information together with the information required in Article 36 of Regulation (EC) No 1907/2006.

1a. In the event of a supplier of a substance or a mixture ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the supplier's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the supplier.

2. The competent authority or the enforcement authorities of a Member State in which a supplier of a substance or a mixture is established or the Agency may require the supplier to submit to it any information referred to in the first subparagraph of paragraph 1.

However, where that information is available to the Agency as part of a registration pursuant to under Regulation (EC) No 1907/2006 or a notification pursuant to Article 41 of this Regulation, the Agency shall use that information and the authority shall address itself to the Agency.

Article 50

Tasks of the Agency

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2. The Secretariat of the Agency shall:

(a) provide industry with technical and scientific guidance and tools where appropriate on how to comply with the obligations of this Regulation;

(b) provide Member State competent authorities with technical and scientific guidance on the operation of this Regulation and provide support to the helpdesks established by Member States under Article 44a.

Article 51

Free movement clause

On grounds relating to the classification, labelling or packaging of substances and mixtures within the meaning of this Regulation, Member States shall not prohibit, restrict or impede the placing on the market of substances or mixtures which comply with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.

Article 52

Safeguard Clause

1. Where a Member State has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this Regulation, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.

2. Within 60 days of receipt of the information from the Member State, the Commission shall in accordance with the regulatory procedure referred to in Article 54 (2) either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.

3. In the case of an authorisation of a safeguard measure related to classification or labelling of a substance as referred to in paragraph 2, the competent authority of the Member State concerned shall in accordance with the procedure laid down in Article 39 submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision.

Article 53

Adaptations to technical progress

1. The Commission may adjust and adapt Articles 6 (5), 11 (3), 12, 14, 18(3)(b), 25, 27 to 31 and 37 (2) second and third subparagraph and Annexes I to VII to technical and scientific progress, taking due account of the further development of the Globally Harmonised System (GHS) at the level of the United Nations, in particular any UN amendments relating to the use of information on similar mixtures, and considering the developments in internationally recognized chemical programmes and of the data from accident databases. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 54 (4).

1a. Member States and the Commission shall, in the manner appropriate to their role in the relevant United Nations fora, promote the harmonisation of the criteria for classification and labelling of substances as persistent, bioaccumulative and toxic (PBT) or as very persistent and very bioaccumulative (vPvB) at the level of the United Nations.

Article 54

Committee procedure

1. The Commission shall be assisted by the Committee instituted by Article 133 of Regulation (EC) No 1907/2006.

2. Where reference is made to this paragraph, Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 (3) and Article 8 thereof.

   The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.

3. Where reference is made to this paragraph, Article 5a (1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a (1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 55

Amendment to Directive 67/548/EEC

Directive 67/548/EEC is amended as follows:

(0) Article 1, paragraph 2, second subparagraph is deleted.

(1) Article 4 is amended as follows:

(a) paragraph 3 is replaced by the following:

"3. Where an entry containing the harmonised classification and labelling for a particular substance has been included in part 3 of Annex VI of Regulation (EC) No … of the European Parliament and of the Council*, the substance shall be classified in accordance with that entry and paragraphs 1 and 2 shall not apply to the danger categories covered by that entry."

(b) paragraph 4 is deleted;

* OJ L …,

(1a) Article 5, paragraph 1, second sub-paragraph is deleted.

(2) in Article 5, paragraph 2 is replaced by the following:

"2. The measures in the first subparagraph of paragraph 1 shall apply until the substance is listed in part 3 of Annex VI of Regulation (EC) No … for the danger categories covered by that entry or until a decision not to list it has been taken in accordance with the procedure laid down in Article 39 of Regulation (EC) No ….";

(3) the text of Article 6 is replaced by the following:

"Manufacturers, distributors and importers of substances which appear in the EINECS but for which no entry has been included in part 3 of Annex VI of Regulation (EC) No … shall carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label dangerous substances according to the rules laid down in Articles 22 to 25 and the criteria in Annex VI.";

(3a) Article 22, paragraphs 3 and 4 are deleted.

(4) in Article 23, paragraph 2 is amended as follows:

(a) in point (a), the words "Annex I" are replaced by the words "part 3 of Annex VI to Regulation (EC) No …";

(b) in point (c), the words "Annex I" are replaced by the words "part 3 of Annex VI to Regulation (EC) No …";

(c) in point (d), the words "Annex I" are replaced by the words "part 3 of Annex VI to Regulation (EC) No …";

(d) in point (e), the words "Annex I" are replaced by the words "part 3 of Annex VI to Regulation (EC) No …";

(e) in point (f), the words "Annex I" are replaced by the words "part 3 of Annex VI of Regulation (EC) No …";

(4a) Article 24, paragraph 4, second subparagraph is deleted.

