COUNCIL OF THE EUROPEAN UNION

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NOTE

From :	General Secretariat of the Council
to :	Working Party on Technical Harmonisation (Dangerous substances)
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 contains a text intended to be examined by the Working Party at its meeting on 18 April 2008. The differences between this version and document 7007/3/08 REV 3 are the following:

- Articles 1(1)(b)(ii), 4(3a), 10(1)(a) and (b), 15(1), 15(2), 15(4), 26(3), 26(3c), 35(2), 39(2). 39(3), 45(1), 49(1), 49(1a), 49(2), 56(20) have been updated as a follow up to the discussions on which responsibilities should be given to the various operators in the supply chain.
- Further, Articles 2(36) and 56(20)(iii) have been corrected.
- Finally, references have been included to amendments voted in the ENVI Committee of the European Parliament on 9 April 2008.

This text which has been prepared by the Presidency and the Council Secretariat sets out Presidency proposals for changes to the Commission Proposal as well as suggestions and comments from delegations.

During the examination in the Working Party, delegations have made oral and written comments that have been used by the Presidency when preparing the proposals for changes to the text. Many of these comments are set out in footnotes to the legal text of the Proposal.

At this stage, all delegations maintain a general scrutiny reservation. The Commission has a general reservation on the Presidency proposals for changes to the text.

As part of the examination, tentative agreements on changes to the text of the Commission Proposal have been achieved.

The changes to the text proposed by the Presidency are indicated as follows:

Normal underline	=	tentatively agreed new text;
~~Normal strikethrough~~	=	tentatively agreed deletion of text;
Bold underline	=	Presidency proposal for new text on which there is not yet an agreement in the Working Party;
~~**Bold strikethrough**~~	=	Presidency proposal for deletion of text, not yet agreed in the Working Party.

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 Directive 67/548/EEC 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 and mixtures, while enhancing competitiveness and innovation.

(2) The efficient functioning of the internal market for substances and mixtures can be achieved only if requirements for substances and mixtures do not differ significantly from Member State to Member State.

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

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1 OJ C

2 OJ C

3 OJ C

(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 the classification and labelling of substances and mixtures 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 of substances and mixtures 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 for substances and mixtures, 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 to provide a competitive advantage to industry in the Community. [ENVI 1]

(8) Therefore it is essential to harmonise the provisions for the classification and labelling of substances and mixtures 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. [ENVI 2]

(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 suppliers of substances and mixtures to properly identify and communicate the hazards of their substances and mixtures. 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

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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.

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 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 and governed by Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation[16], Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road[17], Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail[18] or Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC[19].

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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).

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 373, 31.12.1991, p. 4. Regulation as last amended by Regulation (EC) No 1899/20069 (OJ L 377, 27.12.2006, p. 1).

17 OJ L 319, 12.12.1994, p.7. Directive as last amended by Commission Directive 2006/89/EC (OJ L 305, 4.11.2006, p. 4).

18 OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2006/90/EC (OJ L 305, 4.11.2006, p. 6).

19 OJ L 208, 5.8.2002, p. 10.

(12) Although ammunitions are not covered by this Regulation, explosives marketed to produce an explosive or pyrotechnic effect may, through their chemical composition, present hazards to health. It is therefore necessary as part of a transparent information process to classify them in accordance with the provisions of the Regulation, as this will also allow to label them in accordance with the international rules used for the transport of dangerous goods.

(13) The terms 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[20] 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. [ENVI 3]

(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[21] as well as Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999

[20] OJ L 396, 30.12.2006, p. 1.

[21] 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).

concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[22]. 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. It is also necessary to maintain in this Regulation the concept of "dangerous" as defined by those Directives, which does not include those hazard classes which are part of the GHS but are not covered by Directives 67/548/EEC and 1999/45/EC, to minimise effects on other pieces of Community legislation referring to that concept.

(16) Responsibility for the identification of hazards of substances and mixtures and for deciding on their classification should mainly lie with the suppliers of those substances or mixtures, regardless of whether they are subject to the requirements of Regulation (EC) No 1907/2006. However, there should be a possibility to provide for harmonised classifications of substances for hazard classes of the highest concern which should be applied by all suppliers of such substances and of mixtures containing such substances.

[ENVI 4]

(17) In cases of a decision 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 supplier should apply this harmonised classification, and only self-classify for the remaining, non-harmonised hazard classes or differentiations within the hazard class.

[22] 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).

(18) To ensure that customers receive information on the hazards, manufacturers, importers and downstream users should package and label substances and mixtures according to the classification derived, and distributors should ensure that they transfer the information received by either leaving the labelling unchanged or by labelling in accordance with this Regulation themselves. Where distributors modify the label or the packaging of substances or mixtures, they should also be subject to the obligation to classify the substance or mixture in accordance with the provisions of this Regulation. [ENVI 5]

(19) To ensure information on hazardous substances when they are included in mixtures, mixtures should also be labelled, where appropriate, when they contain at least one substance that is classified as hazardous, even if the mixtures themselves are not classified as hazardous. [ENVI 6]

(20) While the supplier of any substance or mixture should not be obliged to generate new information 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; in doing so, the supplier 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 comply with relevant provisions of 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 should apply where the supplier chooses to generate new information. [ENVI 7]

(22) To facilitate the hazard identification of mixtures, suppliers 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 sensitising properties 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 test data are available for the mixture itself, suppliers should therefore follow the bridging principles to ensure adequate comparability of results of the classification of such mixtures.

[ENVI 8]

(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[23] is of high priority. Accordingly, where the supplier 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.

[ENVI 9]

[ENVI 10]

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

(25) 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. [ENVI 11]

(26) For the purpose of classification, data should not be generated by means of testing on humans and non-human primates. 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 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. [ENVI 12]

(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 in which it is used or reasonably can 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 used or can reasonably be expected to be used.

(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, suppliers should apply weight of evidence determinations involving expert judgment to arrive at adequate results.

(30) Specific concentration limits should be assigned to a substance by a supplier in accordance with the criteria referred to in this Regulation, provided the supplier is able to justify the limits and informs the European Chemicals Agency, hereinafter "the Agency", accordingly. 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.

16.9.2003, p. 32).

(31) For reasons of proportionality and workability, generic cut-off values should be defined, both for 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. [ENVI 13]

(32) To ensure adequate classification of mixtures, available information on synergistic and antagonistic effects should be taken into account for the classification of mixtures. [ENVI 14]

(33) Suppliers should re-evaluate their classifications of mixtures 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 also 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 the attention to the hazards of the substance or mixture.

(35) The two components used to communicate the hazards of substances and mixtures are labels and the safety data sheets provided for in Regulation (EC) No 1907/2006. The label is the only tool for communication to consumers, but it may also serve to draw 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. [ENVI 15]

(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.

[ENVI 16]

(37) It is essential that the substances and mixtures placed on the market be well identified, however, the Agency should allow enterprises, where necessary, to describe the chemical identity in a way that does not put the confidential nature of their businesses at risk. [ENVI 17]

(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. [ENVI 18]

(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 labelling rules in this Regulation should be without prejudice to Council Directive 91/414/EEC concerning the placing of plant protection products on the market[24] and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market[25]. [ENVI 19]

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[24] 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).

[25] 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).

(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. Statements such as "non-toxic", "non-harmful", "non-polluting", "ecological" or other statements inconsistent with the classification are therefore inappropriate and are not to appear on the labels of hazardous substances or mixtures.

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

(43a) 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.

(44) Resources of the authorities should be focused on substances of the highest concern. Provision should therefore be made to enable competent authorities or suppliers to submit proposals to the Agency for a harmonised classification of substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity categories 1A or 1B, for respiratory sensitisation, or in respect of other effects on a case-by-case basis. The Agency should give its opinion on the proposal while interested parties should have an opportunity to comment. The Commission should decide on the final classification. [ENVI 20]

(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 substance placed on the market should therefore be notified to the Agency to be included in the inventory. [ENVI 21]

(47) Different suppliers 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 to jeopardise 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 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.

(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 in addition to the competent authorities for the application and enforcement of this Regulation. [ENVI 22]

(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. [ENVI 23]

(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 should mention the type of hazards, for the same reason.

(57) A safeguard procedure should be foreseen to address situations where a substance or a mixture constitutes a 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. To ensure this, this Regulation maintains the concept of "dangerous" as defined by Directives 67/548/EEC and 1999/45/EC.

(59) It is appropriate to provide for a deferred applicability of this Regulation so that a smooth transition to the new system may be ensured. Moreover, this should allow all parties involved, authorities, enterprises as well as stakeholders, to focus resources in the preparation 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 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 going through the supply chain when the labelling provisions of this Regulation become applicable to them, should not be required to be relabelled.

(61) Since the objectives of this Regulation, namely harmonising the classification, labelling and packaging rules for substances and mixtures, 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[26].

(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[27].

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

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

(64) In particular, power should be conferred on the Commission to adapt this Regulation to technical progress, including incorporating amendments made at UN level to the GHS. In carrying out such adaptations to technical 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. [ENVI 24]

(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,

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL ISSUES

Article 1

~~Subject matter~~ 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, ~~and~~ mixtures and articles as referred to in article 4(2) of this Regulation by: ~~as defined in points 1 and 2 of Article 3 in Regulation (EC) No 1907/2006 by providing for the following:~~

   (a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures; [ENVI 25]

   (b) providing an obligation for: ~~suppliers to classify substances and mixtures;~~

      (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 ~~suppliers to notify such classifications and for registrants to submit such classifications as part of their registrations to the European Chemicals Agency, hereinafter the Agency~~; manufacturers ~~of y<substances~~ and importers of substances to notify the Agency, of such classifications and labelling elements if these have not been submitted to the Agency as part of a registration under 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; [ENVI 26]

(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[28];

(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[29] with a view to re-exportation, or in transit;

(c) non-isolated intermediates ~~as defined in point 15(a) of Article 3 in Regulation (EC) No 1907/2006~~;

(d) substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under ~~such~~ controlled conditions in accordance with Community workplace and environment legislation. ~~minimising exposure as if they were classified as carcinogenic, germ cell mutagenic or toxic to reproduction (CMR) category 1A or 1B according to Annex I.~~[30] [ENVI 27]

3. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council[31] is not a substance, mixture or article within the meaning of paragraph 1.

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

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28 OJ L 159, 29.6.1996, p. 1.

29 **DELETED**: When this wording in (2)(b) is used, the terms "free zone" and "free warehouse" need to be defined in Article 2.

30 **DELETED**: Para. (2)(d) could cause problems in case of small quantities of substances for research and development, especially when they are imported. **DELETED**: Delete "in accordance with…".

