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REPORT

on the proposal for a regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006
(COM(2007)0355 – C6-0197/2007 – 2007/0121(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Amalia Sartori

Draftsman (*):
Andreas Schwab, Committee on the Internal Market and Consumer Protection

(*) Procedure with associated committee - Rule 47 of the Rules of Procedure

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

(*) Procedure with associated Committees - Rule 47 of the Rules of Procedure

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006
(COM(2007)0355 – C6-0197/2007 – 2007/0121(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0355),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0197/2007),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Industry, Research and Energy (A6-0140/2008),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament

Amendment 1

Proposal for a regulation – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(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	(7) The benefits for enterprises will increase as more countries in the world adopt the GHS criteria in their legislation. ***Stricter labelling can strengthen consumers' trust in chemicals.*** The Community should be at the forefront of

advantage to industry in the Community.	this process to encourage other countries to follow and to provide a competitive advantage to industry in the Community ***and in particular to small and medium-sized enterprises (SMEs)***.

Justification

The confidence in chemical industry decreased in the past years. A strict labelling system can help consumers to trust more in the products of chemical industry. The Commission's online consultation of 21 August to 21 October 2006 received 370 replies from enterprises, of which 45% had a workforce of less than 250 employees.

Amendment 2

Proposal for a regulation – amending act
Recital 8

Text proposed by the Commission	*Amendment*
(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.	(8) Therefore it is essential to harmonise the provisions ***and criteria*** for the classification and labelling of substances and mixtures within the Community, taking into ***full*** 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.

Justification

To ensure consistency with the regulation's objectives. The proposed regulation will only serve its purpose of harmonisation if the entire classification criteria and labelling rules of the GHS are transposed into Community legislation.

Amendment 3

Proposal for a regulation – amending act
Recital 13

Text proposed by the Commission	*Amendment*
(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 and with the definitions specified at UN level in the GHS, in order to ensure maximum consistency in the application of chemicals legislation within the Community in the context of global trade. The hazard classes specified in the GHS should be set out in this Regulation for the same reason.	(13) The terms ***and definitions*** used in this Regulation should be consistent with those set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC 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.

Justification

To avoid confusion, terms and definitions must be consistent with the relevant European legislation.

Amendment 4

Proposal for a regulation – amending act
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16 a) Since the principle of classification by the supplier ensures a uniform EU-wide approach to the classification of all substances and mixtures, it is a key factor in guaranteeing the free movement of goods within the internal market. This

classification should therefore apply for all substances and mixtures falling within the scope of this Regulation. The Member States are called upon to implement the principle of supplier classification in all other areas of classification of chemical substances.

Justification

One of the main objectives of this legislation is to harmonise the classification and labelling of chemical substances and mixtures so as to prevent distortions of competition in the internal market. Classification by the manufacturer, as laid out in Article 4, constitutes a fundamental principle to ensure uniform classification within the EU. This principle should therefore apply without exception to all substances and mixtures falling within the scope of this regulation.

Amendment 5

Proposal for a regulation – amending act
Recital 18

Text proposed by the Commission	*Amendment*
(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.	(18) To ensure that customers receive ***reliable and transparent*** 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.

Amendment 6

Proposal for a regulation – amending act
Recital 19

Text proposed by the Commission	*Amendment*
(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.	(19) To ensure information on ***and protection from*** 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.

Justification

Classification, labelling and packaging is not done for information purposes alone but for consumer health and environmental protection purposes.

Amendment 7

Proposal for a regulation – amending act
Recital 21

Text proposed by the Commission	*Amendment*
(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.	(21) The classification of any substance or mixture may be carried out on the basis of available information, ***which should*** be used for the purposes of this Regulation ***and*** 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.

Justification

It must be made clear that any relevant information available can be taken into consideration in the classification of a substance or mixture.

Amendment 8

Proposal for a regulation – amending act
Recital 23a (new)

Text proposed by the Commission	*Amendment*
	(23a) In the interests of providing consumers with appropriate information, of avoiding disproportionate measures, such as child resistant packaging, which may arise from the over-classification of substances and mixtures, and of avoiding the duplication of testing, the Member States should introduce a procedure to assist all suppliers, and particularly SMEs in certain specific product groups to determine the appropriate classification, labelling and packaging for such substances and mixtures.

Justification

Where the manufacturer only has the information provided by the supplier(s) of the substances used in the product (mixture), he will rely on the establishment of the classification of the mixture from an evaluation of information by the procedure given in Article 9 paragraph 4. This may under or (particularly) over estimate the hazardous properties of the mixture. The availability and recognition of a procedure whereby expertise, additional information and data can be made available to evaluate a mixture will ensure a more accurate classification and be of particular value to SME's.

Amendment 9

Proposal for a regulation – amending act
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) When conducting or overseeing validation studies to assess non-animal tests, or methods that reduce the number of animals used or the suffering experienced by test animals, account should be taken of the need to classify and label substances according to this Regulation and legislation implementing the GHS.

Justification

Validation studies in the past have on occasion failed to ensure that new tests are tailored to satisfy classification and labelling as well as safety requirements. This can delay the uptake of new alternative methods, and prolong the use of animal tests even when scientifically valid alternative methods exist.

Amendment 10

Proposal for a regulation – amending act
Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) In the event that non-animal tests, or animal tests that have been refined to reduce the number of animals used or the suffering experienced by test animals, generate data that are not directly compatible with certain classification and labelling criteria under this Regulation, but in all respects satisfy the requirements of scientific validation for the purpose of protection of human health and the environment, this Regulation should be adapted, where there is adequate scientific justification, to ensure that classification and labelling criteria do not become a barrier to use of such test methods.

Justification

Although the GHS is often referred to as 'test method neutral', it is possible that alternative test methods (applying the principle of replacement, reduction and refinement of animal use) may provide data that do not directly correspond to current classification criteria, many of which refer to in vivo phenomena or refer directly to effects in 'tested animals'. It should therefore be possible to adapt classification and labelling criteria to accommodate methods which, by their very nature, do not involve testing on animals.

Amendment 11

Proposal for a regulation – amending act
Recital 25

Text proposed by the Commission	*Amendment*
(25) ***New information as regards*** physical	(25) ***Tests to determine the*** physical

hazards should always be necessary, except if ***the*** data are already available or if a derogation is foreseen in part 2.	hazards ***of a substance or mixture*** should always be necessary, except if ***reliable and adequate*** data are already available or if a derogation is foreseen in part 2.

Amendment 12

Proposal for a regulation – amending act
Recital 26

Text proposed by the Commission	*Amendment*
(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***.	(26) For the purpose of classification, data should not be generated by means of testing on non-human primates. ***For the sole purpose of classification, the generation of data by means of testing on humans is generally not acceptable and should only be undertaken when no other alternatives are possible.*** Available, reliable epidemiological data and ***scientifically valid*** 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 ***compared with*** results of data from humans and expert judgement should be used to ensure the best protection of human health ***and that the classification of the substance or mixture is in accordance with its actual effects on human health.***

Justification

Tests on non-human primates should not be allowed at all for the purpose of classification of substances and mixtures. Tests on humans should be allowed in exceptional cases to ensure the protection of human health. More accurately reflects existing text in GHS and the Dangerous Substances and Preparations Directives.

Amendment 13

Proposal for a regulation – amending act
Recital 31

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

Justification

The current Annex VI to the Dangerous Substances Directive (section 1.7.2.1) requires to classify substances where impurities, additives or individual constituents are identified equal or above specified limits according to the requirements of the Dangerous Preparations Directive.

Amendment 14

Proposal for a regulation – amending act
Recital 32

Text proposed by the Commission	*Amendment*
(32) To ensure adequate classification of mixtures, available information on synergistic and antagonistic effects should be taken into account for the classification of mixtures.	(32) To ensure adequate classification of mixtures, available information on synergistic and antagonistic effects should be taken into account for the classification of mixtures. ***Account should also be taken of information on effects which are carcinogenic, mutagenic, harmful to reproduction or allergenic.***

Justification

The aim is to supplement the list of effects. Particular emphasis is placed on these factors in Recital 22 of the proposal.