(4b) Article 28 is deleted.

(4c) Article 31, paragraphs 2 and 3 are deleted.

(4d) The following new Article 33 shall be inserted:

"*Article 33*

Transitional provision regarding labelling and packaging of substances

Articles 22 to 25 shall not apply to substances from 1 December 2010."

(5) Annex I is deleted.

Article 55a

Amendment to Directive 1999/45/EC

Directive 1999/45/EC shall be amended as follows:

In Article 3(2) first indent, Article 3(3), Article 10(2) points 2.3.1, 2.3.2, 2.3.3 and 2.4 first indent, Annex II, points (a) and (b) of the Introduction, Part A point 1.1.1 (a) and (b), point 1.2 (a) and (b), point 2.1.1 (a) and (b), point 2.2 (a) and (b), point 2.3 (a) and (b), point 3.1.1 (a) and (b), point 3.3 (a) and (b), point 3.4 (a) and (b), point 4.1.1 (a) and (b), point 4.2.1 (a) and (b), point 5.1.1 (a) and (b), point 5.2.1 (a) and (b), point 5.3.1 (a) and (b), point 5.4.1 (a) and (b), point 6.1 (a) and (b), point 6.2 (a) and (b), point 7.1 (a) and (b), point 7.2 (a) and (b), point 8.1 (a) and (b), point 8.2 (a) and (b), point 9.1 (a) and (b), point 9.2 (a) and (b), point 9.3 (a) and (b), point 9.4 (a) and (b), the introductory paragraph of Part B, Annex III, point (a) and (b) of the Introduction, section (a) Aquatic environment point 1.1 (a) and (b), point 2.1 (a) and (b), point 3.1 (a) and (b), point 4.1 (a) and (b), point 5.1 (a) and (b), point 6.1 (a) and (b), section (b) Non-aquatic environment point 1.1 (a) and (b), Annex V section A points 3 and 4, section B point 9, Annex VI Part A, the third column of the table under point 2, Part B point 1, first paragraph, paragraph 3 first indent and paragraph 5, the first column of the table under point 3 and point 4.2 final paragraph and Annex VIII Appendix 1, second column of the table and Appendix 2, second column of the table, the words "Annex I to Directive 67/548/EEC" shall be replaced by the words "part 3 of Annex VI to Regulation (EC) No & ".

Article 56

Amendment to Regulation (EC) No 1907/2006

Regulation (EC) No 1907/2006 is amended as follows:

(1) Article 14 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) point (b) is replaced by the following:

"(b) the specific concentration limits, that have been set in part 3 of Annex VI to Regulation (EC) No … of the European Parliament and of the Council*;

(b bis) for substances classified as hazardous to the aquatic environment, if a multiplying factor, hereinafter referred to as "M-factor", has been set in part 3 of Annex VI to Regulation (EC) No … of the European Parliament and of the Council*, the cut-off value in Table 1.1 of Annex I to that Regulation adjusted using the calculation set out in section 4.1 of Annex I to that Regulation";

(ii) point (e) is replaced by the following:

"(e) the specific concentration limits given in an agreed entry in the classification and labelling inventory referred to in Article 43 of Regulation (EC) No …;";

"(e bis) for substances classified as hazardous to the aquatic environment, if an M-factor has been set in an agreed entry in the classification and labelling inventory referred to in Article 43 of Regulation (EC) No … of the European Parliament and of the Council*, the cut-off value in Table 1.1 of Annex I to that Regulation adjusted using the calculation set out in section 4.1 of Annex I to that Regulation";

* OJ L…"

(b) from 1 December 2010, the introductory sentence of paragraph 4 shall be replaced by the following:

"4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No …:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1,

or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

(…)

(c) from 1 June 2015, paragraph 2 is amended as follows:

(ia) the first sentence is replaced by:

"A chemical safety assessment in accordance with the paragraph 1 need not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than:"

(i) points (a) to (e bis) are replaced by the following:

"(a) the cut-of value referred to in Article 11, paragraph 3 of Regulation (EC) No….of the European Parliament and of the Council *

* OJ L …"

(2) Article 31 is amended as follows:

(aa) In Paragraph 8, the following shall be added after the word "electronically": "no later than the date on which the substance or mixture is first supplied".