31 OJ L 114, 27.4.2006, p. 9.

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 ~~19~~ 36 applies this Regulation shall not apply to ~~cases governed by Regulation (EEC) No 3922/91, Directive 94/55/EC, Directive 96/49/EC or Directive 2002/59/EC.~~ the transport of the dangerous goods by air, see, road, rail and inland waterways.

Article 2

Definitions

For the purpose of this Regulation, ~~the definitions in points 1 to 14, the introductory phrase in point 15 and (a) of that point, points 23 and 24 of Article 3 of Regulation (EC) No 1907/2006 shall apply.~~

~~In addition,~~ 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;[32]

~~(3) *supplier* means a manufacturer, importer, downstream user or distributor placing on the market a substance or a mixture;~~

~~(4) *competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation.~~

[ENVI 28]

~~Alloys as defined in point 41 of Article 3 in Regulation (EC) No 1907/2006 shall be considered as mixtures for the purposes of this Regulation.~~

(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;

[32] **DELETED** (acceptable also to **DELETED**): Add "...specifying hazard severity or available evidence." Furthermore include information about the physical state.

(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;[33]

(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;

[33] **DELETED**: Delete last part "alloys are…"

(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;[34]

(19) *Notifier*[35] means the manufacturer or the importer, or group of manufacturers or importers notifying to the Agency;[36]

(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");

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34 **DELETED**: Delete last part "under Regulation…".

35 **DELETED**: Unclear definition. It could be moved to Article 41.

36 **DELETED**: Replace: "… or importers notifying to the Agency" by: "…or importers, placing a substance or mixture in accordance with Art. 41 of this Regulation on the market, notifying to the Agency required information."

(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. [37]

(23) *Supplier of a substance or a mixture* 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;

[38]

[37] **DELETED**: Align Definition 2 (22) to that in REACH.

[38] **DELETED**: Additional definition of "formulator" might be useful. N.B.: "Formulator" is not yet used in the text of the articles.

(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;[39]

(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 applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, used to derive by the summation method the classification of a mixture in which the substance is present.

[39] **DELETED**: Delete words "for third parties". **DELETED**: Misinterpretation is unlikely, no need for deletion.

(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, orarticles, and an outer packaging.

Article 3

Hazardous substances and mixtures and specification of hazard classes

1. 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 ~~the case of the hazard classes referred to in sections 3.1, 3.4, 3.7, 3.8 and 4.1 of~~ Annex I ~~, those~~ 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. [ENVI 29]

~~2. A substance or mixture fulfilling the criteria for any of the following hazard classes or categories set out in Annex I is dangerous:~~ [ENVI 30]

~~(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.~~

~~3. The Commission may develop further differentiations for hazard classes on the basis of the route of exposure or the nature of the effects and shall amend the second subparagraph of paragraph 1 as a result. 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).~~ [ENVI 31]

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. [ENVI 32]

~~3.~~2. [40] In addition to the requirements of paragraph 1, manufacturers ~~Manufacturers~~, producers of articles and importers shall classify those substances not placed on the market ~~, in addition to the classification provided for in paragraph 1, classify substances~~ 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.

~~6.~~3. If a substance is subject to harmonised classification and labelling in accordance with Title V through an entry in part 3 of Annex VI, ~~the supplier shall classify~~ that substance shall be classified in accordance with that entry, and a classification of ~~the~~ 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.

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[40] Several delegations: The paragraphs, in particular paragraphs 2 and 3, could be reordered.

3a. Where a substance or mixture is classified as hazardous, **suppliers of a substance or a mixture**[41] **shall ensure that the substance or mixture is ~~it shall be~~** labelled and packaged in accordance with Titles III and IV, **before placing it on the market**.

3b. **In fulfilling their responsibilities under paragraph 3a, distributors may use the classification for a substance or mixture derived in accordance with Title II by an actor in the supply chain.**

3c. **In fulfilling their responsibilities under paragraphs 1 and 3a, downstream users may use the classification for a substance or mixture derived in accordance with Title II by an actor up the supply chain; provided that they do not change the composition of the substance or mixture** [42]

~~4.~~ ~~Where a distributor modifies the original label or packaging provided by any of the actors referred to in paragraph 1 for the purpose of placing a substance or mixture classified as hazardous on the market, the distributor shall fulfil the requirements set out in Titles II, III and IV.~~

~~In all other cases, the distributor shall ensure that the labelling or packaging provided by those operators is correct and unchanged.~~

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

~~2.~~6. 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.

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41 **DELETED**: Replace "suppliers" by "manufacturers, importers and downstream users". Consequentially, first sub-paragraph of paragraph. 1b could be deleted. **DELETED**: The concept "classifier" could be defined and used from here and onwards.

42 **DELETED**: Scrutiny reservation on paragraph 3c.

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

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

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 ~~The supplier~~ of a substance[43] 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; [ENVI 33]

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

[ENVI 34]

[ENVI 35]

[43] **DELETED**: Replace "of a substance" by "placing a substance on the market".

The information shall relate to the forms or physical states in which the substance is ~~used or can reasonably be expected to be used~~ placed on the market and reasonably foreseeable use after it is placed on the market.[44]

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

Article 6

Identification and examination of available information on mixtures

1. Manufacturers, importers and downstream users ~~The supplier~~ of a mixture[45] shall identify the relevant available information 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; [46]

   (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.

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44 **DELETED**: 1) Modify wording "form or physical state in which the substance is used or can reasonably be expected to be used after it is placed on the market", because the classification can only refer to the intrinsic properties of a substance. Alternatively, delete the sentence. " 2) Delete in last subparagraph of (1): "and reasonably foreseeable use after it is placed on the market".

45 **DELETED**: Replace "of a mixture" by "placing a mixture on the market".

46 **DELETED**: Replace text in (b) by: "reliable epidemiological data and existing scientifically valid experience on the effects of chemicals on humans (e.g. occupational data, data from accident databases)."

The information shall relate to the forms or physical states in which the mixture is placed on the market and reasonably foreseeable use ~~used or can reasonably be expected to be used~~ after it is placed on the market.[47] [ENVI 36]

2. Subject to paragraphs 3 and 4, where the information referred to in paragraph 1(a) is available for the mixture itself, and the ~~supplier~~ manufacturer, importer and downstream user has ascertained that information to be adequate and reliable, he shall use that information for the purposes of the evaluation pursuant to Chapter 2. [ENVI 37]

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 ~~supplier~~ manufacturer, importer and 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 ~~supplier~~ manufacturer, importer and 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). [ENVI 38]

[47] **DELETED**: Replace "form or physical state in which the mixture is used or can reasonably be expected to be used after it is placed on the market" with "form or physical state which the mixture is placed on the market".

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 are possible.

   Tests on non-human primates shall be prohibited for the purposes of this Regulation. [ENVI 39]

2. Tests on humans ~~and non-human primates shall not be performed~~ for the purposes of this Regulation are discouraged and shall **normally** not be carried out to negate positive animal or other data.[48] [ENVI 40]

[ENVI 41]

[ENVI 42]

[48] **DELETED**: Reservation on the word "normally". **DELETED**: Would prefer own suggestion or coming back to **DELETED** proposal. ". **DELETED**: Suggests different wording in Working Document GHS-109. **DELETED**: Reword to "Testing on humans [and non-human primates] solely for hazard identification purposes is generally not acceptable".

Article 8[49]

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 ~~supplier~~ 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 ~~supplier~~ manufacturer, importer and downstream user shall perform the tests required in that part, unless there is adequate and reliable information ~~the data resulting from those tests are~~ already available.

3. The tests referred to in paragraphs 1 and 2 shall be conducted in accordance with one of the following methods:

   (a) the test methods in the fourth revised edition of the ~~United Nations Recommendations on the Transport of Dangerous Goods (~~UN RTDG~~)~~ Manual of Tests and Criteria ~~ST/SG/AC.10/11/Rev.4~~[50];

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

   (c) in respect of health and environmental hazards as set out in parts 3 and 4 of Annex I, internationally recognised scientific principles or methods validated according to international procedures; or [ENVI 43]

   (d) internationally accepted methods for the classification of physical hazards.

   Where the ~~supplier~~ manufacturer, importer and 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.

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[49] **DELETED**: See **DELETED** suggestions in Working Documents GHS-129 and GHS-132.
DELETED: See **DELETED** suggestion in Working Document GHS-146.

[50] OJ […] The text of the fourth revised edition of the UN RTDG Manual of Tests and Criteria will be published as soon as it is available in all official languages of the Community.

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 or physical state(s) in which the substance or mixture ~~it is used or reasonably can be expected to be used after it~~ is placed on the market and reasonable foreseeable use after it is placed on the market.[51] [ENVI 44]

[51] **DELETED** suggests: "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 they are placed on the market."

Chapter 2

Evaluation of Hazard Information and Decision on Classification

Article 9

Evaluation of hazard information for substances and mixtures

1. ~~The supplier~~ **manufacturers, importers and downstream users**[52] 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), ~~the supplier~~ **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~~, the supplier~~ **manufacturers, importers and downstream users**[53] 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.

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[52] Several delegations: Wording "supplier" versus "manufacturer, importer and downstream user" can only be decided upon after having clarified Article 4.

[53] Several delegations: Wording "supplier" versus "manufacturer, importer and downstream user" can only be decided upon after having clarified Article 4. Distributors cannot be exempted from the obligation in para. 3 in certain cases.

4. Where only the information referred to in Article 6(5) is available, ~~the supplier~~ **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, 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.
[ENVI 45]

[ENVI 46]

[ENVI 47]

Article 10

Specific concentration limits and multiplying factors for classification of substances and mixtures

~~**1. Subject to paragraph 3, specific concentration limits whereby a threshold is indicated on or over which the presence of that substance in another substance or in a mixture as an impurity, additive or individual constituent may lead to the classification of the substance or mixture as hazardous may be set by the supplier in the following situations:**~~

~~**(a) where information shows that the hazard of a substance is evident when it 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 cases, where information shows that a substance classified as hazardous is present at a level above the concentrations set for any hazard class in part 2 of Annex I or above the generic concentration limits set for any hazard class in parts 3 to 5 of that Annex, but there are conclusive data showing that the hazard of the substance is not evident.**~~ [ENVI 48]

1. **Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold on or above which the presence of that substance in another substance or in a mixture as an 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 the supplier 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 any[54] hazard class in part 2 of Annex I or above the generic concentration limits set for any[55] hazard class in parts 3 to 5 of that Annex. [56]

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 or m-factors shall not be set in accordance with paragraph 1 and 2 for harmonised hazard classes or differentiations for substances included in part 3 of Annex VI.[57]

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54 **DELETED**: Replace "any" by "the relevant".

55 **DELETED**: Replace "any" by "the relevant".