Amendment 15

Proposal for a regulation – amending act
Recital 35

Text proposed by the Commission	*Amendment*
(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.	(35) Two ***important*** 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. ***Of these only*** the label is ***readily available*** for communication to consumers ***and it therefore needs to be sufficiently detailed and relevant to the use of the product. It is thus essential that, as provided for in Regulation (EC) No 1907/2006, the Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, provides guidance for the communication of information to the general public on the risks and safe use of chemical substances and mixtures. The label*** 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.

Justification

An appropriate and consistent communication system will provide consumers with the necessary information and advice to enable them to manage their risk safely and effectively when using a substance, preparation or product containing chemicals. Also consistent with GHS where the label for consumers needs to be "sufficiently detailed and relevant to the use of the product".

Amendment 16

Proposal for a regulation – amending act
Recital 35a (new)

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

Justification

Where large amounts of information are printed on packaging which is too small or otherwise unsuitable for the display of such information, there is no guarantee that the consumer will take it on board. The address of an Internet site or a freephone number would be visible even on small packages and could therefore provide a useful alternative channel through which consumers could obtain relevant information.

Amendment 17

Proposal for a regulation – amending act
Recital 37

Text proposed by the Commission	*Amendment*
(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.	(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 ***of certain substances*** in a way that does not put the confidential nature of their businesses at risk.

Justification

It should not be possible to conceal the name of a substance of very high concern, such as substances that are carcinogenic, mutagenic or toxic to reproduction, for reasons of business confidentiality.

Amendment 18

Proposal for a regulation – amending act
Recital 38

Text proposed by the Commission	*Amendment*
(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.	(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 ***with the common name, if available,*** for the purposes of this Regulation.

Justification

Many chemicals has a common name, which is much widely known as the IUPAC name, therefore the available common name should also be indicated.

Amendment 19

Proposal for a regulation – amending act
Recital 41

Text proposed by the Commission	*Amendment*
(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 ***and*** Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.	(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, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ***and Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents[1].*** ***[1] OJ L 104, 8.4.2004, p. 1. Regulation as amended by Commission Regulation (EC) No 907/2006 (OJ L 168, 21.6.2006, p. 5).***

Justification

The Detergent Regulation contains specific labelling provisions for detergent products that have to be complied with.

Amendment 20

Proposal for a regulation – amending act
Recital 44

Text proposed by the Commission	*Amendment*
(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.	(44) Resources of the authorities should be focused on substances of the highest concern ***with regard to health and the environment***. 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. ***PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances should be included later in this Regulation.***

Justification

The labelling of persistent, bioaccumulative and toxic chemicals, where data is available, is essential for the consumers.

Amendment 21

Proposal for a regulation – amending act
Recital 46

Text proposed by the Commission	*Amendment*
(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	(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.	established for a classification and labelling inventory. The classification and labelling for any substance placed on the market ***– for substances subject to registration in quantities of 1 tonne or more per year under Regulation (EC) No 1907/2006 –*** should therefore be notified to the Agency to be included in the inventory.

Justification

Article 6 of Regulation (EC) 1907/2006 lays down an obligation to register substances above a threshold of one tonne. In the light of the REACH provisions and the detailed assessments on the basis of which that threshold was set, the same threshold should apply in connection with the notification to the Agency of the information required under the GHS system.

Amendment 22

Proposal for a regulation – amending act
Recital 52

Text proposed by the Commission	*Amendment*
(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.	(52) In order to provide focal points for information on hazardous substances and mixtures, Member States should appoint bodies responsible for receiving ***and processing*** information ***and compiling data*** relating to health in addition to the competent authorities for the application and enforcement of this Regulation. ***The Commission should make the information received available to the public, via the Internet.***

Justification

It is not just the receiving of information which is important for public health, but also the compiling of large amounts of data. The information on the substances with their classifications should be available and easily accessible to the public.

Amendment 23

Proposal for a regulation – amending act
Recital 55

Text proposed by the Commission	*Amendment*
(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.	(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. ***Member States should also set up an effective supervisory and control system.***

Justification

An efficient supervisory and control system is required in order for the system established under this regulation to be effective.

Amendment 24

Proposal for a regulation – amending act
Recital 64

Text proposed by the Commission	*Amendment*
(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.	(64) In particular*, the Commission should be empowered* to adapt this Regulation to technical ***and scientific*** progress, including incorporating amendments made at UN level to the GHS. In carrying out such adaptations to technical ***and scientific*** progress the biannual working rhythm at UN level should be considered. ***The development and validation of new testing methods should also be reflected in this Regulation.*** 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 *must* be adopted in accordance with

	the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Justification

In the field of chemicals there is rapid scientific and technical progress. It is necessary to adapt the regulation to the scientific developments, including those which deal with testing methods.

Amendment 25

Proposal for a regulation – amending act
Article 1 - paragraph 1 - point (a)

Text proposed by the Commission	*Amendment*
(a) harmonising the classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;	(a) harmonising the ***criteria for and*** classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

Justification

To ensure consistency with the regulation's objectives.

Amendment 26

Proposal for a regulation – amending act
Article 1 - paragraph 1 - point (d)

Text proposed by the Commission	*Amendment*
(d) establishing a list of substances with their harmonised classifications and labelling at Community level in part 3 of Annex VI;	(d) establishing ***and making publicly available*** a list of substances with their harmonised classifications and labelling at Community level in part 3 of Annex VI;

Justification

The list of the substances with their harmonised classifications and labelling should be available for the public.

Amendment 27

Proposal for a regulation – amending act
Article 1 - paragraph 2 - point (d)

Text proposed by the Commission	*Amendment*
(d) substances and mixtures for scientific research and development, which are not placed on the market***, provided they are used under such controlled conditions minimising exposure as if they were classified as carcinogenic, germ cell mutagenic or toxic to reproduction (CMR) category 1A or 1B according to Annex I***.	(d) substances and mixtures for scientific research and development ***or for process oriented research and development***, which are not placed on the market ***or are placed on the market at an annual volume below 1 tonne per supplier***.

Justification

Scientific research and development can identify safer and less polluting alternative solutions. Therefore, in line with the REACH provisions, quantities below a given threshold of substances and mixtures for scientific research and development should not be covered by the regulation.

Amendment 28

Proposal for a regulation – amending act
Article 2 - paragraph 2 - point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) preparation means a mixture or solution composed of two or more substances; mixture and preparation are synonyms.

Justification

For the sake of completeness, a definition of mixtures, based on that for preparations already set out in the REACH provisions, is included. The term mixture is synonymous with the term preparation.

Amendment 29

Proposal for a regulation – amending act
Article 3 - paragraph 1 - subparagraph 2

Text proposed by the Commission	*Amendment*
Where, in the case of the hazard classes	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 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.	referred to in sections 3.1, 3.4, ***3.5, 3.6,*** 3.7, 3.8***, 3.9*** and 4.1 of Annex I, those 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.

Justification

For completeness - germ cell mutagenicity, carcinogenicity and STOT repeated exposure can be differentiated on the basis of route of exposure.

Amendment 30

Proposal for a regulation – amending act
Article 3 - paragraph 2 - introduction

Text proposed by the Commission	*Amendment*
2. A substance or mixture fulfilling the criteria for any of the following hazard classes or categories set out in Annex I is dangerous:	2. A substance or mixture fulfilling the criteria for any of the following hazard classes or categories set out in Annex I is dangerous ***within the meaning of Regulation (EC) No 1907/2006 and for the purposes of downstream legislation***:

Justification

To bring the provision into line with the provisions of the REACH regulation (EC 1907/2006), so as to avoid confusion about the meaning of hazard and danger.