(a) the following paragraph 10 is added:

"10. Where substances are classified in accordance with Regulation (EC) - No … during the period from its entry into force until 1 December 2010, that classification may be added in the safety data sheet together with the classification in accordance with Directive 67/548/EEC.

From 1 December 2010 until 1 June 2015, the safety data sheets for substances shall contain the classification according to both Directive 67/548/EEC and Regulation (EC) No ….

Where mixtures are classified in accordance with Regulation (EC) No… during the period from its entry into force until 1 June 2015, that classification may be added in the safety data sheet, together with the classification in accordance with 1999/45/EC. However, until 1 June 2015, where substances or mixtures are both classified and labelled in accordance with Regulation (EC) No… that classification shall be provided in the safety data sheet, together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively, for the substance, the mixture and its constituents. ";

(b) from 1 December 2010, in paragraph 1, point (a) is replaced by the following:

"(a) where a substance meets the criteria for classification as hazardous in accordance with Regulation (EC) No … or a mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC; or";

(b1) from 1 December 2010, paragraph 4 shall be replaced by the following:

"4. The safety data sheet need not be supplied where substances that are hazardous in accordance with Regulation (EC) No …or mixtures that are dangerous in accordance with Directive 1999/45/EC, offered or sold to the general public, are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor."

(c) from 1 June 2015, paragraphs 1 and 3 are amended as follows:

(i) in paragraph 1, point (a) shall be replaced by the following:

"(a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No …; or";

(ii) paragraph 3 is amended as follows:

The introductory phrase is replaced by the following:

"The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No …, but contains:";

- point (b) is replaced by the following:

"(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitizer category 1, respiratory sensitizer category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or";

(d) from 1 June 2015, paragraph 4 shall be replaced by the following:

"4. The safety data sheet need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor."

(3) from 1 December 2010, in Article 40, paragraph 1 **shall be replaced by the following:**

"1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances above 100 tonnes per year with uses resulting in widespread and diffuse exposure, provided they fulfil the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No …:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard **classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;**

(c) hazard **class 4.1;**

(d) hazard class **5.1."**

(4) in Article 56, paragraph 6, point (b) is amended as follows:

(a) from the date of entry into force of this Regulation, it shall be replaced by the following:

"(b) for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in part 3 of Annex VI to Regulation (EC) No … which result in the classification of the mixture as dangerous.";

(b) from 1 June 2015, it shall be replaced by the following:

"(b) for all other substances, below the values specified in Article 11 (3) of Regulation (EC) No … which result in the classification of the mixture as hazardous.";

(5) from 1 December 2010, in Article 57, paragraphs (a), (b) and (c) are replaced by the following:

"(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of part 3 of Annex I to Regulation (EC) No …;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of part 3 of Annex I to Regulation (EC) No …;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of part 3 of Annex I to Regulation (EC) No …;";

(6) in Article 59, paragraphs 2 and 3 are amended as follows:

(a) in paragraph 2, the second sentence is replaced by the following:

"The dossier may be limited, if appropriate, to a reference to an entry in part 3 of Annex VI to Regulation (EC) No ….";

(b) in paragraph 3, the second sentence is replaced by the following:

"The dossier may be limited, if appropriate, to a reference to an entry in part 3 of Annex VI to Regulation (EC) No ….";

(7) Article 65 is amended as follows:

(a) from 1 December 2010, the words "Directive 67/548/EEC" are replaced by "Directive 67/548/EEC and Regulation (EC) No …";

(b) from 1 June 2015, the words "and Directive 1999/45/EC" are deleted;

(8) from 1 December 2010, Article 68 (2) is replaced by the following:

"For a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.";

(9) in Article 76, in point (c) of paragraph 1, the words "Title XI" are replaced by "Title V of Regulation (EC) No …";

(10) Article 77 is amended as follows:

(a) in paragraph 2, the first sentence of point (e) is replaced by the following:

"(e) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list established in accordance with Regulation (EC) No ….;"

(b) in paragraph 3, point (a), the words "Titles VI to XI" are replaced by "Titles VI to X";

(11) Title XI is deleted;

(12) from 1 December 2010, Article 119 paragraphs 1 and 2 shall be amended as follows:

(a) in paragraph 1, point (a)**shall be replaced by the following:**

"(a) without prejudice to paragraph 2(f) and (g) of this Article, the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No …:

- hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

- hazard **classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;**

- hazard **class 4.1;**

- **hazard class 5.1.”**;