56 **DELETED**: For the former (b) use wording "in such cases, the supplier should submit to the Agency a proposal for a harmonised procedure in accordance with Art. 39 (2)."

57 **DELETED**: Use wording "harmonised hazard classifications for substances". **DELETED**: Keep text as it is.

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.[58]

[ENVI 49]

Article 11

Cut-off values

1. Where a substance contains another substance, itself classified as hazardous ~~itself~~, whether in the form of an identified impurity, additive or individual constituent, this ~~information~~ shall be taken into account[59] for the purposes of classification, if the concentration of the impurity, additive or individual constituent is equal to, or greater than ~~its~~ the applicable cut-off value ~~referred~~ according to ~~in~~ paragraph 3. [ENVI 50]

2. Where a mixture contains a substance classified as hazardous, either as a component or in the form of an 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 referred to in paragraph 3. [ENVI 51]

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[58] **DELETED**: Specify a time-frame; "within 12 months after the entry into force of the Regulation,….". **DELETED**: Specifying would be against current practice.

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

3. The cut-off value referred to in paragraphs 1 and 2 shall be the ~~lower~~ lowest of the following:[60]

(a) the generic cut-off values specified in Table 1.1 of part 1 of Annex I;

(b) any specific concentration limits **for the substance** set in part 3 of Annex VI or in the classification and labelling inventory referred to in Article 43;

(c) any concentrations in the relevant sections of part 2 of Annex I or any generic concentration limits for classification in the relevant sections of parts 3 to 5 of Annex I, where the specific concentration limits referred to in point b are not available. [ENVI 52]

(d) for substances classified as hazardous to the aquatic environment, if an m-factor has been set in part 3 of Annex VI or in the classification and labelling inventory referred to in Article 43, any concentration limits derived by dividing the generic [concentration limits] [cut-off values] with the established m-factor.

[60] **DELETED**: Include wording: "Where specific concentration limits are not available and where they are available and higher than the generic cut-off values, they should be used instead of the generic cut-off values." **DELETED**: Para. 3 should read: "The cut-off value referred to in paragraphs 1 and 2 shall be referred to in the following sequence: (a) any specific concentration limits set in part 3 of Annex VI; (b) concentration limits set in the classification and labelling inventory referred to in Article 43 if harmonisation has been reached amongst the notifiers**;** (c) the generic cut-off values specified in Table 1.1 of part 1 of Annex I; (d) any concentrations in the relevant sections of part 2 of Annex I or any generic concentration limits for classification in the relevant sections of parts 3 to 5 of Annex I, where the specific concentration limits referred to in point a and b are not available." **DELETED**: Reword (3) to: Amongst the cut-off values which may be contained in (a) Table 1.1 of part 1 of Annex I (generic cut-off values); (b) Part 3 of Annex VI or in the classification and labelling inventory referred to in Article 43 (specific cut-off values/specific concentration limits) or (c) The relevant sections of part 2 of Annex I or in the relevant sections of parts 3 to 5 of Annex I, where the specific cut-off values/concentration limits referred to in point b are not available; the lowest one has to be applied.

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, ~~the supplier~~ **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 ~~properties~~ **hazards** of a substance or a mixture ~~other than an organic peroxide~~ 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. [ENVI 53]

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, ~~the supplier~~ **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;

   (b) that the substances in the mixture react very slowly with other substances in the mixture to form different substances; [ENVI 54]

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

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 ~~such~~ <u>any of these properties</u> 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 ~~of known composition~~, 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, it satisfies the provisions of Article 9a of Council Directive 75/324/EEC.[61].

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

Article 15

Review of classification for substances and mixtures

1. ~~Subject to paragraph 3, where the supplier of a substance or mixture may reasonably be expected to have become aware of new scientific or technical information that he has ascertained to be adequate and reliable for the purposes of the evaluation pursuant to this Chapter and that warrants a change, in the classification of the substance or mixture, he shall carry out a new evaluation of that information in accordance with this Chapter~~.

Manufacturers, importers and downstream users[62] **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 supplier becomes aware of such information which he considers to be adequate and reliable he shall without undue delay**[63] **carry out a new evaluation in accordance with this chapter.** [64]

2. Where the ~~**supplier**~~ **manufacturer, importer or downstream user** introduces a change to a mixture **not within the scope of Directive 91/414/EEC or Directive 98/8/EC,**[65] ~~**of a known composition**~~ 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 ~~which meet~~ the cut-off value referred to in Article 11 (3).

~~Where the mixture concerned is covered by Directive 91/414/EEC or Directive 98/8/EC the first subparagraph shall not apply~~.

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62 **DELETED**: Acceptance of "Supplier" depends on the solutions found in Articles 2 and 4. Scrutiny reservation.

63 **DELETED**: "without undue delay" might not be useful as an addition.

64 **DELETED**: Support addition for "physical form or state", but not for packaging.

65 Scrutiny reservation by **DELETED**.

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.[66]

4. The ~~**supplier**~~ **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.**

For mixture[67] **within the scope of Directive 91/414/EEC or Directive 98/8/EC and subject to an authorization or registration decision according to one of those directives, the classification shall be adapted in accordance with the provisions of that directive**.

Article 16

Classification of substances included in the classification and labelling inventory

1. ~~**A supplier**~~ **Manufacturers, importers or downstream users**[68] may classify a substance differently from the classification already included in the classification and labelling inventory, provided ~~**he**~~ **they** submit~~s~~ the reasons for ~~**his**~~ **the** classification to the Agency together with the notification in accordance with Article 41.[69]

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.

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66 **DELETED**: Delete paragraph 3.

67 **DELETED**: Use wording "for a substance or a mixture…".

68 **DELETED**: Use wording "notifiers in the meaning of Art. 41" in order to normally exclude "downstream users".

69 **DELETED**: Lack of coherence between Art. 16, Art. 41 and Art. 113 of REACH.

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: [ENVI 55]

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

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

   (c) product identifiers as specified in ~~accordance with~~ Article 18;

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

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

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

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

   (h) where appropriate, a section for supplemental information in accordance with Article 27. [ENVI 56]

2. [70]~~Member States may require the use of their official language or languages on the label when substances and mixtures covered by this Regulation are made available to the end user within their territories~~. 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 **[within their territories,]** 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. [ENVI 57]

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.

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;

[70] **DELETED** suggests: "the information on the label "shall be supplied in an official language of the Member State(s) where the substance or [mixture] is placed on the market, unless the Member State(s) concerned provide otherwise". See also **DELETED** suggestion in a Working Document.

(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, ~~a common name~~ 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 ~~common~~ other name used.[71]

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 acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, or specific target organ toxicity (STOT), aspiration hazard **[or PBT substances]**. [ENVI 58]

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 ~~necessary as a consequence of~~ 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.

[ENVI 59]

[71] **DELETED**: Delete paragraph "Where the name in IUPAC nomenclature exceeds ..."

Article 19

Hazard pictograms

1. The label shall include the relevant hazard pictogram(s), ~~consisting of a symbol together with other graphic elements~~ , intended to convey specific information on the hazard concerned.

2. Hazard pictograms shall fulfil the requirements laid down in section 1.2.1 of Annex I and in Annex V.

   In cases mentioned in Article 36(1), the pictograms according to Annex V may be replaced by equivalent pictograms according to the requirements/provisions of the transport of dangerous goods.

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 ~~parts 2, 3 and 4 of~~ Annex I.

~~4. The Commission may set hazard pictograms for other hazard classes than those referred to in paragraph 3. 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).~~

Article 20

Signal words

~~The following signal words shall be used on the label:~~

~~(a) 'danger', indicating the more severe hazard categories;~~

~~(b) 'warning', indicating the less severe hazard categories.~~

~~Where the signal word 'danger' is used on the label, the signal word 'warning' shall not appear on the label.~~

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 ~~describing the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard~~. in accordance with the classification of the hazardous substance or mixture. [ENVI 60]

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

3. Where ~~However, 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 ~~the first sub~~ paragraph 2 for any other classification not covered by that entry.

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

Article 22

Precautionary statements

1. The label shall include the relevant precautionary statements. ~~, whereby a description is provided in the form of a phrase or pictogram of the measure or measures recommended to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use.~~

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

~~However, where a substance is included in part 3 of Annex VI, the precautionary statements relevant for each specific classification covered by the entry in that part shall be used on the label, together with the precautionary statements referred to in the first subparagraph for any specific classification not covered by that entry.~~

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*~~

~~***Specific rules relating to classification in accordance with part 5 of Annex I***~~

~~Where a substance or mixture is classified in accordance with part 5 of Annex I the following shall apply:~~

~~(a) a 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 as referred to in Article 27.~~

~~*Article 24*~~

~~***Specific rules relating to mixtures not classified as hazardous***~~

~~A mixture not classified as hazardous but containing at least one substance classified as hazardous shall be labelled in accordance with part 2 of Annex II.~~

~~The statements shall be worded in accordance with part 3 of Annex III.~~

~~The label shall also include the product identifier referred to in Article 18 and the name, address and telephone number of the manufacturer, importer or downstream user of the mixture concerned.~~

Article 25

~~***Specific rules relating to certain packaging and certain substances and mixtures***~~

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) ~~mobile~~ 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 ~~**point (c) of**~~ section 2.1 of Annex I, placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2. The Commission may add further packaging, substances or mixtures to those referred to in paragraph 1 to which specific provisions on labelling shall apply. 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).

Article 26

Request for ~~confidentiality~~[72] [73]use of an alternative chemical name

1.[74] The supplier of a substance or[75] a mixture may submit a request to the Agency to use a product identifier which refers to a substance or mixture either by means of a name that identifies the most important functional chemical groups or by means of a**n alternative ~~common~~** name[76], where he can demonstrate that the disclosure on the label **or in the safety data sheet**[77] of the chemical identity of a substance or mixture puts the confidential nature of his business, in particular his intellectual property rights, at risk. [ENVI 61]

1a. Use of an alternative chemical name may be granted for a substance where the substance meets the criteria in part X of Annex X.

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). [ENVI 62]

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72 **DELETED**: Delete Art. 26 or reword it in order to mirror the Art. 15 of the Dangerous Preparations Directive. **DELETED**: Scrutiny reservation on the latest version of Art. 26.

73 **DELETED**: Replace the word "confidentiality" by "the use of an alternative chemical name" in the title and throughout the article.

74 **DELETED**: Reinstall the exemption to confidentiality requirement in article 15 of Directive 1999/45/EC; alternatively delete in (1) the possibility to use a common name. Moreover, in order to use a name that identifies the most important functional chemical groups, the supplier should make reference to annex VI part B of Directive 1999/45/EC.

75 **DELETED**: Delete "a substance or", alternative names should not be allowed for pure substances. **DELETED**: Restriction to mixtures would not have practical effects because it could easily be evaded.