Amendment 31

Proposal for a regulation – amending act
Article 3 - paragraph 3

Text proposed by the Commission	*Amendment*
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	3. The Commission may develop ***and incorporate*** further differentiations for hazard classes***, if internationally agreed,*** 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

to in Article 54 (3).	regulatory procedure with scrutiny referred to in Article 54 (3).

Justification

Need to always strive for consistency with the objective of global harmonisation.

Amendment 32

Proposal for a regulation – amending act
Article 4 - paragraph 1 - subparagraph 1

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

Justification

Clarity. Downstream users have specific responsibilities under REACH but these do not extend to C&L. However, if a downstream user uses a substance to produce a mixture for supply, they then become a manufacturer with C&L responsibilities.

Amendment 33

Proposal for a regulation – amending act
Article 5 - paragraph 1 - point (b)

Text proposed by the Commission	*Amendment*
(b) epidemiological data and experience on the effects on humans;	(b) ***reliable*** epidemiological data and ***scientifically valid*** experience on the effects ***of substances*** on humans ***(e.g. occupational data, data from accident databases and from prospective studies)***;

Justification

It is important to draw attention to the reliability and nature of the data to be used and to the availability of data from internationally recognised programmes or sources.

Amendment 34

Proposal for a regulation – amending act
Article 5 - paragraph 1 - point (c a) (new)

Text proposed by the Commission	*Amendment*
	(ca) any new reliable scientific information.

Justification

The data on the substances shall be updated with the latest scientific information.

Amendment 35

Proposal for a regulation – amending act
Article 5 - paragraph 1 - point (c b) (new)

Text proposed by the Commission	*Amendment*
	(cb) any other information generated under international chemical programmes.

Justification

It is important to draw attention to the reliability and nature of the data to be used and to the availability of data from internationally recognised programmes or sources.

Amendment 36

Proposal for a regulation – amending act
Article 6 - paragraph 1

Text proposed by the Commission	*Amendment*
1. The supplier of a mixture 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:	1. The supplier of a mixture shall identify 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;	(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	(b) ***reliable*** epidemiological data and ***scientifically valid*** experience on the

or the substances contained in it;	effects on humans for the mixture itself or the substances contained in it ***(e.g. occupational data, data from accident databases and from prospective studies)***;
(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.	(c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006 for the mixture itself or the substances contained in it;
	(ca) any other information generated under international chemical programmes for the mixture itself or the substances contained in it;
	(cb) information regarding the composition and classification of existing mixtures within a group of similarly related mixtures.
The information shall relate to the 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.	The information shall relate***, when relevant,*** to the 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.

Justification

It is important to draw attention to the reliability and nature of the data to be used and to the availability of data from internationally recognised programmes or sources.

Amendment 37

Proposal for a regulation – amending act
Article 6 - paragraph 2

Text proposed by the Commission	*Amendment*
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 has ascertained that information to be adequate and reliable, he shall use that information for the purposes of the evaluation pursuant to Chapter 2.	2. Subject to paragraphs 3 and 4, where the information referred to in ***paragraph 1*** is available for the mixture itself, and the supplier has ascertained that information to be adequate and reliable, he shall use that information for the purposes of the evaluation pursuant to Chapter 2.

Justification

The reference should be to paragraph 1 as a whole, so as to include all available relevant

data.

Amendment 38

Proposal for a regulation – amending act
Article 6 - paragraph 5

Text proposed by the Commission	*Amendment*
5. Where no ***test*** data on the mixture itself of the kind referred to in paragraph 1 are available, the supplier 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).	5. Where no data on the mixture itself of the kind referred to in paragraph 1 are available, the supplier shall use ***all*** available information on individual substances and mixtures ***or mixtures within a group of similarly related 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).

Justification

For the application of expert judgement and weight of evidence determinations, foreseen in Annex I Part I, Section 1.1.1., it is necessary to collate available data on mixtures within any groups of similarly related mixtures. Not all of the data referred to in paragraph 1 are 'test' data (in the conventional sense), e.g. that in paragraph 1 (b), and consequently reference to 'test' data should be deleted.

Amendment 39

Proposal for a regulation – amending act
Article 7 - paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no other alternatives***, which provide the same level of reliability and quality of data,*** are possible. ***Testing methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals***

and the number of animals involved.

Justification

It is necessary to reiterate here the commitment to reduce animal testing.

Amendment 40

Proposal for a regulation – amending act
Article 7 - paragraph 2

Text proposed by the Commission	*Amendment*
2. Tests on humans ***and non-human primates shall not be performed for the purposes*** of this Regulation.	2. Tests on humans ***for the sole purpose*** of this Regulation ***are generally not acceptable and shall only be undertaken when no other alternatives are possible to ensure the best protection of human health and the classification of a substance or mixture according to its actual effects on human health.*** ***Tests on non-human primates shall not be performed for the purposes of this Regulation.***

Justification

In order to protect human health and to classify substances and mixtures accurately, it may be necessary to carry out tests on humans (e.g. human patch tests) to get information on the actual effects on human health. Such tests should be limited, however, to those cases where no other alternatives are available. Tests on non-human primates should not be allowed for the purposes of this regulation.

Amendment 41

Proposal for a regulation – amending act
Article 7 - paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Validation studies to assess non-animal tests, or methods that reduce the number of animals used or the suffering experienced by test animals, shall be designed to ensure that new test methods take account of the requirements contained in this Regulation and similar

	legislation implementing the Globally Harmonised System of Classification and Labelling of Chemicals in other jurisdictions so that classification and labelling requirements do not become a barrier to the replacement, reduction and refinement of animal testing.

Justification

Validation studies in the past have on occasion failed to ensure that new tests are tailored to satisfy classification and labelling as well as safety requirements. This can delay the uptake of new alternative methods, and prolong the use of animal tests even when scientifically valid alternative methods exist.

Amendment 42

Proposal for a regulation – amending act
Article 7 - paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Where there is sufficient scientific justification, and in order to minimise animal testing, the Commission shall adapt this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 54(3) to ensure that classification and labelling requirements do not become a barrier to the use of test methods that replace, reduce or refine animal testing.

Justification

Although the GHS is often referred to as 'test method neutral', it is possible that alternative test methods (applying the principle of replacement, reduction and refinement of animal use) may provide data that do not directly correspond to current classification criteria, many of which reference in vivo phenomena or refer directly to effects in 'tested animals'. It should therefore be possible to adapt classification and labelling criteria to accommodate methods which, by their very nature, do not involve testing on animals.

Amendment 43

Proposal for a regulation – amending act
Article 8 - paragraph 3 - point (c)

Text proposed by the Commission	*Amendment*
(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.	(c) in respect of health and environmental hazards as set out in parts 3 and 4 of Annex I, ***complying with sound*** scientific principles, ***preferably internationally recognised,*** or methods validated according to international procedures.

Justification

For the purpose of identifying health and environmental hazards, a reference needs to be made to sound scientific principles that are internationally recognised.

Amendment 44

Proposal for a regulation – amending act
Article 8 - paragraph 4

Text proposed by the Commission	*Amendment*
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 in which it is used or ***reasonably can be expected to be used after it is*** placed on the market.	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 in which it is ***intended to be*** used***,*** or ***in the form and/or physical state as*** placed on the market.

Justification

Consistency with text of GHS 1.3.3.1.1 (b) "the evaluation is based on the actual product involved".

Amendment 45

Proposal for a regulation – amending act
Article 9 - paragraph 4 - subparagraph 2

Text proposed by the Commission	*Amendment*
However, where that information does not permit the application of the bridging principles, the supplier shall evaluate the information by applying the other method	However, where that information does not permit the application of the bridging principles, ***and expert judgement cannot justify extensions beyond the bridging***

or methods described in each section of parts 3 and 4 of Annex I.	***principles,*** the supplier shall evaluate the information by applying the other method or methods described in each section of parts 3 and 4 of Annex I.