(aa) in paragraph 2, point (f) shall be replaced by the following:

"subject to Article 26 of Regulation (EC) No…, the name in the IUPAC nomenclature for non-phase-in substances referred to in paragraph 1a for a period of six years;"

(b) in paragraph 2, point (g)**, the introductory phrase shall be replaced by the following:**

"(g) subject to Article 26 of Regulation (EC) No …, the name in the IUPAC nomenclature for substances referred to in paragraph 1(a) that are only used as one or more of the following:";

(13) from 1 December 2010, in Article 138 (1) in paragraph 1, the second sentence of the introductory phrase is replaced by the following:

"However, for substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No …, the review shall be carried out by 1 June 2014.";

(13a) from 1 June 2015 Annex II shall be amended as follows:

(a) Point 1.1 shall be replaced by:

"1.1 Identification of the substance or mixture

The term used for identification of a substance shall be identical to that provided on the label in accordance with Article 18 (2) of Regulation (EC) No….

The term used for identification of a mixture shall be identical to that provided on the label in accordance with Article 18 (3) (a) of Regulation (EC) No…."

(b) Footnote 1 to Point 3.3(a), first indent, shall be deleted.

(c) Point 3.6 shall be replaced by:

"3.6 Where, in accordance with the provisions in Article 26 of Regulation (EC) No…, the Agency has agreed that the chemical identity of a substance may be kept confidential on the label and in the safety data sheet, their chemical nature shall be described under heading 3 in order to ensure safe handling.

The name used on the safety data sheet (including for the purposes of paragraphs 1.1, 3.2, 3.3 and 3.5 above) shall be the same as that used on the label, agreed in accordance with the procedure set out in Article 26 of Regulation (EC) No….";

(14) from 1 December 2010, Annex III is amended as follows:

(a) point (a) is replaced by the following:

"(a) substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII;";

(b) in point (b), point (ii) is replaced by the following:

"(ii) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under Regulation (EC) No ….";

(15) from 1 December 2010, in Annex V, point 8., the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(16) Annex VI is amended as follows:

(a) from 1 December 2010, sections 4.1 4.2 and 4.3. are amended as follows:

(i) Section 4.1 is amended as follows:

– the first subparagraph is replaced by the following:

"The hazard classification of the substance(s), resulting from the application of Title I and II of Regulation (EC) No … for all hazard classes and categories in that Regulation;";

– the second subparagraph is replaced by the following:

"In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification);";

(ii) Section 4.2 is replaced by the following:

"4.2. The resulting hazard label for the substance(s), resulting from the application of Title III of Regulation (EC) No …;";

(iii) Section 4.3 shall be replaced by the following:

“4.3 Specific concentration limits, where applicable, resulting from the application of Article 10 of Regulation (EC) No… and Articles 4 to 7 of Directive 1999/45/EC.”

(b) From 1 June 2015, section 4.3 is replaced by the following:

"4.3. Specific concentration limits, where applicable, resulting from the application of Article 10 of Regulation (EC) No ….";

(16a) from 1 December 2010, Annex VIII is amended as follows:

(a) in column 2, the second indent of point 8.4.2 is replaced by the following:

– "the substance is known to be carcinogenic category 1A or 1B or germ cell mutagenic category 1A, 1B or 2."

(b) in column 2, the second and third paragraphs of point 8.7.1 are replaced by the following:

"If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.

If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered."

(16b) from 1 December 2010, in Annex IX , column 2, point 8.7, the second and third paragraphs of the third indent are replaced by the following:

"If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.

If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered."

(16c) from 1 December 2010, Annex X is amended as follows:

(a) in column 2, point 8.7, the second and third paragraphs of the third indent are replaced by the following:

"If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered.

If a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered."

(b) in column 2, point 8.9.1, the second indent of the first paragraph is replaced by the following:

– "the substance is classified as germ cell mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions."

(c) in column 2, the second paragraph of point 8.9.1 is replaced by the following:

"If the substance is classified as germ cell mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required."