76 **DELETED**: "an alternative name" is not the correct wording.

77 **DELETED**: Clarify whether reference to Safety Data Sheet in paragraphs 1 and 3c is necessary. SDS are an issue for REACH only. **DELETED**: A reference is necessary here, but indeed requires additional consequential amendments in Art. 56. (amendments to REACH).

3. The Agency may require further information from the supplier **of a substance or a mixture** making the request if such information is necessary ~~**to take a decision**~~. ~~**The**~~ **If the** Agency ~~**shall notify the person making the request of its decision**~~ **raises no objection** within **[**six**]** weeks of the request or the receipt of further required information~~**. If the Agency does not take any decision within the time specified**~~, the use of the requested name is deemed to be allowed.[78] [ENVI 63]

3a. If the Agency does not accept the request, an appeal may be brought in accordance with Articles 91, 92 and 93 of Regulation (EC) No 1907/2006 against the decision not to accept the request.

3b. The Agency shall inform Member State competent authorities of the outcome of the request according to paragraph 3 or 3a and provide the information submitted by the supplier.

3c. Where the use of an alternative chemical name has been established in accordance with the procedure in Paragraph 3, but the classification of the substance for which the alternative name is used no longer meets the criteria in part X of Annex X, the supplier of a substance or a mixture shall use the product identifier for the substance in accordance with Article 18 and not the alternative name on the label and in the safety data sheet provided in accordance with Article 31 of Regulation (EC) No 1907/2006.

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[78] **DELETED**: Add the following wording at the end of para. 3: "If the Agency does not accept the request, it shall inform the manufacturer or importer at least four weeks before any intended publication of the information. An appeal may be brought against the decision not to accept the request. This appeal shall have suspensive effect (and the data shall not be published)." **DELETED**: Delete last sentence, "tacit agreement" should not be possible. The applicant could always use a common name before applying for an alternative name, if he does not want to disclose the chemical identity. Consequential changes in 3b and 3c are necessary. **DELETED**: Tacit agreement might be needed to stop a situation of suspension, at some stage the product has to come to the market with a product identifier.

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** ~~**approved**~~ alternative name for the purposes of this Regulation.[79]

[ENVI 64]

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.

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. [ENVI 65]

[ENVI 66]

4. Statements such as “non-toxic”, " non-harmful", “non-polluting”, “ecological” or any other statements indicating that **the substances 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.

5. Where a substance or mixture is classified in accordance with part 5 of Annex I, ~~the following shall apply:~~

(a) ~~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 ~~as referred to in Article 27~~of the label.

6. Where a mixture ~~not classified as hazardous but containing at least one substance~~ 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 ~~manufacturer, importer or downstream user~~ supplier of the mixture ~~concerned.~~.

Article 28

Principles of precedence ~~as regards the~~ for hazard pictograms

1. [80]~~If a substance or mixture is classified within several hazard classes or within several differentiations of one or more hazard classes, the following shall apply in respect of the hazard pictograms to be applied on the label:~~ Where the classification of a substance or mixture, would result in more than one pictogram on the label the following rules of precedence shall apply to reduce the number of pictograms required:

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[79] **DELETED**: Clarify relationship of Art. 26 to other legal acts dealing with confidentiality.

[80] **DELETED**: See written comment to Art. 28 (1).

(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 pictogram is 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. ~~If a substance or mixture is classified within several differentiations of one or more hazard classes, the label shall include the most severe hazard pictogram for each hazard class concerned.~~ Where the classification of a substance or mixture would result in more than one 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.

~~In cases where the entry included in part 3 of Annex VI for the substance corresponds to a less severe hazard category than that resulting from the classification pursuant to Title II of that substance in relation to that hazard class, the label shall include the hazard pictogram corresponding to the most severe hazard category.~~ 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 ~~as regards the~~ for hazard statements

If a substance or mixture is classified ~~both~~ within several hazard classes ~~and~~ 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 ~~as regards the~~ for precautionary statements

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

2. Where the substance or mixture is ~~sold~~ 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, where appropriate. [ENVI 67]

   In all other cases, a precautionary statement addressing ~~the~~ disposal shall not be required, ~~if~~ 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 ~~any~~ the label, unless necessary ~~as a consequence of~~ to reflect the nature and the severity of the hazards.

Article 31

Exemptions from labelling ~~for small or otherwise unsuitable~~ and packaging requirements[81]

1. 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 1.4.1*** of Annex ***I***.

2. If the full label information cannot be provided in the way specified in paragraph 1 the label information may be reduced in accordance with ***Point 1.4.2*** of Annex ***I***.

[81] **DELETED**: See written comment to Art. 31.

3. ***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.

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

~~1. For packaging containing 125 ml or less, hazard and precautionary statements need not be indicated on the label, if the substance or mixture is classified as:~~

~~(a) Flammable Gas of category 2;~~

~~(b) Flammable Liquid of category 2 or 3;~~

~~(c) Flammable Solid of category 1 or 2;~~

~~(d) Substances which in contact with water emit Flammable Gases of categories 2 or 3;~~

~~(e) Oxidising Liquid of category 2 or 3;~~

~~(f) Oxidising Solid of category 2 or 3;~~

~~(g) Acutely Toxic of category 4, if the substances or mixtures are not supplied to the general public;~~

~~(h) Skin Irritant of category 2;~~

~~(i) Eye Irritant of category 2;~~

~~(j) Acutely Aquatic Hazardous of category 1;~~

~~(k) Chronically Aquatic Hazardous of category 1,2, 3 and 4.~~ [ENVI 68] *See also Annex I Section 1.4.2.1 Point 1.b.18*

[ENVI 69] *See also Annex I Section 1.4.2.1 Point 1.b.18*

~~2. Where the Commission so requests, the Agency shall prepare and submit to the Commission draft exemptions from the obligations to label provided for in Articles 17 and 34 as follows:~~

~~(a) where the packaging is either too small or otherwise unsuitable for affixing the label, the conditions for applying the label elements;~~

~~(b)) where packaging contains a quantity other than 125 ml which does not entail a risk to workers or human health or the environment, the quantities and the appropriate exemptions from the labelling requirements for substances and mixtures classified as follows:~~ [ENVI 70]

~~(i) Flammable Gases;~~

~~(ii) Oxidising Gases;~~

~~(iii) Flammable Liquids ;~~

~~(iv) Flammable Solids ;~~

~~(v) Substances which in contact with water emit Flammable Gases;~~

~~(vi) Oxidising Liquids;~~

~~(vii) Oxidising Solids;~~

~~(viii) Acutely Toxic of category 4;~~

~~(ix) Skin Irritant of category 2;~~

~~(x) Eye Irritant of category 2;~~

~~(xi) Hazardous to the Environment.~~

[ENVI 71]

[ENVI 72]

~~*Article 32*~~[82]

~~***Exemption from labelling for substances and mixtures sold to the general public***~~

~~Packaging destined for the general public on which it is physically impossible to apply a label in accordance with Article 34, shall be exempted from the obligation to bear a label, provided that such packaging is accompanied by precise and clear instructions for use, including, where appropriate, instructions for its disposal, and provided that it contains substances or mixtures classified in accordance with the following hazard classes and categories in Annex I:~~

~~(a) Section 3.1, acute toxicity category 1, 2 or 3;~~

~~(b) Section 3.2, skin corrosion category 1;~~

~~(c) Section 3.8, specific target organ toxicity (STOT) – single exposure category 1;~~

~~(d) Section 3.9, specific target organ toxicity (STOT) – repeated exposure category 1~~.

[ENVI 73]

[ENVI 74] *See also Annex 1, Section 1.4.2.1 Last point*

[ENVI 75]

[82] Article 32 has been deleted; the substance thereof being dealt with in the new section 1.4. of Annex I.

Article 33

Updating information on labels[83]

The supplier[84] of a substance or a mixture shall update the label without undue delay[85] following any change to the classification and labelling of the substance or mixture.

The supplier[86] of a mixture referred to in Article ~~24~~ **27(6)** shall update the label without undue delay[87] following any change to the classification of the substance and the labelling of the mixture. [ENVI 76]

The supplier of a mixture within the scope of ~~This Article shall be without prejudice~~ to Directives 91/414/EEC ~~and~~ or 98/8/EC **shall update the label in accordance with the provisions of these Directives**.[88] [ENVI 77]

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83 **DELETED**: Clarify whether the provisions are in line with the requirements for updating SDS in REACH. **DELETED**: Provisions are compatible, and this article is necessary for labels. **DELETED** suggests: The supplier of a substance or mixture shall undertake all appropriate measures to update the label, following a change to the classification or labelling information, as soon as is reasonably possible, taking into account the significance of the change on the protection of human health and the environment.

84 **DELETED**: Reservation on the use of "supplier". Final solution only possible after clarification of Art. 4.

85 **DELETED**: Replace "without delay" by "within a period of x months".

86 **DELETED**: Reservation on the use of "supplier". Final solution only possible after clarification of Art. 4

87 **DELETED**: Replace "without delay" by "within a period of x months".

88 **DELETED**: Instead of "undue delay" use a wording similar to: "Following a change in the classification and labelling of a substance or mixture, the supplier shall take all necessary measures to update the label as soon as is reasonable possible, taking into account the significance of the change for the protection of human health and safety and the environment."

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 ~~and its background~~ stands out clearly ~~from it.~~

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 **and precautionary** statements on the label**, unless otherwise specified. 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 as referred to in Article 27, and shall be located with the other label elements specified in Article 17 (1) (a) to (g) and the location of that section shall not make it more difficult to identify the elements specified in Article 17 (1). [ENVI 78]

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 Annex XVII of Regulation (EC) No 1907/2006, Article 16 of Directive 91/414/EEC and Article 20 of Directive 98/8/EC the requirements provided for in other Community acts** shall be placed in the section for supplemental label information referred to in Article 27. [89]

6. The Commission may adopt measures adding to paragraph 5 other Community acts requiring additional labelling elements. 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).

[89] **DELETED**: Paragraph (5) should also mention the authorisation number according to Article 65 of REACH. The authorisation number shall be included in the safety data sheet, section 15, which should then also correspond to the labelling.

Article 36

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

1. Where ~~both an~~ a package consists of outer and an inner packaging ~~is used~~, together with any intermediate packaging, and the outer packaging ~~does not bear a pictogram~~ meets labelling provisions in accordance with the rules on the transport of dangerous goods ~~provided for in Regulation (EEC) No 3922/91, Directive 94/55/EC, Directive 96/49/EC or Directive 2002/59/EC, both the outer and~~ 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 pictogram(s) required by this Regulation relate to the same hazard as in the rules for the transport of dangerous goods, the pictogram(s) required by this Regulation need not appear on the outer packaging.