Justification

For consistency with the UN GHS wording on expert judgement (1.3.2.4.8 of the Purple Book): "The approach to classifying mixtures includes the application of expert judgement in a number of areas in order to ensure existing information can be used for as many mixtures as possible to provide protection for human health and the environment".

Amendment 46

Proposal for a regulation – amending act
Article 9 - paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. When evaluating the data the manufacturer or importer shall consider additional information such as the form and/or physical state in which the substance or mixture is used after it is placed on the market and may refine the classification accordingly. Normal handling and use should be taken into consideration in the classification of a substance or mixture.

Justification

Consistency with the current level of protection to retain the principle of normal handling and use as a necessary 'left over' from existing EU legislation like for example the class 'hazardous to the ozone layer.

Amendment 47

Proposal for a regulation – amending act
Article 9 - paragraph 4b (new)

Text proposed by the Commission	*Amendment*
	4b. Where a specific product sector group has established a Hazard and Classification Centre, which brings together expertise in the evaluation of

information, test data, weight of evidence determinations, and bridging principles, any supplier within the product sector may rely on an evaluation from that centre for the establishment of the hazards associated with, and the corresponding classification of, the mixture.

Justification

Where the manufacturer only has the information provided by the supplier(s) of the substances used in the product (mixture), he will rely on an evaluation of information under the procedure given in Article 9 paragraph 4 to establish the classification of the mixture. This may under- or (particularly) over-estimate the hazardous properties of the mixture. The availability and recognition of a procedure whereby expertise, additional information and data can be made available to evaluate a mixture will ensure a more accurate classification and be of particular value to SMEs.

Amendment 48

Proposal for a regulation – amending act
Article 10 - paragraph 1

Text proposed by the Commission	*Amendment*
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:	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 ***identified*** 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;	(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	(b) ***on occasion***, 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

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.	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.

Justification

(i) "identified impurity" - Workability, particularly for complex substances, and consistency with the scope of the current legislation; (ii) "on occasion" - in line with GHS text 1.3.3.2.3

Amendment 49

Proposal for a regulation – amending act
Article 10 - paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The supplier shall set concentration limits in accordance with the criteria set out in the guidance made available by the Agency, and shall include the justification therefor either in his notification according to the classification and labelling inventory or in his registration according to Regulation (EC) No 1907/2006.

Justification

In line with supplier SCL and m-factor reporting as originally proposed for Internet version Annex I, Part 1, 1.1.4.3 and GHS text 1.3.3.2.4..

Amendment 50

Proposal for a regulation – amending act
Article 11 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a substance contains another substance, classified as hazardous itself, in the form of an impurity, additive or individual constituent, this information shall be taken into account for the purposes of classification, if the concentration of the impurity, additive or individual constituent	1. Where a substance contains another substance, classified as hazardous itself, in the form of an ***identified*** impurity, additive or individual constituent, this information shall be taken into account for the purposes of classification, if the concentration of the impurity, additive or individual constituent

is equal to or greater than its cut-off value referred to in paragraph 3.	is equal to or greater than its cut-off value referred to in paragraph 3.

Justification

The current Annex VI to the Dangerous Substances Directive (section 1.7.2.1) requires to classify substances where impurities, additives or individual constituents are identified equal or above specified limits according to the requirements of the Dangerous Preparations Directive. This has been found appropriate for the classification of many complex substances with varying level impurities or constituents and the impossibility to identify all of them. The formulation used in the proposal would lead automatically to the lowest cut-off value, regardless of justification.

Amendment 51

Proposal for a regulation – amending act
Article 11 - paragraph 2

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

Justification

The current Annex VI to the Dangerous Substances Directive (section 1.7.2.1) requires to classify substances where impurities, additives or individual constituents are identified equal or above specified limits according to the requirements of the Dangerous Preparations Directive. This has been found appropriate for the classification of many complex substances with varying level impurities or constituents and the impossibility to identify all of them. The formulation used in the proposal would lead automatically to the lowest cut-off value, regardless of justification.

Amendment 52

Proposal for a regulation – amending act
Article 11 - paragraph 3

Text proposed by the Commission	*Amendment*
3. The cut-off value referred to in paragraphs 1 and 2 shall be ***the lower*** of the following:	3. The cut-off value referred to in paragraphs 1 and 2 shall be ***one*** of the following:
(a) ***the generic cut-off values specified in Table 1.1 of part 1 of Annex I;***	(a) ***the specific concentration limits set in part 3 of Annex VI, or***
(b) ***any specific*** concentration limits set ***in part 3 of Annex VI or*** in the classification and labelling inventory referred to in Article 43***;***	(b) ***the*** concentration limits set in the classification and labelling inventory referred to in Article 43 ***if the notifiers have reached agreement; or***
	(ba) the generic cut-off values specified in Table 1.1 of part 1 of Annex I, where the concentration limits referred to in points (a) and (b) are not available;
(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.	(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 points (a), (b) or (ba)*** are not available.

Justification

The text, as it now stands, would result automatically in the lowest cut-off values, irrespective of justification. In the past there was some justification for setting specific concentration limits for substances above the generic limits.

Amendment 53

Proposal for a regulation – amending act
Article 12 - point (c)

Text proposed by the Commission	*Amendment*
c) where adequate and reliable 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***.	c) where adequate and reliable information demonstrates the potential occurrence of synergistic or antagonistic effects ***between*** the substances in a mixture.

Amendment 54

Proposal for a regulation – amending act
Article 14 - paragraph 1 - points (a) and (b)

Text proposed by the Commission	*Amendment*
(a) that the substances in the mixture react slowly with atmospheric gases, in particular oxygen, carbon dioxide, water vapour, to form different substances;	(a) that the substances in the mixture react slowly with atmospheric gases, in particular oxygen, carbon dioxide, water vapour, to form different ***non-hazardous*** substances;
(b) that the substances in the mixture react very slowly with other substances in the mixture to form different substances;	(b) that the substances in the mixture react very slowly with other substances in the mixture to form different ***non-hazardous*** substances;

Justification

The possibility of the formation of hazardous substances shall be labelled.

Amendment 55

Proposal for a regulation – amending act
Article 17 - paragraph 1 - introductory part

Text proposed by the Commission	*Amendment*
1. A substance or mixture classified as hazardous shall bear a label including the following elements:	1. A substance or mixture classified as hazardous shall bear a label ***on the packaging*** including the following elements:

Justification

Labelling can only be done on the packaging. Indication on the packaging of the neutralising substance to be used is an emergency safety measure, as is the indication of the emergency number (112).

Amendment 56

Proposal for a regulation – amending act
Article 17 - paragraph 1 - points (d) to (h)

Text proposed by the Commission	*Amendment*
(d) ***where appropriate,*** hazard pictograms in accordance with Article 19;	(d) hazard pictograms in accordance with Article 19;
(e) ***where appropriate,*** signal words in accordance with Article 20;	(e) signal words in accordance with Article 20;
(f) ***where appropriate,*** hazard statements in accordance with Article 21;	(f) hazard statements in accordance with Article 21;
(g) ***where appropriate,*** precautionary statements in accordance with Article 22;	(g) precautionary statements in accordance with Article 22;
(h) ***where appropriate,*** a section for supplemental information in accordance with Article 27.	(h) a section for supplemental information in accordance with Article 27.

Justification

The classification should always occur according to the relevant article, and not just "where appropriate".

Amendment 57

Proposal for a regulation – amending act
Article 18 - paragraph 2 - subparagraph 2

Text proposed by the Commission	*Amendment*
Where the name in the IUPAC nomenclature exceeds 100 characters, a common name may be used provided that the notification in accordance with Article 41 includes both the name in the IUPAC Nomenclature and the common name used.	***If a common name is available, it shall also be indicated.*** Where the name in the IUPAC nomenclature exceeds 100 characters, a common name may be used provided that the notification in accordance with Article 41 includes both the name in the IUPAC Nomenclature and the common name used.

Justification

Many chemicals has a common name which is much widely known as the IUPAC name, therefore the available common name should also be indicated.