(17) from 1 December 2010, in Annex XIII, the second and third indents of point 1.3 are replaced by the following:

– "the substance is classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2), or

– there is other evidence of chronic toxicity, as identified by the classifications STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) according to Regulation (EC) No …"

(18) Annex XV, sections I and II are amended as follows:

(a) section I is amended as follows:

(i) the first indent is deleted;

(ii) the second indent is replaced by the following:

"- the identification of CMRs, PBTs, vPvBs, or a substance of equivalent concern in accordance with Article 59,";

(b) in section II, point 1 is deleted;

(19) Annex XVII is amended as follows:

(a) from 1 December 2010, the table is amended as follows:

(i) in the column "Designation of the substance, of the groups of substances or of the preparation", entries 3., 28., 29., 30. and 40. are replaced by the following:

"3. Liquid substances or mixtures **fulfilling the criteria** for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No …:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard **classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;**

(c) hazard class 4.1;

(d) hazard class 5.1."

28. Substances which appear in Part 3 of Annex VI to Regulation (EC) No … classified as carcinogen category 1A or 1B and listed as follows :

– Carcinogen category 1A listed in Appendix 1

– Carcinogen category 1B listed in Appendix 2

29. Substances which appear in Part 3 of Annex VI to Regulation (EC) No … classified as germ cell mutagen category 1A or 1B and listed as follows:

– Mutagen category 1A listed in Appendix 3

– Mutagen category 1B listed in Appendix 4

30. Substances which appear in Part 3 of Annex VI to Regulation (EC) No … classified as toxic to reproduction category 1A or 1B and listed as follows:

– Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development listed in Appendix 5

– Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development listed in Appendix 6

40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in part 3 of Annex VI to that Regulation or not.";

(ii) in the column " Conditions of restriction", in entry 28, the first indent of point 1. is replaced by the following:

"– either the relevant specific concentration limit specified in part 3 of Annex VI of Regulation (EC) No …, or";

(aa) from 1 June 2015, the column “Designation of the substance, of the group or of the mixture” of the table, is amended as follows:

in entry 3, the words “and Directive 1999/45/EC” are deleted.

(b) from 1 June 2015, the column " Conditions of restriction" of the table is amended as follows:

(i) in entry 28, the second indent of point 1. is replaced by the following:

"– the relevant generic concentration limit specified in part 3 of Annex I of Regulation (EC) No ….";

(ii) in entry 30., point 2 (d) is replaced by the following:

"(d) artists' paints covered by Regulation (EC) No ….";

(20)[30] Appendices 1 to 6 are amended as follows:

(a) the Foreword is amended as follows:

(i) in the section entitled “Substances”, the words “Annex I of Directive 67/548/EEC” are replaced by “part 3 of Annex VI to Regulation …”;

(ii) in the section entitled “Index number”, the words “Annex I of Directive 67/548/EEC” are replaced by “part 3 of Annex VI to Regulation …”;

(iii) in the section entitled “Notes”, the words “the foreword of Annex I to Directive 67/548/EEC” are replaced by “part 1 of Annex VI to Regulation …”;

[30] For legal linguists: Should become sub-point (c) of (19).

(iv) Note A is replaced by the following:

"**The name of the substance must appear on the label in the form of one of the designations given** in part 3 of Annex VI to Regulation (EC) No ….

In that part, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the supplier who places such a substance on the market is required to state on the label the correct name, due account being taken of paragraph 1.1.1.6 of part 1 of Annex VI of Regulation (EC) No ….

In accordance with Regulation (EC) No …, where a substance is included in part 3 of Annex VI to that Regulation, the labelling elements relevant for each specific classification covered by the entry in that part shall be included in the label, together with the applicable labelling elements for any other classification not covered by that entry, and any other applicable labelling elements according to Article 17 of that Regulation.

For substances belonging to one particular group of substances included in part 3 of Annex VI to Regulation (EC) No …, the labelling elements relevant for each specific classification covered by the entry in that part shall be included in the label, together with the applicable labelling elements for any other classification not covered by that entry, and any other applicable labelling elements according to Article 17 of that Regulation.

For substances belonging to more than one group of substances included in part 3 of Annex VI to Regulation (EC) No …, the labelling elements relevant for each specific classification covered by both entries in that part shall be included in the label, together with the applicable labelling elements for any other classification not covered by that entry, and any other applicable labelling elements according to Article 17 of that Regulation. In cases where two different classifications are given in the two entries for the same hazard class or differentiation, the classification reflecting the more severe classification shall be used."

(v) Note D is replaced by the following:

"Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in part 3 of Annex VI to Regulation (EC) No ….

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised"."

(va) Note E shall be deleted.

(vi) Note H is replaced by the following:

"The classification and label shown for this substance applies to the hazard or hazards indicated by the hazard statement or hazard statements in combination with the hazard classification shown. The requirements of Article 4 of Regulation (EC) No … on suppliers of this substance apply to all other hazard classes, differentiations and categories.