~~However, if the outer packaging bears a pictogram in accordance with rules on the transport of dangerous goods, only the inner packaging shall be labelled in accordance with this Regulation.~~ [ENVI 79]

2. ~~In case of a single~~ Where the outer packaging~~, the packaging shall be labelled~~ of a package is not required to meet labelling provisions ~~in accordance with this Regulation and~~ in accordance with rules on the transport of dangerous goods ~~referred to in paragraph 1~~., both the outer and any inner packaging, including any intermediate packaging, shall be labelled in accordance with this Regulation. However,~~ where those rules provide for a pictogram relating to the same hazard, the hazard pictogram resulting from the application of this Regulation shall not appear on the packaging~~. ~~Moreover, where those rules provide for other label elements, the corresponding label elements resulting from the application of this Regulation shall not appear.~~ if the outer packaging permits the inner or intermediate packaging labelling to be clearly seen, the outer packaging need not be labelled.

[ENVI 80]

3. In the case of single package 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 pictogram(s) required by this Regulation relate to the same hazard as in rules on the transport of dangerous goods, the pictogram(s) required by this Regulation need not appear.

[ENVI 82]

TITLE IV

PACKAGING

Article 37

Packaging

1. Packaging containing ~~Substances and mixtures classified as~~ hazardous substances or mixtures shall ~~be contained in packaging that shall~~ satisfy the following requirements:

(a) the packaging shall be ~~so~~ designed and constructed **so** that its contents cannot escape, except in cases where other more specific safety devices are prescribed; [ENVI 83]

(b) the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form ~~dangerous~~ 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 ~~in the form of containers~~ fitted with replaceable fastening devices shall be ~~so~~ designed so that ~~the container~~ it can be refastened repeatedly without the contents escaping.

2. Packaging ~~in the form of containers~~ containing a hazardous substance or a mixture supplied ~~sold or made available~~ to the general public shall not have either a shape or design ~~graphic decoration~~ likely to attract or arouse the active curiosity of children or to mislead consumers, or have a similar ~~a~~ presentation or a design~~ation~~ used for foodstuff or animal feeding stuff or medicinal or cosmetic products.[90]

Where **the packaging contains a substance or mixture which** ~~such containers~~ meet**s** the requirements in section 3.1.1 of Annex II **it** ~~they~~ shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II.[91] [92]

Where **the packaging contains a substance or mixture which** ~~such containers~~ meet**s** the requirements in section 3.2.1 of Annex II **it** ~~they~~ shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II. [93][94] [ENVI 84]

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90 **DELETED**: Add "…or cosmetic products which would mislead the consumer."

91 **DELETED**: Replace this subparagraph by:
"(2a) Containers which contain certain substances and mixtures offered or sold to the general public covered by the requirements in section 3.1.1 of Annex II, shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II"

92 **DELETED**: Reword to "… the requirements in sections 3.1.1.1, 3.1.1.2 and 3.1.1.3 of Annex II they shall be fitted with child-resistant fastenings in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II."
DELETED: Replace by:
Where containers meet the requirements in section 3.1.1 of Annex II they shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II unless specific packaging provisions apply to the mixture in a separate EU Regulation or Directive.

93 **DELETED**: Replace this subparagraph by:
"(2b): Containers which contain certain substances and mixtures offered or sold to the general public covered by the requirements in section 3.2.1 of Annex II, shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II."

94 **DELETED**: Reword to: "…meet the requirements in section 3.2.1 of Annex II they shall be fitted with a tactile warning of danger in accordance with section 3.2.2 of Annex II."
DELETED: Replace by:
"Where containers meet the requirements in section 3.2.1 of Annex II they shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II unless specific packaging provisions apply to the mixture in a separate EU Regulation or Directive."

3. 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, see, road, rail and inland waterways

95

95 **DELETED**: A new article on updating of packaging similar to Art. 33 (Updating of labels) is needed.

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 ~~**may**~~ **shall normally** be subject[96] to harmonised classification and labelling in accordance with Article 39:

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

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

   (c) carcinogenicity, ~~section 3.6,~~ category 1A, 1B or 2 (Annex I, Section 3.6);[97]

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

   [98]

[96] **DELETED**: Scrutiny reservation, these delegations originally preferred the wording "shall be subject…". **DELETED**: It is not a strict obligation, as it requires a dossier to be prepared in accordance with Article 39(1) or (2).

[97] **DELETED**: Questions reference to Art. 39 procedure for (a) and (c).

[98] **DELETED**: Include harmonised classification of biocides and pesticides. Prsdy: Covered by new para. 1a and wording of para. 2.

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.[99]

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 ~~shall~~ may **also** be ~~**possible**~~ **added to Annex VI** on a case-by-case basis, if justification is provided demonstrating the need for such action at Community level.

[99] Scrutiny reservation by several delegations on this solution for plant protection and biocidal products.

Article 39

Procedure for harmonisation of classification and labelling[100] of substances

101

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[102]**, 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.[103]

2. A ~~**supplier**~~ **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 ~~**supplier**~~ **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

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100 **DELETED**: Delete "and labelling". **DELETED**: Against deletion, would create a gap for hazard statements. At the margins, an acceptable wording could be "labelling elements" instead of "labelling". As an alternative, one can think about adjusting Annex VI.

101 **DELETED**: Precautionary statements are less harmonised at UN level, can they already be implicitly covered here ? **DELETED**: Wording is ok, we will however scrutinise the current and future UN developments further.

102 **DELETED** (supported by **DELETED**): Updating of classification and labelling by a Member State should be covered in greater detail, see WD-GHS-114.

103 **DELETED**: The normal procedure according to REACH is missing. No, it is covered; Art. 39 (2) mirrors the Annex XV requirements. **DELETED**: Agency should play a larger role in updating. **DELETED**: Against, Agency always works on the basis of existing procedures, not on its own initiative.

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 ~~12~~ **18** months of receipt of the proposal, giving the parties concerned the opportunity to comment.[104] 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, ~~within 6 12 months of receipt of the opinion referred to in paragraph 4, include~~ **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.[105]

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).

6. 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.

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104 **DELETED**: Use wording "participant" instead of "parties".

105 Scrutiny reservation on "draft decision" by **DELETED**: Against "undue delay", better specify a time-limit. **DELETED**: Difficult to specify a time-limit because of 'regulatory procedure with scrutiny' and necessity to notify draft decision to WTO.

Article 40

Content of opinions and decisions for harmonised classification and labelling <u>in part 3 of</u> Annex VI; accessibility of information [ENVI 85]

1. Any opinion referred to in Article 39 (4) and any decision[106] 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) the labelling elements for the substance;[107]

   (e) any other parameter[108] 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 impurities, additives and constituents, if relevant. [ENVI 86]

[109]

[106] **DELETED**: Clarify in the wording that *the Commission* shall decide…"

[107] **DELETED**: The elements are more on hazard communication than on hazard classification.
DELETED: Use wording "labelling elements related to the classification."

[108] **DELETED**: Define "any other parameter".

[109] **DELETED**: Link to Table 3.1. and 3.2. might be useful.

2. ~~**The information referred to in Article 118(2) of Regulation (EC) No 1907/2006 shall not be disclosed in the opinion or in the decision referred to in Article 39(4) and (5) of this Regulation respectively. Article 119 of Regulation (EC) No 1907/2006 shall apply.**~~

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.[110]

[ENVI 87]

[110] **DELETED**: Suggestion: For making an opinion or a decision as referred to in Article 39(4) and (5) of this Regulation respectively, Article 118(2) and Article 119 of Regulation (EC) No 1907/2006 shall apply. **DELETED**: Current text is better. **DELETED**: Idea of current wording is ok, but could be improved in semantics.

Chapter 2

Notification to ~~of~~ the Agency and Establishing the Classification and Labelling Inventory

[111]

Article 41

Obligation to notify the Agency

1. Any manufacturer or importer[112] [113], or group of manufacturers or importers, hereinafter "the notifiers"[114], who places on the market[115] a substance subject to registration in accordance with Regulation (EC) No 1907/2006 or a substance classified as hazardous on its own or in a mixture[116] above the concentration limits specified in Directive 1999/45/EC or in this Regulation, where relevant, which results in the classification of the mixture as hazardous, shall notify[117] to the Agency the following information in order for it to be included in the inventory referred to in Article 43: [ENVI 88]

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111 **DELETED**: Suggest a new article on scope of this title and several amendments to the wording of Art. 41. (see Working Document GHS-138).

112 **DELETED**: Add "producers of articles". Alternatively, align to Art. 7 of REACH. **DELETED**: Not relevant.

113 **DELETED**: In line with Art. 4 (1) and Art. 38 (4) of REACH, downstream users should also have the obligations to notify and to report to the Agency in the cases described. **DELETED**: Downstream users do not classify "substances" under REACH nor do they notify classification and labelling to the inventory under REACH. Art. 38 (4) REACH is obligation for reporting, not for notification.

114 **DELETED**: Given that notifier is defined in Art. 2 the text could be simplified by saying "Any notifier who places on the market…"

115 **DELETED**: Certain derogations are needed, e.g. for substances placed on the market and produced in quantities less than 1 ton per year. Quantity restriction is also in EP draft amendment. **DELETED**: against. **DELETED**: Quantity restriction is acceptable, but should be lower than 1 ton. **DELETED**: Such derogations would not be in accordance with REACH.

116 **DELETED**: A problem with this wording can occur, if a mixture is placed on the market before the contained substances have been classified. **DELETED**: Problem can only occur when importing mixtures, all contained substances then have to be notified. No need to change the text.

117 **DELETED**: Clarify time-limits for the notification. **DELETED**: Scrutiny reservation on Para. 1 which is not very clear on the obligations in general; para. 2 should specify a time-limit (f.ex. 5 years after the first notification or if classified differently from existing registration).

(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;

[ENVI 89]

(d) [118] where a substance has been classified[119] 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) the labelling elements for the substance or substances in accordance with Title III of this Regulation.[120]

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118 **DELETED**: This subparagraph seems to go further than REACH e.g. covering many more substances. Explain why or go back to REACH requirements. **DELETED**: The text "in some but not all hazard classes" needs to be clarified and specified, as at the moment the obligation of reasoning might be avoided in several ways (e.g. by classifying in all hazard classes). **DELETED**: Satisfied with this subparagraph. **DELETED**: REACH Annex VI 4.1 requires it for registration and the 6th paragraph of the Introduction to REACH Annex II requires it for safety data sheets; the wording has been supported by stakeholders because the information will be of use to them.

119 **DELETED**: Use wording "Where a substance has not been classified or has been…". **DELETED**: Against.

120 **DELETED**: Inclusion of all labelling elements goes too far.