Amendment 58

Proposal for a regulation – amending act
Article 18 - paragraph 3 - point (b)

Text proposed by the Commission	*Amendment*
(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).	(b) the identity of all substances in the mixture that contribute to ***the classification of the mixture as regards*** acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, or specific target organ toxicity (STOT).

Justification

For clarity - consistent with the wording of Art. 18.3 last paragraph.

Amendment 59

Proposal for a regulation – amending act
Article 18 - paragraph 3 - subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In the case of natural materials, a designation such as 'essential oil from ...' or '... extract' may be used instead of the names of the components of this essential oil or extract*.*

Justification

To list all the names of substances in a mixture would mean a disproportionate amount of effort for flavouring or perfume manufacturers, given the small amounts of such substances which end up in the final product.

Amendment 60

Proposal for a regulation – amending act
Article 21 - paragraph 1

Text proposed by the Commission	*Amendment*
1. The label shall include the relevant hazard statements describing the nature of the hazards of a hazardous substance or	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.	mixture, including, where ***applicable***, the degree of hazard.

Justification

It should not be a question of whether it is appropriate or not to include the degree of hazard. It should be where such a distinction applies.

Amendment 61

Proposal for a regulation – amending act
Article 26 - paragraph 1

Text proposed by the Commission	*Amendment*
1. The supplier of a substance or 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 common name, where he can demonstrate that the disclosure ***on the label*** of the chemical identity of a substance or mixture puts the confidential nature of his business, in particular his intellectual property rights, at risk.	1. The supplier of a substance or 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 common name, where he can demonstrate that the disclosure of the chemical identity of a ***non-hazardous*** substance or ***non-hazardous*** mixture puts the confidential nature of his business, in particular his intellectual property rights, at risk.

Justification

Hazardous substances should not get alleviation from labelling. Business risk can be a used as a reason for exception only at non-hazardous substances. It should be possible to use the generic name also on the safety data sheet (SDS). Confidentiality does make no sense. In the SDS only the clear name is replaced by a generic name, not the classification and relevant danger information.

Amendment 62

Proposal for a regulation – amending act
Article 26 - paragraph 2 - subparagraph 2

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

reduced fee shall be set for SMEs.

Justification

Given the financial implications of the REACH and GHS legislation for SMEs, they should pay a reduced fee.

Amendment 63

Proposal for a regulation – amending act
Article 26 - paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency may require further information from the supplier making the request if such information is necessary to take a decision. The Agency shall notify the person making the request of its decision 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.	3. The Agency may require further information from the supplier making the request if such information is necessary to take a decision. The Agency shall notify the person making the request of its decision 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. ***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, in accordance with Articles 92 and 93 of Regulation (EC) No 1907/2006, against the decision not to accept the request. This appeal shall have a suspensive effect and the data shall not be published.***

Justification

The proposal is table to ensure a right of appeal and the protection of confidential business information (CBI).

Amendment 64

Proposal for a regulation – amending act
Article 26 - paragraph 4a (new)

Text proposed by the Commission	*Amendment*
	4a. The supplier shall inform the Agency without delay if the classification of a substance or a mixture is adapted in accordance with Article 15.

Justification

It is necessary to foresee a situation where the classification of a substance or a mixture, for which certain confidentiality of the chemical identity has been granted, changes.

Amendment 65

Proposal for a regulation – amending act
Article 27 - paragraph 3

Text proposed by the Commission	*Amendment*
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.	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. ***Any misleading information or supplemental information concerning false health or environmental effects shall be prohibited.***

Justification

All false or misleading supplemental information should be prevented.

Amendment 66

Proposal for a regulation – amending act
Article 27 - paragraph 3a (new)

Text proposed by the Commission	*Amendment*
	3a. The Agency shall, in accordance with Article 123 of Regulation (EC) No 1907/2006, provide as a matter of high priority, and in consultation with the Commission, competent authorities and stakeholders, guidance and/or recommendations for any supplemental information on the label that is considered necessary for the protection of human health or the environment when a mixture contains substances with persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties in excess of 0.1%.

Amendment 67

Proposal for a regulation – amending act
Article 30 - paragraph 2 - subparagraph 1

Text proposed by the Commission	*Amendment*
2. Where the substance or mixture is sold to the general public, one precautionary statement addressing the disposal of that substance or mixture shall appear on the label***, where appropriate***.	2. Where the substance or mixture is sold to the general public, one precautionary statement addressing the disposal of that substance or mixture shall appear on the label.

Justification

It should not be a question of whether it is appropriate or not to include a precautionary statement, this should always be the case.

Amendment 68

Proposal for a regulation – amending act
Article 31 - paragraph 1 - point (k)

Text proposed by the Commission	*Amendment*
(k) Chronically Aquatic Hazardous of category 1, 2, ***3 and 4***.	(k) Chronically Aquatic Hazardous of category 1 ***and*** 2.

Justification

Chronically Aquatic Hazardous categories 3 and 4 are not associated with a hazard pictogram; if the hazard statement is omitted from the package then users would not be aware of this particular hazard. This proposed amendment reflects current practice in the DPD for mixtures classified as R10 or R52/53 i.e. classifications not associated with a hazard symbol.

Amendment 69

Proposal for a regulation – amending act
Article 31 - paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. For packaging containing 125 ml or less, precautionary statements need not be indicated on the label, if the substance or mixture is classified as Chronically Aquatic Hazardous of category 3 or 4.

Justification

Chronically Aquatic Hazardous categories 3 and 4 are not associated with a hazard pictogram; if the hazard statement is omitted from the package then users would not be aware of this particular hazard. This proposed amendment reflects current practice in the DPD for mixtures classified as R10 or R52/53 i.e. classifications not associated with a hazard symbol.

Amendment 70

Proposal for a regulation – amending act
Article 31 - paragraph 2 - introductory part

Text proposed by the Commission	*Amendment*
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:	2. Where the Commission ***or, where appropriate, a Member State*** so requests, the Agency shall prepare and submit to the Commission draft exemptions from the obligations to label ***(including the***

application rules) provided for in Articles 17 and 34 as follows:

Justification

With a view, inter alia, to making it easier for SMEs to implement the provisions, Member States should also be able, where appropriate, to ask the Agency to draw up draft exemptions, which the Agency will anyway submit to the Commission.

Amendment 71

Proposal for a regulation – amending act
Article 31 - paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. Without prejudice to paragraphs 1 and 2, hazard and precautionary statements regarding substances or mixtures in small or unsuitable packaging may be accessed via an Internet site address or a freephone number printed on the packaging. Where a substance or mixture is classified as hazardous, the relevant hazard pictogram shall be displayed on the label.

Justification

Where large amounts of information are printed on packaging which is too small or otherwise unsuitable for the display of such information, there is no guarantee that the consumer will take it on board. The address of an Internet site or a freephone number would be visible even on small packages and could therefore provide a useful alternative channel through which consumers could obtain relevant information. As a further precaution, the relevant hazard pictogram must be displayed on all hazardous substances.

Amendment 72

Proposal for a regulation – amending act
Article 31 - paragraph 2b (new)

Text proposed by the Commission	*Amendment*
	2b. Packaging for single use (or one-way packaging, portion-packaging or single-dose packaging), which is contained in outer packaging labelled in accordance with this Regulation, is removed only for

uses in accordance with the instructions for use and is used up immediately, shall not be subject to the labelling requirement.

Justification

To clarify the situation where mixtures are involved that are supplied as a single dose, when the product, such as a tablet, (a) is intended only for a single use, (b) is removed before use direct from the outer packaging, and (c) all the instructions (and further labelling) are on the outer packaging.This amendment replaces existing Amendment 8 to Article 26, paragraph 4a (new) by the rapporteur and thus corrects a technical error.