The final label shall follow the requirements of section 1.2 of Annex I of Regulation (EC) No …."

(vii) Note K is replaced by the following:

"The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1 % w/w 1,3-butadiene (Einecs No 203-450-8). If the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (102-)210-403 should apply. This note applies only to certain complex oil-derived substances in part 3 of Annex VI to Regulation (EC) No …."

(viii) Note S is replaced by the following:

"This substance may not require a label according to Article 17 of Regulation No. (EC) No. (see section 1.3 of Annex I)."

(b) in Appendix 1, the title is replaced by the following:

"Point 28 – Carcinogens: category 1A";

(c) in Appendix 2, the title is replaced by the following:

"Point 28 – Carcinogens: category 1B";

(d) in Appendix 3, the title is replaced by the following:

"Point 29 – Mutagens: category 1A";

(e) in Appendix 4, the title is replaced by the following:

"Point 29 – Mutagens: category 1B";

(f) in Appendix 5, the title is replaced by the following:

"Point 30 – Reproductive toxicants: category 1A";

(g) in Appendix 6, the title is replaced by the following:

"Point 30 – Reproductive toxicants: category 1B";

(21) the word « preparation » or "preparations" within the meaning of Article 3 (2) of Regulation (EC) 1907/2006 is replaced by the word « mixture » or "mixtures" respectively throughout the text.

(21a) Appendices 1 to 6 are amended as follows:

In the entries index Nos. 024-017-00-8, 611-024-001, 611-029-00-9, 611-030-00-4 and 650-017-00-8, the words "Annex I to Directive 67/548/EEC" shall be replaced by "Annex VI to Regulation (EC) No…."

(21b) In Appendix 2 the words "Annex I to Directive 67/548/EEC" shall be replaced by "Annex VI to Regulation (EC) No…."

Article 57

Repeal

Directive 67/548/EEC and Directive 1999/45/EC are repealed with effect from 1 June 2015.

Article 58

Transitional provisions

1. Until 1 December 2010, substances shall be classified, labelled and packaged in accordance with Directive 67/548/EEC.

   Until 1 June 2015, mixtures shall be classified, labelled and packaged in accordance with Directive 1999/45/EC.

2. By way of derogation from the second sentence of Article 60 and in addition to the requirements of paragraph 1 of this Article, substances and mixtures may, before 1 December 2010 and 1 June 2015 respectively, be classified, labelled and packaged in accordance with this Regulation. In that case, the provisions on labelling and packaging in Directives 67/548/EEC and 1999/45/EC shall not apply.

3. From 1 December 2010 until 1 June 2015, substances shall be classified in accordance with both Directive 67/548/EEC and this Regulation. They shall be labelled and packaged in accordance with this Regulation.

4. By way of derogation from the second sentence of Article 60, substances classified, labelled and packaged in accordance with Directive 67/548/EEC and already placed on the market before 1 December 2010, are not required to be relabelled and repackaged in accordance with this Regulation until 1 December 2012.

By way of derogation from the second sentence of Article 60, mixtures classified, labelled and packaged in accordance with Directive 1999/45/EC and already placed on the market before 1 June 2015 are not required to be relabelled and repackaged in accordance with this Regulation until 1 June 2017**.**

4a. Where a substance or mixture has been classified in accordance with Directive 67/548/EEC or 1999/45/EC before 1 December 2010 or 1 June 2015 respectively, manufacturers, importers and downstream users may amend the classification of the substance or mixture using the conversion table in Annex VII.

4b. Until 1 December 2011 a Member State may maintain any existing and more stringent classification and labelling of substances entered into part 3 of Annex VI, provided that these classifications and labelling elements have been notified to the Commission in accordance with the safeguard clause in Directive 67/548/EEC before the entry into force of this Regulation and that the Member State submits a proposal for harmonised classification and labelling containing these classifications and labelling elements to the Agency in accordance with Art. 39 (1) by 1 June 2009.

It is a precondition that a decision on the proposed classification and labelling by the Commission in accordance with the safeguard clause of Directive 67/548/EEC has not yet been taken before the entry into force of this Regulation.

If the proposed harmonised classification and labelling submitted under the first subparagraph is not included or is included in an amended form in part 3 of Annex VI in accordance with Article 39 (5), the exemption in the first subparagraph of this paragraph is no longer valid.

Article 59 [Deleted]

Article 60

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Titles II, III and IV shall apply in respect of substances from 1 December 2010 and in respect of mixtures from 1 June 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*