The information referred to in (a) to (**e** **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**. [ENVI 90]

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. For substances placed on the market before 1 December 2010, notifications shall be made in accordance with paragraph 1 before that date[121]. [ENVI 91]

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.[122]

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121 **DELETED**: "notifications before that date" does not seem to be correct, because Regulation is not yet in force. **DELETED**: Replace this paragraph by "Notifications in accordance with paragraph 1 shall be done after 1 December 2010. They have to be performed within a time-frame of six months after the first placing on the market of the substance or the substance in a mixture after 1 December 2010." **DELETED**REACH obligation to notify already in force before 1 Dec. 2010, this provision should facilitate a parallel system for voluntary application of UN-GHS for notification before that date. Inventory has to be set up in good time in order to work for mixtures. **DELETED**: Reservation on date 1 December 2010. **DELETED**: Add a provision on how to proceed after 1 December 2010, f.ex.: "For substances placed on the market after 1 December 2010, notifications shall be made within x months after being placed on the market". **DELETED**: Sceptical to this suggestion. **DELETED**: Use better wording clarifying that all substances have to be notified either according to GHS or according to REACH before 1 December 2010. **DELETED**: Use better wording, clarifying also the situation for mixtures.

122 **DELETED**: Add: "If the notifiers or registrants fail to reach an agreement, the Agency shall take care in due time that a harmonised classification will be set up, if appropriate." **DELETED**: would go beyond REACH. **DELETED**: Provision of Art. 39 (2) is sufficient. **DELETED**: Exact wording of Art. 42 can only be fixed after agreement on Art. 41.

Article 43

The classification and labelling inventory

1. The Agency shall establish and maintain a classification and labelling inventory[123] 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)[124] of Regulation (EC) No 1907/2006 shall be publicly accessible**,**[125] **except where a request for use of an alternative chemical name in accordance with Article 26 was accepted by the Agency or by the authority of a Member State in accordance with Article 26(4).** 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.[126] It shall grant access to such information to other parties subject to Article 118 of that Regulation. [ENVI 92]

2. The Agency shall update[127] the inventory when it receives updated information in accordance with Article 41 (2) or Article 42.

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123 **DELETED**: Clarify the relation between the classification and labelling inventory and Tables 3.1 and 3.2 in Annex VI.

124 **DELETED**: This reference should point to the entire Article 119. **DELETED**: The wording comes from Article 114(1) second sentence REACH; Article 119(2) allows requests/justifications not to divulge information.

125 **DELETED**: Add "… shall be publicly accessible, except where a manufacturer or importer has submitted a request in accordance with Article 26, which the Agency has accepted as valid." **DELETED**: Wording has a clear link to Art. 26, text should be modified in parallel.

126 **DELETED**: Add new sentence: "Access shall not be granted to other notifiers or registrants of the substance, if a request for confidentiality according to Article 119 paragraph 2 f) and g) of Regulation (EC) No. 1907/2006 was accepted by the Agency.".

127 **DELETED**: Is there any validation of the information by the Agency?

3. In addition to the information referred to in paragraph 1, the Agency shall, where appropriate, include the following information in each entry: [ENVI 93]

(a) whether, in respect of the entry, there is a harmonised classification and labelling **at Community level by inclusion in Annex VI**;[128]

(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).

[128] Rewording based on **DELETED** suggestion. **DELETED**: Use wording "included in Annex VI."

TITLE VI

COMPETENT AUTHORITIES AND ENFORCEMENT

Article 44

Appointment of competent authorities and ~~bodies~~ 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.

~~Member States shall ensure cooperation and coordination of all authorities competent for legislation related to chemicals.~~ 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[129]

Member States shall establish national helpdesks to provide advice to manufacturers, importers, distributors, downstream users[130] **and any other interested parties on their respective responsibilities and obligations under this Regulation.**

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129 A number of delegations (**DELETED**): Reservations or scrutiny reservations on obligatory helpdesks, for example due to financial implications.

130 To be checked whether enumerative list could be replaced by "suppliers and any interested parties".

Article 45

Appointment of bodies responsible for receiving information relating to emergency health response[131] [132]

1. Member States shall appoint a body or bodies responsible for receiving information by the ~~**suppliers**~~ **manufacturers, importers and downstream users**, including chemical composition of the mixtures placed on the market and classified ~~**or considered**~~[133] as hazardous[134] on the basis of their health effects or on the basis of their physical effects **and the chemical identity of substances for which a request for use of an alternative chemical name**[135] **has been accepted by the Agency, according to article 26**.[136]

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131 **DELETED**: Against addition to the title.

132 **DELETED**: Reservation on the whole of Art. 45.

133 **DELETED**: Re-introduce "or considered".

134 **DELETED**: Reword to "hazardous to health on the basis of their toxicological character…" Furthermore include a provision that the information should be available 24 hours a day. (**DELETED**: Against suggestion).

135 The word "confidentiality" shall be reconsidered as a follow-up to the changes to Article 26.

136 Scrutiny reservation on this addition by **DELETED**.

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**.[137]

The information shall not be used for other purposes.

3. The appointed bodies shall have at their disposal all the information required[138] from the suppliers responsible for marketing to carry out the tasks for which they are responsible. [ENVI 94]

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137 Scrutiny reservation on this addition by **DELETED**.

138 **DELETED**: Either in this paragraph or in the annexes, a harmonised list of required information is needed. Minimum information in this list:
a) the full composition of the mixture with the exact concentration of the substances which are acute toxic category 1-3 or corrosive or STOT single and repeated category 1 or CMR category 1 or respiratory sensitizers. Ranges for the substances of the other health hazard classes and categories respecting the cut-off values in article 11;
b) the reason for the notification;
c) (medical) toxicological properties;
d) the kind of packaging and content;
e) the presence of a child-resistant closure.
This list should be subject to modification through Comitology.

DELETED: As an alternative, a generic wording on what Member States are asked to do in order to harmonise existing systems, e.g. in the area of data collection, might be added. e.g in a new paragraph: "3a. The Commission shall elaborate orientations so that the bodies, responsible for receiving information by supplier, could act following harmonised procedures." (**DELETED**: Add a deadline for harmonisation, f. ex. by 2010, see also suggestion in MD-GHS-139) (**DELETED**: Take wording from Regulation on cosmetic products.).
DELETED: Keep provision unchanged but add a new recital "The Commission and Member States shall explore the possibility of harmonising across the EU the information provided by suppliers relating to the health and physical properties of mixtures received by appointed bodies in accordance with Article 45 of this Regulation". Presidency suggests a joint statement by Commission and Council on harmonisation of required information.

[ENVI 95]

[ENVI 96]

Article 46[139]

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**[140] and packaged in accordance with this Regulation. [ENVI 97]

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** ~~**exchange information about the**~~ enforcement of this Regulation.

Article 47

Penalties for non-compliance

Member States shall **introduce** ~~**lay down the**~~ provisions ~~**on**~~ **for** penalties **for non-compliance with** ~~**applicable to infringement of**~~ the provisions of this Regulation and shall take all measures necessary to ensure that ~~**they**~~ **the provisions of this Regulation** are implemented. The penalties ~~**provided for**~~ must be effective, proportionate and dissuasive. Member States shall notify **the Commission of the** ~~**those**~~ provisions ~~**to the Commission**~~ **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. [ENVI 98]

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139 **DELETED**: Clarify here or in Article 49 that Member States authorities should havefull access to the Classification and Labeling Inventory for the purpose of enforcement.

TITLE VII

COMMON AND FINAL PROVISIONS

Article 48

Advertisement[141]

1. Any advertisement for a substance classified as hazardous shall ~~be prohibited if no~~ mention ~~is made therein of~~ the hazard classes or hazard categor~~y~~ies concerned.

2. Any advertisement for a mixtures classified as hazardous or covered by Article ~~24~~ 27(6) which allows a member of the general public to conclude a contract for purchase without first ~~**being informed of those hazards through the label for that mixture**~~ **having sight of the label** shall mention the type or types of hazard indicated on the label.[142]

   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.[143]

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140 Scrutiny reservation by **DELETED**.

141 **DELETED** suggests merged wording for para 1 and 2: "Any advertisement for a substance classified as hazardous or a mixture classified as hazardous or covered by Article 24 shall be prohibited if no mention is made therein of the hazard class, hazard category or type or types of hazard." **DELETED**: Against, we have different treatment in current law and this should not be changed by UN GHS.

142 Scrutiny reservation on new wording by **DELETED**.

143 **DELETED**: Include provision on e-commerce.

Article 49

Obligation to maintain information and requests for information

1. **~~Any~~ The** supplier of a substance or mixture **~~shall~~ is required to** assemble and keep available all the information **used by that supplier ~~required~~** 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 ~~he~~** last supplied **by that supplier ~~the substance or the mixture~~**.

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 ~~to it~~.

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 **~~competent~~** 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 ~~**undertake the following tasks**~~:

   (a) provid**~~e~~ing** **industry with** technical and scientific guidance and tools where appropriate **on how to comply with the obligations of** ~~**for the operation of**~~ this Regulation ~~**by industry**~~;

   (b) provid**~~e~~ing** **Member State competent authorities with** technical and scientific guidance on the operation of this Regulation ~~**for Member State competent authorities**~~**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[144] to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures.[145] The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision. [ENVI 99]

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[146] 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[147] 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.

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144 **DELETED**: Replace "risk" by "hazard". **DELETED**: Risk is correct wording in line with urgency procedures under REACH.

145 **DELETED**: Prefer deletion of part of the sentence "due to…". **DELETED** against deletion.

146 **DELETED**: Wording on "time period" is not very clear.

147 **DELETED**: Scrutiny reservation on direct obligation of a Member State.

Article 53

Adaptations to technical progress

The Commission may adjust and adapt Articles **6 (5), 8 (3), 11 (3),**12, 14, ~~**23,**~~ **25 (2),** 27 to **31** ~~**32**~~ and 37 (2)[148] second and third subparagraph and Annexes I to VII to technical progress. 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). [ENVI 100]

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.

[148] **DELETED**: Add Art. 39 (5). **DELETED**: Against, Art. 39 (5) points to more implications than comitology procedures. **DELETED**: If the **DELETED** suggestion to Art. 8 in Working Document
GHS-129 is accepted, mentioning of Art. 8 (3) would become unnecessary.

Article 55

Amendment to Directive 67/548/EEC

Directive 67/548/EEC is amended as follows:

(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 …,

(2) in Article 5, paragraph 2 is replaced by the following:[149]

"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.";

[149] **DELETED**: Add: a deletion of Article 5, second subparagraph of paragraph 1. (Caused by deletion of Article 27 of 67/548) (see GHS-149)

(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 …”;

150

(5) Annex I is deleted.[151]

152

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150 **DELETED**: Suggests new point (4a): A new article 33 is inserted as follows: “*Article 33* ***Transitional provision regarding labelling and packaging of substances*****: "**Articles 22 to 25 shall not apply to substances from 1 December 2010." (Caused by deletion of Article 27 of 67/548)

151 **DELETED**: There is a need for a standard high priority working routine to amend converted entries of Annex I of 67/548/EEC also in case the amendment is not related to CMR nor respiratory sensitisation.