Amendment 73

Proposal for a regulation – amending act
Article 32

Text proposed by the Commission	*Amendment*
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:***	***When substances or mixtures supplied to*** the general public ***are*** classified ***as*** acute toxicity category 1, 2 or 3***,*** specific target organ toxicity (STOT) – single exposure category 1, specific target organ toxicity (STOT) – repeated exposure category 1 ***or*** skin corrosion category 1 ***and where it is physically impossible to apply a label on the package itself, then packages containing such substances or mixtures shall be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the disposal of the empty package.***
(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.	

Justification

The change is proposed to further clarify the text.

Amendment 74

Proposal for a regulation – amending act
Article 32 - paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Packaging of substances and mixtures destined for the general public and fulfilling the criteria for Hazard Class 2.16 shall be exempted from the obligation to bear a label relating to this hazard, provided that where both an outer and an inner packaging is used, the outer packaging does bear a pictogram in accordance with 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.

Justification

Corrosive to metals is not relevant for supply - Hazard class 2.16 is a new requirement that is not included in the DSD/DPD, but only in the transport regulations. This property is only relevant for transport and storage of bulk quantities. i.e. not relevant for individual consumer packs. This hazard class is assigned a corrosive pictogram - for consumers using the symbol will lead to confusion with skin corrosion and serious eye damage.

Amendment 75

Proposal for a regulation – amending act
Article 32 - paragraph 1b (new)

Text proposed by the Commission	*Amendment*
	1b. For certain mixtures classified as hazardous to the environment, exemptions to certain provisions on environmental labelling or specific provisions in relation to environmental labelling may be determined in accordance with the procedure referred to in Article 53, where it can be demonstrated that there would be a reduction in the environmental impact. Such exemptions or specific provisions

are defined in Part 2 of Annex II.

Justification

In line with current DPD text – Article 10 (3).

Amendment 76

Proposal for a regulation – amending act
Article 33 – paragraphs 1 and 2

Text proposed by the Commission	*Amendment*
The supplier of a substance or a mixture shall update the label ***without delay*** following any change to the classification and labelling of the substance or mixture.	The supplier of a substance or a mixture shall ***take all appropriate measures to*** update the label following any change to the classification and labelling of the substance or mixture***, without delay and in any case not later than twelve months after the change of classification.***
The supplier of a mixture referred to in Article 24 shall update the label without delay following any change to the classification of the substance and the labelling of the mixture.	

Justification

All changes in classification of substances and mixtures should lead to an update of the label without delay. The supplier should act as quickly as possible, but even in less urgent cases (e.g. updating the postal address of the manufacturer) within a clearly defined timeframe. For safety reasons, labels should be updated as soon as possible after such changes have been made.

Amendment 77

Proposal for a regulation – amending act
Article 33 - paragraph 3

Text proposed by the Commission	*Amendment*
This Article shall be without prejudice to Directives 91/414/EEC and 98/8/EC.	This Article shall be without prejudice to Directives 91/414/EEC and 98/8/EC ***and Article 4 of this Regulation***.

Justification

The changes in Annex I of the Dangerous Substances Directive 67/548/EEC come into effect normally with a transitional period of at least 12 months. These transitional periods should also apply in this regulation, since they would ensure that suppliers of substances and mixtures can feasibly put them into effect. Classification by manufacturers, as laid down in Article 4, ensures uniform classification. This basic principle should therefore apply without exception to all substances and mixtures falling within the scope of the regulation.

Amendment 78

Proposal for a regulation – amending act
Article 35 - paragraph 3

Text proposed by the Commission	*Amendment*
3. The supplemental information shall be placed in the supplemental information section as referred to in Article 27 and the location of that section shall not make it more difficult to identify the elements specified in Article 17 (1).	3. The supplemental information shall be placed in the supplemental information section as referred to in Article 27 and the location of that section shall not make it more difficult to identify the elements specified in Article 17 (1). ***The supplier may decide to place all labelling information according to Chapter 1 on one area of the packaging.***

Justification

Incorporated in the report without vote on the base of Rule 47. The supplier should be allowed to put all hazard communication, including supplemental information in one area together in close proximity.

Amendment 79

Proposal for a regulation – amending act
Article 36 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Where both an outer and an inner packaging ***is*** used ***and the outer packaging does not bear a pictogram*** in accordance with 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 packaging shall be*** labelled in accordance with this	1. Where both an outer and an inner packaging ***are*** used***, the labelling requirements shall be deemed to be satisfied if the outer packaging is labelled*** in accordance with 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, ***and if the inner packaging is***

Regulation.	labelled in accordance with this Regulation.
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.	

Justification

Paragraph 1: In line with DPD Article 11.6(a).

Amendment 80

Proposal for a regulation – amending act
Article 36 - paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. If the necessary labelling on the inner packaging is clearly visible due to transparency of the outer packaging (e.g. shrink-wrap), an additional labelling of the outer packaging shall not be required.

Justification

If the outer packaging is transparent, there is no need for additional labelling of the outer packaging which could, furthermore, cause confusion.

Amendment 81

Proposal for a regulation – amending act
Article 36a (new)

Text proposed by the Commission	*Amendment*
	Article 36a
	Labelling of detergents
	The labelling rules provided for in this Title shall be without prejudice to Regulation (EC) No 648/2004.

Justification

Linked to Recital 41. The Detergent Regulation contains specific labelling provisions for

detergent preparations that have to be complied with.

Amendment 82

Proposal for a regulation – amending act
Article 36b (new)

Text proposed by the Commission	*Amendment*
	Article 36b
	Guidance by the Agency
	1. Notwithstanding the labelling rules provided for in Title III, the supplier of a substance or a mixture intended for use by the general public shall label the product in accordance with the guidance provided by the Agency for the communication of information to the general public on the risks and safe use of chemical substances and mixtures, as provided for in Regulation (EC) No 1907/2006.
	2. The Agency shall produce the guidance referred to in paragraph 1 in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice. It shall be available within 18 months of the entry into force of this Regulation.

Justification

Proper information provision to consumers is necessary in order to ensure higher protection and safety standards. An appropriate and consistent information provision system will provide consumers with the information they require in order to deal with risks safely and effectively when using products containing chemicals.

Amendment 83

Proposal for a regulation – amending act
Article 37 - paragraph 1 - point (a)

Text proposed by the Commission	*Amendment*
(a) the packaging shall be so designed and constructed that its contents cannot escape,	(a) the packaging shall be so designed and constructed that its contents cannot escape

except in cases where other more specific safety devices are prescribed;	***during normal handling and use***, except in cases where other more specific safety devices are prescribed;

Justification

Clarity.

Amendment 84

Proposal for a regulation – amending act
Article 37 - paragraph 2

Text proposed by the Commission	*Amendment*
2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products.	2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products ***which would mislead the consumer***.
Where such 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.	Where such 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 there are specific provisions on packaging applying to the mixture, in particular the provisions of Regulation (EC) No 648/2004.***
Where such 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.	Where such 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 there are specific provisions on packaging applying to the mixture, in particular the provisions of Regulation (EC) No 648/2004***.

Justification

This amendment avoids overlapping with provisions of other EU directives or regulations.

Amendment 85

Proposal for a regulation – amending act
Article 40 - title

Text proposed by the Commission	*Amendment*
Content of opinions and decisions for harmonised classification and labelling in Annex VI; accessibility of information	Content of opinions and decisions for harmonised classification and labelling in ***part 3 of*** Annex VI; accessibility of information

Justification

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

Amendment 86

Proposal for a regulation – amending act
Article 40 - paragraph 1 - point (e)

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

Justification

The current Annex VI to the Dangerous Substances Directive (section 1.7.2.1) requires to classify substances where impurities, additives or individual constituents are identified equal or above specified limits according to the requirements of the Dangerous Preparations Directive. This has been found appropriate for the classification of many complex substances with varying level impurities or constituents and the impossibility to identify all of them. The formulation used in the proposal would lead automatically to the lowest cut-off value, regardless of justification.