152 Following interventions by several delegations, it was agreed that a separate article with adaptations of Directive 1999/45/EC should be inserted.

Article 56

Amendment to Regulation (EC) No 1907/2006

Regulation (EC) No 1907/2006 is amended as follows:[153]

(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 and multiplying factors, hereinafter referred to as "m-factors", [154]that have been set in part 3 of Annex VI to Regulation (EC) No … of the European Parliament and of the Council*;";

(ii) point (e) is replaced by the following:[155]

"(e) the specific concentration limits and m-factors given in an agreed entry[156] in the classification and labelling inventory established under Title V of Regulation (EC) No …;";

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153 **DELETED**: Clarification needed whether a change in para. 20 of Art. 3 of Reg. 1907/2006 is needed as well.

154 **DELETED**: Delete "and multiplying factors, hereinafter referred to as "m-factors"," Add a new (b bis): for substances classified as hazardous to the aquatic environment, if a multiplying factor, hereafter referred to as "m-factors", has been set in part 3 of Annex VI to Regulation (EC) No…. of the European Parliament and of the Council *, any concentration limits derived by dividing the generic cut-off values with the established m-factor";

155 **DELETED**: Reword (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 42 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 *, any concentration limits derived by dividing the generic cut-off values with the established m-factor";.

156 **DELETED**: Clarify that the agreed entry is that referred to in Article 43.3 (c).

(b) from 1 December 2010, ~~in~~ paragraph 4 ~~the words "Directive 67/EEC" are replaced by "Regulation (EC) No..."; is~~ **is 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[157] 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:

(…)

[157] **DELETED**: Scrutiny reservation on restriction to some hazard classes only.

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

(i) points (a) and (b) are[158] replaced by the following:

"(a) the applicable concentrations and generic concentration limits defined in each of the parts 1 to 5 of Annex I to Regulation (EC) No … of the European Parliament and of the Council*;";

* OJ L …

(b) the specific concentration limits and m-factors that have been set in part 3 of Annex VI to Regulation (EC) No …;";

(ii) Points (c) and (d) are deleted;

* OJ L …

[159]

[158] **DELETED**: Use wording "point (a) is replaced by…"; delete section on additional change to (b)."

[159] **DELETED**: Add: "(iii) Point (b bis) is replaced by the following: (b bis) for substances classified as hazardous to the aquatic environment, if an m-factor has been set in part 3 of Annex VI to Regulation (EC) No…. of the European Parliament and of the Council *, any concentration limits derived by dividing the generic cut-off values with the established m-factor". Scrutiny reservation on **DELETED** suggestions by **DELETED**.

(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. 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 ….

[160]Where substances and mixtures are classified in accordance with Regulation (EC) - No … during the period from its entry into force until 1 December 2010 or 1 June 2015, that classification **may** ~~**shall**~~ be added in the safety data sheet together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively.";

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.[161]

[160] New wording following **DELETED** suggestion.
[161] New wording following **DELETED** suggestion.

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

"(a) where a substance ~~**or mixture**~~ meets the criteria for classification as ~~dangerous~~ hazardous in accordance with ~~**Article 3 (2) of**~~ Regulation (EC) No … or **a mixture meets the criteria for classification as dangerous in accordance with** ~~**Article 2 (2) of**~~ Directive 1999/45/EC; or";

(b1) from 1 December 2010, paragraph 4 is 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)~~, the words "or Article 2(2) of Directive 1999/45/EC" are deleted;~~ 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 ~~dangerous~~ 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 sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation** or **is**[162] [163] 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";

[162] New wording following **DELETED** suggestions.

[163] **DELETED**: Consequential change is needed in Annex II , Point 3.3. (b) of REACH Regulation.

(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, ~~in~~ paragraph 1~~, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";~~**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 ~~is~~ 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 ~~**is**~~ shall be replaced by the following:

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

(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**[164] in accordance with section 3.7 of part 3 of Annex I to Regulation (EC) No …;";

[164] Scrutiny reservation by **DELETED** on this addition following a **DELETED** suggestion.

(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 ~~**are**~~ **shall be** amended as follows:

(a) in paragraph 1, point (a)~~**, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …"**~~**shall be replaced by the following:**

“(a) subject to Article 26 of Regulation (EC) No … and 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[165] 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.”**;

[165] **DELETED**: Given that Art. 119 is on public access to information, the restriction to some hazard classes in this paragraph is not necessary. Scrutiny reservation concerning this issue by **DELETED**.

(b) in paragraph 2, point (g)**, ~~in~~ the introductory phrase**~~, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …"~~ 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 and 4.2 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 ….";

(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~~, which are regarded as dangerous according to Regulation (EC) No … and Directive 1999/45/EC.~~ **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 l**isted 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)[166] 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 ~~**of**~~ **to** Directive 67/548/EEC" are replaced by "part ~~**3**~~ **1** of Annex VI to Regulation …";

[166] 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 ~~**manufacturer or any other person**~~ **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 ….

Regulation (EC) No … also requires that the appropriate label elements[167] to be used for each substance shall be those shown in part 3 of Annex VI to that Regulation.

For substances belonging to one particular group of substances included in part 3 of Annex VI to Regulation (EC) No …, the appropriate label elements to be used for each substance shall be those shown in the appropriate entry in that part.

For substances belonging to more than one group of substances included in part 3 of Annex VI to Regulation (EC) No …, the appropriate label elements to be used for each substance shall be those shown in both the appropriate entries given in that part. 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."

[167] **DELETED**: Scrutiny reservation on wording "appropriate label elements".

(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, ~~**the manufacturer or any person**~~ **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 ~~**manufacturers, distributors and importers**~~ **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:[168]

"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:

[168] Reservation by **DELETED**.

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

(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.

169 *This footnote o be used for redrafting and can then be deleted!*

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169 **DELETED**: Further references to REACH might need to be amended: - References to 67/548/EEC or 1999/45/EC ; Articles 23.1 (a), 23.1 (b), Annex I ; 0.6, 1.0.1, 1.3.1, 2.1, 2.5, 3.0.1, 3.2.1, 3.3.1 (note) ; Annex II Introduction, 1.1, 1.4, 2, 3.2, 3.3, 3.4, 3.5, 3.6, 11, 15, note on page 84;
References to Title XI of REACH Articles 14.2 (e), 76.1 (c), Annex II part… Comment: The articles in REACH cannot be changed via Comitology. According to REACH Article 138(4) Annexes I, IV and V shall be reviewed by the Commission by 1 June 2008. Amendments to these Annexes could therefore be handled outside this proposal. It might however be appropriate to introduce further amendments to other REACH Annexes through Article 56 Art. 23.1 of REACH should not be adapted at all. Title XI is already covered by Art. 56 (1)

[170]

(21a) [171] **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 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…."

[172] *This footnote o be used for redrafting!*

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and 56 (9).

[170] **DELETED**: Add a new point on REACH Article 2.10 "The provisions of Titles [to be specified] shall not apply to substances or mixtures classified for the following hazard classes or categories (a): Gases under pressure; (b): Self-reactive substances and mixtures types C – G; (c): Self-heating substances and mixtures, (d) Oxidising liquids category 3; (e) Oxidising solids category 3; (f) Organic peroxides type G, (g) Corrosive to metals, (h) Reproductive toxicity, effects on or via lactation; (i) target organ toxicity (STOT) single exposure category 3, narcotic effects."

[171] **DELETED** suggests following additional changes to REACH: "The references in points 1.3.1 and 3.2.1 of Annex I and in the Note and point 1.1, points 3.2, 3.4, 3.5 and 3.6 of Annex II, need to be revised in accordance with Article 58, the date of entry into force of this Regulation and dates of repeal of Directives 67/548/EEC and 1999/45/EC; moreover in Annex I; point 0.6.4 the words "Directive 67/548/EEC or Directive 1999/45/EC " should be replaced by "Regulation (EC) No …"; and in point 1.0.1, first indent, "Directive 67/548/EEC" should be replaced by "Regulation (EC) No …"; as well as in points 2.1, 2.5 and 3.0.1 "Directive 67/548/EEC" should be replaced by "Regulation (EC) No …"; Furthermore in Annex II; in point 1.4 the words "Article 17 of Directive 1999/45/EC" should be replaced by "Article 45 of Regulation (EC) No …"; and in point 2:- in the first sentence the words "Directive 67/548/EEC or Directive 1999/45/EC " should be replaced by "Regulation (EC) No …"; - in the second sentence the words "Directive 1999/45/EC" should be replaced by "Regulation (EC) No …". and also in point 3.3 the words "Directive 1999/45/EC" and "Directive 67/548/EEC" should be replaced by "Regulation (EC) No …"; moreover, in points 11 and 15 the words "Directive 67/548/EEC" and "Directive 1999/45/EC" should also be replaced by "Regulation (EC) No …"

[172] **DELETED** suggest the following changes in Appendices 1 to 6: a) Note E in the Foreword should be revised; **DELETED**: Appendix I **:** Chromium (VI) compounds;Benzidine based azo dyes ; o-Dianisidine based azo dyes o-Tolidine based dyes ; Refactory Ceramic Fibres

Article 57

Repeal

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

Article 58

Transitional provisions[173]

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

   Until 1 June 2015[174], 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, ~~the~~ substances and mixtures ~~classified in accordance with paragraph 1~~ may, ~~as regards the period~~ before 1 December 2010 and 1 June 2015 respectively, be classified**, ~~and~~** 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.

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[173] **DELETED**: Use relative time periods for example 3,5 years after publication for substances and 4,5 years after publication for mixtures. Reservation on date 1 December 2010. **DELETED**: Clarify situation for notifications which might have to be done according to two legal acts.

[174] **DELETED**: Suggests "1 June 2013". **DELETED**: prefers "2013" or "2014". **DELETED**: Date "1 June 2016" would be more convenient, especially for producers of mixtures that have bought mixtures by themselves which still followed old classification scheme."

3. From 1 December 2010 until 1 June 2015, substances shall be classified in accordance with both Directive 67/548/EEC and this Regulation.[175] They shall be labelled and packaged in accordance with this Regulation.[176]

[175] **DELETED**: Clarify the situation (overlap in legislation), if changes in Dir. 67/548/EC, especially repeal of Articles 22 to 25 thereof, are not provided for. **DELETED**: Impossible to repeal parts of Dir. 67/548/EC immediately, because references by Dir. 99/45/EC to Dir. 67/548/EC would then be unlogic. Art. 58 of this Regulation in general clarifies transitional measures on when to apply which legal act, but it does not repeal provisions as such. Pres: suggests that the Working Party ask for further legal advice on the issue whether it is necessary to explicitly repeal parts of Dir. 67/548/EC.

[176] **DELETED**: An explicit transitional measure for substances only has to deal with classification. For labelling and packaging the relevant provisions of Dir. 1999/548/EC can simply be repealed with effect from 1 December 2010, as the GHS Regulation will already apply. **DELETED**: Deletion or repeal is not the preferred option, the provisions are simply no longer applied from the relevant dates onwards.

4. **By way of derogation from the second sentence of Article 60**, substances ~~and mixtures~~ classified, **labelled and packaged in accordance with Directive 67/548/EEC and already** placed on the market before 1 December 2010, ~~shall not be~~ are not required to be **re**labelled and **re**packaged in accordance with this Regulation **until 1 December 2012**.[177]

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.[178]

5. 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.

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177 **DELETED**: Scrutiny reservation on question of relative reference (x years after entry-into-force) or direct date , furthermore on the length of the time period.

178 **DELETED**: Scrutiny reservation on question of relative reference (x years after entry-into-force) or direct date , furthermore on the length of the time period.

179 **DELETED**: Add a provision explaining that notwithstanding Article 36, a labelling with both transport and "supply and use" pictograms (two pictograms for the same hazard) should be allowed for transport packages up to 50 kg until 1 June 2015. Furthermore, add a provision on follow-up to UN progress by the **DELETED**.

6. **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 1967/548/EEC before the entry into force of this Regulation No. (EC)…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 [date to be specified].**

It is a precondition that a decision on the proposed classification and labelling by the Commission in accordance with the safeguard clause of Directive 1967/548/EEC has not yet been taken before the entry into force of this Regulation (EC) No…

If the proposed harmonised classification and labelling submitted under the first subparagraph is not included in part 3 of Annex VI in accordance with Article 39 (5), the exemption in the first section of this paragraph is no longer valid.[180]

[180] On this addition following a suggestion by **DELETED**, the following delegations have entered a scrutiny reservation: **DELETED**. The **DELETED** agrees with the idea, but needs to check the wording further.

~~*Article 59*~~

~~***Reclassification***~~

~~Where a substance has already been classified in accordance with Directive 67/548/EEC before 1 December 2010, the suppliers shall from that date reclassify such a substance in accordance with Title II of this Regulation or may adapt the classification by using the conversion table in Annex VII.~~

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*

ANNEX ***I***[181]

1.4. Exemptions from labelling and packaging requirements

1.4.1 Exemptions from Article 34 (Article 31(1))

1. Where Article 31(1) applies, the label elements in Article 17 may be provided:

a) In fold-out labels; or
b) On tie-on tags; or
c) On an outer package.[182]

2. The label on any inner package shall contain at least hazard pictograms, *the* product identifier referred to *in* Article 18 and name and telephone number of the supplier of the substance or mixture.[183]

1.4.2 Exemptions from Article 17 (Article 31(2))

1.4.2.1 Labelling of packages where the contents do not exceed 125 ml

1. The hazard statements and the precautionary statements[184] linked to the hazard categories listed below may be omitted from the label elements required by Article 17 where:

a) The contents of the package do not exceed 125 ml; and
b) The substance or mixture is classified in one or more of the following hazard categories:
   1) Flammable Gas of category 1;
   2) Oxidising gas of category 1;
   3) Gas under pressure;
   4) Flammable Liquid of category 1, 2 or 3
   5) Flammable Solid of category 1 or 2;
   6) Self-reactive substance or mixture Types C to F
   7) Self-heating substance or mixture, category 2

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181 This new section 1.4. of Annex I is suggested in order to simplify the structure of Article 31 and to delete Article 32.

182 **DELETED**: Reword c) as follows: "c) on an outer package, *provided that the substance or mixture is placed on the market or sold to the consumer at least in outer and inner packaging and the label of the immediate packaging bears at least information referred to in point 1.4.1.2 of Annex I*"; and insert a new subparagraph d) as follows: "*d) on a separate information sheet which accompanies the package of the substance or mixture, the label of the immediate packaging bears at least information referred to in point 1.4.1.2 of Annex I*".

183 **DELETED**: Reword as follows: "*Where exemptions referred to in 1(c) and 1(d) apply, the immediate packaging of the substance or mixture shall contain at least hazard pictograms, product identifier referred to the Article 18, name and telephone number of the supplier of the substance or mixture and a reference, that all other safety information is provided on the outer package or information sheet.*"

184 **DELETED**: Use "or" instead of "and".

8) Substance which in contact with water emits Flammable Gases of categories 1, 2 or 3;
9) Oxidising Liquid of category 2 or 3;
10) Oxidising Solid of category 2 or 3;
11) Organic peroxides Types C to F;
12) Acutely Toxic category 4, if the substance or mixture is not supplied to the general public;
13) Skin Irritant of category 2;
14) Eye Irritant of category 2;

15) Specific Target Organ Toxicity – single exposure of category 2 and 3, if the substance or mixture is not supplied to the general public;
16) Specific Target Organ Toxicity – repeated exposure of category 2, if the substance or mixture is not supplied to the general public
17) Hazardous to the Aquatic Environment – Acute of category 1;
18) Hazardous to the Aquatic Environment – Chronic of category 1 or 2. [ENVI 68]

The exemptions for labelling of small packages of aerosols as flammable laid down in Directive 75/324/EEC shall apply to aerosol dispensers.

2. [185]The precautionary statements linked to the hazard categories listed below may be omitted from the label elements required by Article 17 where:

a) The contents of the package do not exceed 125 ml and
b) The substance or mixture is classified in one or more of the following hazard categories:

1) Flammable Gas of category 2;
2) Reproductive toxicity: effects on or via lactation
3) Hazardous to the Aquatic Environment - Chronic of category 3 or 4.

3. The pictogram, the hazard statement and the precautionary statement linked to the hazard categories listed below may be omitted from the label elements required by Article 17 where:
a) the contents of the package do not exceed 125 ml and
b) the substance or mixture is classified in one or more of the following hazard categories:

1) Corrosive to metals [ENVI 74]

[185] **DELETED**: Add in the beginning "*It shall be necessary to indicate hazard statement but* the precautionary…"

ANNEX II[186]

3. PART 3: SPECIAL RULES ON PACKAGING

3.1. Provisions relating to child-resistant fastenings

3.1.1. ~~*Containers*~~ ***Packaging*** *to be fitted with child-resistant fastenings*

3.1.1.1. ~~Containers~~ **Packaging** containing **a substance or mixture** supplied to the general public and classified as acutely toxic, categories 1 to 3, specific target organ toxicity (Stot) - single exposure Category 1 and 2, Stot - repeated exposure Category 1, skin corrosion or serious eye damage shall be fitted with child-resistant fastenings.

3.1.1.2. ~~Containers~~ **Packaging** containing **a substance or mixture** presenting an aspiration hazard and classified according to section 3.10.2 of Annex I and labelled according to section 3.10.4.1 of Annex I, with the exception of substances and mixtures placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment, shall be fitted with child-resistant fastenings.

3.1.1.3 ~~Containers~~ **Where a substances or mixture** has ~~having~~ at least one of the substances mentioned below present in a concentration equal to or greater than the maximum individual concentrations specified, which are supplied to the general public, **the packaging** shall be fitted with child-resistant fastenings.

No.	Identification of the substance			Concentration limit
	CAS No:	Name	EC No:	
1	67-56-1	methanol	200-659-6	≥ 3%
2	75-09-2	dichloromethane	200-838-9	≥ 1%

[186] Modifications to Annex II following from new wording of Art. 37.

3.1.2 Reclosable packages

Child-resistant fastenings used on reclosable packages shall comply with ISO standard 8317 as amended relating to "Child-resistant packages - Requirements and methods of testing for reclosable packages" adopted by the International Standard Organisation (ISO).

3.1.3 Non-reclosable packages

Child-resistant fastenings used on non-reclosable packages shall comply with CEN standard EN 862 as amended relating to "Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products" adopted by the European Committee for Standardisation (CEN).

3.1.4 Notes

3.1.4.1. Evidence of conformity with the above standards may be certified only by laboratories which conform to European Standards Series EN 45 000.

3.1.4.2. Specific cases

If it seems obvious that packaging is sufficiently safe for children because they cannot get access to the contents without the help of a tool, the test referred to in 3.1.2 or 3.1.3 does not need to be performed.

In all other cases and when there are sufficient grounds for doubting the security of the closure for a child, the national authority may ask the person responsible for putting the product on the market to give it a certificate from a certifying laboratory, referred to in 3.1.4.1, stating that either:

– the type of closure is such that it is not necessary to perform the test referred to in 3.1.2. or 3.1.3 ; or

– the closure has been tested and has been found to conform with the standards referred to above.

3.2. Tactile Warnings

*3.2.1. ~~Containers~~ **Packaging** to be fitted with a tactile waning*

~~Containers containing~~ **Where substances** or mixtures are supplied to the general public and classified as acutely toxic, skin corrosion or serious eye damage, germ cell mutagenicity Category 2, carcinogenicity Category 2, reproductive toxicity Category 2, skin or respiratory sensitisation, or specific target organ toxicity (STOT), aspiration hazard, or flammable gases, liquids and solids in Categories 1 and 2, **the packaging** shall be fitted with a tactile warning of danger.

3.2.2 Provisions relating to tactile warning

3.2.2.1 This provision does not apply to aerosols which are only classified and labelled as "extremely flammable aerosols" or "flammable aerosols".

3.2.2.2. The technical specifications for tactile warning devices shall conform to ISO standard 11683 as amended “Packaging - Tactile warnings of danger-Requirements”.

Part X of Annex X[187]

Requests for use of an alternative chemical name under Article 26 may be granted only where the substance has not been assigned a Community exposure limit, and where the substance is classified exclusively as one or more of the following hazard categories:

(a)[188 189] **Any of the hazard categories referred to in part 2 of Annex I;**

(b) Acute toxicity, Category 4;

(c) Skin corrosion/irritation, Category 2;

(d) Serious eye damage/eye irritation, Category 2;

(e) Specific target organ toxicity – Single exposure, Category 2 or 3;

(f) Specific target organ toxicity – Repeated exposure, Category 2;

(g) Hazardous to the aquatic environment – Chronic, Category 3 or 4

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187 **DELETED**: Scrutiny reservation.

188 **DELETED**: Scrutiny reservation on (a) and (g) - are they necessary in view of the contents of Article 18(3)?

189 Scrutiny reservation by some delegations on this list.