Amendment 87

Proposal for a regulation – amending act
Article 40 a (new)

Text proposed by the Commission	*Amendment*
	Article 40 a
	Classification and labelling of hazardous substances under Directive 67/548/EEC for hazard categories other than those specified in Article 38(1)
	The classifications and forms of labelling set out in part 4 of Annex VI may be applied by suppliers.
	Where a supplier decides not to apply those classifications and forms of labelling, he shall be required to re-evaluate the substance in question on the basis of the criteria laid down in parts 2 to 5 of Annex I.

Justification

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

Amendment 88

Proposal for a regulation – amending act
Article 41 - paragraph 1 - introductory part

Text proposed by the Commission	*Amendment*
1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market 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 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 to	1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market a substance ***classified as hazardous and*** subject to registration in accordance with Regulation (EC) No 1907/2006 or***, in quantities of one tonne or more per year,*** a substance classified as hazardous on its own or in a mixture above the concentration limits specified in Directive 1999/45/EC or in this Regulation, where relevant, which results in the classification

the Agency the following information in order for it to be included in the inventory referred to in Article 43:	of the mixture as hazardous, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 43:

Justification

The obligation, starting from 1 December 2010, to notify the Agency for the purposes of the classification inventory should not apply to every case in which a substance subject to registration is to be placed on the market, but only to substances classified as hazardous, including where REACH is concerned. In the last two cases mentioned (a substance classified as hazardous on its own or in a mixture ...), a threshold (1 tonne a year) should be laid down. Failure to do so would undermine legal certainty and adversely affect R & D activities.

Amendment 89

Proposal for a regulation – amending act
Article 41 - paragraph 1 - point (c a) (new)

Text proposed by the Commission	*Amendment*
	(ca) where the classification is different from the classification already included in the classification and labelling inventory, the reasons for it;

Justification

According to Article 16, a supplier may classify a substance differently from the classification already included in the classification and labelling inventory, provided the submits the reasons for his classification together with the notification in accordance with Article 41. For reasons of coherence, this should be reflected in Article 41.

Amendment 90

Proposal for a regulation – amending act
Article 41 - paragraph 1 - subparagraph 2

Text proposed by the Commission	*Amendment*
The information referred to in (a) to ***(e)*** shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006.	The information referred to in (a) to ***(f)*** shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006.

Amendment 91

Proposal for a regulation – amending act
Article 41 - paragraph 3

Text proposed by the Commission	*Amendment*
3. For substances placed on the market before 1 December 2010, notifications shall be made in accordance with paragraph 1 before that date.	3. For substances ***classified as hazardous on their own or in a mixture 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,*** placed on the market ***in quantities of one tonne or more per year per manufacturer or importer*** before 1 December 2010, notifications shall be made in accordance with paragraph 1 before that date.

Justification

The paragraph requires notification to the inventory of substances that are placed on the market and subject to registration under (EC) No 1907/2006 (REACH) i.e. at a quantity above 1 ton/year, or substances classified as hazardous on their own or in a mixture resulting in that mixture being classified as hazardous, i.e. irrespective of quantity. In accordance with REACH substances placed on the market below a threshold value of 1 ton/year are not subject to registration and should not be notified to the Inventory. Otherwise, the costs of compliance would exceed the costs of the market.

Amendment 92

Proposal for a regulation – amending act
Article 43 - paragraph 1 - subparagraph 3

Text proposed by the Commission	*Amendment*
Information in the inventory which corresponds to the information referred to in Article 119 (1) of Regulation (EC) No 1907/2006 shall be publicly accessible. The Agency shall grant access to the other information on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance with Article 29(1) of Regulation (EC) No 1907/2006. It shall grant access to such information to other	Information in the inventory which corresponds to the information referred to in Article 119 (1) of Regulation (EC) No 1907/2006 shall be publicly accessible ***via the Internet, except where a supplier has submitted a request in accordance with Article 26, which the Agency has accepted.*** The Agency shall grant access to the other information on each substance in the inventory to the notifiers and registrants who have submitted information

parties subject to Article 118 of that Regulation.	on that substance in accordance with Article 29(1) of Regulation (EC) No 1907/2006. It shall grant access to such information to other parties subject to Article 118 of that Regulation.

Justification

The easiest way to make the data publicly accessible is to make available on the internet. Requests for intellectual property right protection must be guaranteed.

Amendment 93

Proposal for a regulation – amending act
Article 43 - paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. In addition to the information referred to in paragraph 1, the Agency shall, where ***appropriate***, include the following information in each entry:	3. In addition to the information referred to in paragraph 1, the Agency shall, where ***applicable***, include the following information in each entry:

Justification

It should not be a question of whether it is appropriate or not to provide supplementary information, but rather whether to do so where the information is applicable.

Amendment 94

Proposal for a regulation – amending act
Article 45

Text proposed by the Commission	*Amendment*
1. Member States shall appoint a body or bodies responsible for receiving information by the suppliers***, including chemical composition of*** the mixtures placed on the market and classified or considered as hazardous on the basis of their health effects or on the basis of their physical effects.	1. Member States shall appoint a body or bodies responsible for receiving information by the suppliers ***on*** the mixtures placed on the market and classified or considered as hazardous on the basis of their health effects or on the basis of their physical effects.
	1a. The information referred to in paragraph 1 shall be presented in the format to be laid down in Annex VIIa[1]

	and shall be sufficient to meet medical needs for the purpose of determining preventive and curative measures, in particular in case of emergency.
2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to ***meet medical demand by formulating preventative and curative measures, in particular in case of emergency.***	2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to ***satisfy the medical needs referred to in paragraph 1a and shall not be used for other purposes***.
The information shall not be used for other purposes.	
3. The appointed bodies shall have at their disposal all the information required from the suppliers responsible for marketing to carry out the tasks for which they are responsible.	3. The appointed bodies shall have at their disposal all the information required from the suppliers responsible for marketing to carry out the tasks for which they are responsible.
	3a. Every year Member States shall submit to the European accident database set up under the EHLASS programme (European Home and Leisure Accident Surveillance System) data detailing the number of accidents, and the mixtures involved, in respect of which appointed bodies have received requests for medical information concerning treatment and curative measures.
	[1]The information requirements laid down in the entire body of directions issued by the EACCPT shall form the basis of Annex VIIa.

Justification

The European Association of Poisons Centres and Clinical Toxicologists has published information requirements that would form the basis of a new Annex VIIa. The accident database set up by the Health and Consumer Protection DG would provide a vehicle for reporting data gathered by appointed bodies on mixtures and accidents in which these were involved.

Amendment 95

Proposal for a regulation – amending act
Article 45 - paragraph 3b (new)

Text proposed by the Commission	*Amendment*
	3b. Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers, although classified according to the criteria of Annex I, shall however, if they present no risk of acute toxicity to human health and are intended for industrial use by professionals, be exempt from the notification requirement in paragraph 1.

Justification

The current legislation (1999/45/CE) and some provisions of this proposal recognise that certain substances are enclosed in a matrix, are not easily bioavailable (in the case of mixtures in solid form) and are insoluble in water, such as alloys, mixtures containing polymers and preparations containing elastomers. Some consistency is therefore needed between the requirement of paragraph 1 and the provision on special mixtures in point 1.3.4 of Annex I.

Amendment 96

Proposal for a regulation – amending act
Article 45 - paragraph 3c (new)

Text proposed by the Commission	*Amendment*
	3c. No later than 1 December 2010 the Commission shall present a legislative proposal with a view to the harmonisation of the information referred to in paragraph 1.

Justification

A recent study shows that this provision has been implemented differently in different Member States. This amendment justifies the further harmonisation of emergency response procedures in the EU. This regulation is also intended to guarantee the free movement of chemical substances and mixtures.

Amendment 97

Proposal for a regulation – amending act
Article 46 - paragraph 1

Text proposed by the Commission	*Amendment*
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 and packaged in accordance with this Regulation.	1. Member States shall take all necessary measures, including maintaining a system of official controls ***and other activities, as appropriate to the circumstances***, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled and packaged in accordance with this Regulation.

Justification

From REACH.

Amendment 98

Proposal for a regulation – amending act
Article 47

Text proposed by the Commission	*Amendment*
Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission no later than eighteen months after entry into force of this Regulation and shall notify it without delay of any subsequent amendment affecting them.	Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission no later than eighteen months after entry into force of this Regulation and shall notify it without delay of any subsequent amendment affecting them. ***The Commission shall assess the data on penalties and disseminate best practice in terms of their effectiveness.***

Justification

The Commission should analyse the measures that Member States take to ensure a proper implementation of this Regulation. Information on the most effective penalties should be disseminated to Member States.

Amendment 99

Proposal for a regulation – amending act
Article 52 - paragraph 1

Text proposed by the Commission	*Amendment*
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 risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.	1. Where***, in the event of a dispute with a supplier,*** a Member State has justifiable grounds for believing that a substance or a mixture, ***whether or not it satisfies*** the requirements of this Regulation, constitutes a risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.

Justification

It would be desirable to allow both for the possibility that disputes might arise between suppliers and Member States over the interpretation of requirements under the regulation and for the need to have a procedure for achieving a harmonised classification in the event of such a dispute.

Amendment 100

Proposal for a regulation – amending act
Article 53

Text proposed by the Commission	*Amendment*
The Commission may adjust and adapt ***Articles 12, 14, 23, 27 to 32 and 37 (2) 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).	***1.*** The Commission ***shall adopt Annex VIIa and*** may adjust and adapt Annexes I to ***VIIa*** to technical ***and scientific*** progress ***in accordance with the rules laid down in this Regulation***. ***The Commission shall take due account of the further development of the GHS within the United Nations, developments in international chemical programmes and conventions, data from accident databases, such as poison information units and the European Home and Leisure Accident Surveillance System***

(EHLASS), and the validation of alternative tests by ECVAM. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 54 (4).

1a. The Commission shall promote the harmonisation of the labelling of PBT and vPvB at the level of the United Nations and shall, as appropriate, subsequently adjust and adapt sections 1.1 and 1.2 of Annex II and part 2 of Annex III referred to in Article 27(1) and/or part 2 of Annex II and part 3 of Annex III referred to in Article 24.

Justification

The adaptation of the regulation to technical and scientific progress is necessary, but it can only take place within the legal framework adopted in co-decision. Articles of this Regulation should only be amended in co-decision. In the further adaptations, developments in GHS and other international chemical programmes and conventions must be taken into account. Accident databases provide information on practical impacts of this legislation, which should also be considered.

EXPLANATORY STATEMENT

In 1980 the debate on chemicals and the part they play in our lives opened at international level, first within the International Labour Organisation and then within the United Nations which, following various interim stages (Rio in 1992, Johannesburg in 2002), adopted the GHS in December 2002 (with a revision in 2005).

At European level:

- In 2001, the Commission published a White Paper entitled 'Strategy for a future Chemicals Policy', in which it stated that it intended to propose that the GHS be incorporated into Community legislation.

- 29 October 2003: in the Explanatory Memorandum to the amendment to Directive 67/548/EC adopted together with REACH, the Commission stated its intention to draft a proposal on the GHS.

- Stakeholder consultations were held between 21 August 2006 and 21 October 2006. 370 contributions were received.

- 27 June 2007: the Commission adopted the proposal.

- In June 2007, REACH, one of the main strands of the chemicals policy, entered into force.

GHS

The GHS is an voluntary international harmonisation programme which the EU decided to join in order to establish a common, consistent basis for dealing with chemical hazards which set out fundamental rules to ensure:
- safety in the transport of hazardous goods;
- protection of consumer and worker health and safety and of the environment.

Specifically, the proposal for a regulation:

- harmonises the classification of substances and mixtures and the rules on the labelling and packaging of hazardous substances and mixtures;

- introduces an obligation for suppliers to classify substances and mixtures;

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

- establishes a classification and labelling inventory which is made up of all notifications, submissions and harmonised classifications.

Given the scale of international trade in chemicals, it was felt that an international harmonised classification and labelling system was the best means of ensuring – in addition to safety – the

quality and consistency of information on products manufactured locally or imported and of monitoring exposure to substances and, thereby, health and environmental protection standards worldwide. Clearer, understandable and relevant information provision to consumers will ensure that this legislation produces optimum results.

As things currently stand, the same substance or percentage concentration of a substance may be classified in a very different way from one country to another owing to the use of different classification systems. The classifications for the same substance may be vary from hazardous, toxic or harmful to non-hazardous (e.g. oral toxicity LD50 = 257mg/kg is classified as hazardous under the GHS classification; in the EU and countries such as Australia, Malaysia and Thailand, it is classified as harmful, with the St. Andrews Cross; in the USA, Canada, Japan and Korea, it is classified as toxic; in New Zealand as hazardous; and in China as non-hazardous).

Substances which in Europe are classified as hazardous may – for example in countries such as China – not carry any warnings on their labels. In addition to giving rise to unfair competitive advantages, this situation is a serious threat to consumers everywhere, particularly in a global market. This is one of the main reasons why the Commission and the Member States took part in the work carried out by the United Nations and decided to incorporate the system into European legislation.

Chemicals are produced and traded throughout the world, and the risks are the same irrespective of location. The risk classification system must therefore not differ from country to country. The risk or lack of risk is the same for consumers everywhere.

GHS time limits

The reclassification and labelling of substances must be completed by:

- **1 December 2010** for substances (3.5 years after the entry into force of REACH);
- **1 June 2015** for mixtures (4.5 years after the entry into force of REACH).

The time limits run from the entry into force of REACH, and any further delay in the adoption of this regulation could place a heavy burden on companies and their staff. Therefore, given that the text comes from the United Nations and is the product of international negotiations in which the Commission and all the Member States took part, it has been decided to table only as many amendments as are necessary to bring the proposal into line with existing provisions in the sector and make it more consistent with REACH.

27.3.2008

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION (*)

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006
(COM(2007)0355 – C6-0197/2007 – 2007/0121(COD))

Draftsman (*): Andreas Schwab

(*) Procedure with associated committees - Rule 47 of the Rules of Procedure

SHORT JUSTIFICATION

Background on the proposal

The proposal for a regulation on classification, labelling and packaging of substances and mixtures[1] is implementing in the EU the international criteria agreed by the United Nations Economic and Social Council for the classification and labelling of hazardous substances and mixtures. This is also known as the Globally Harmonised System (GHS).

The objective is to ensure a high level of protection of human health and the environment, while guaranteeing the free movement of substances and mixtures within the internal market.

GHS establishes harmonized criteria for classifying substances and mixtures according to the health, environmental and physical hazards, as well harmonized hazard communication elements, including requirements for labelling and safety data sheets. This applies to transport of chemicals, the use in the workplace of chemicals as well as labelling in the consumer sector.

The new legislation will replace the currently existing provisions on classification and labelling of chemicals. The current EU system and the GHS system are conceptually similar and cover the same structural elements: classification, packaging and hazard communication including labelling and safety data sheets. Some of the criteria for classification will however

[1] COM(2007)355 of 27.6.2007

change with the new system.

The purpose of the regulation is to facilitate trade and hence to ensure a well-functioning internal market and it will benefit producers, professional users and consumers.

Relation to REACH

The recent adopted Regulation on Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH)[1] includes references to substance and preparation classification as well to Safety Data Sheet but does not include the criteria for such classification. The identification of these criteria is the core of the GHS proposal. In particular, potential registrants are required to submit information on substance classification at the registration stage. This information, as well as any other provisions based on classification criteria, will therefore relies on the criteria set up in the GHS proposal. Finally, the provisions on the mandatory notification to the classification and labelling inventory currently included in REACH will be moved in to the GHS Regulation.

Essentially, the new regulation will establish the provisions for suppliers of substances and mixtures to obtain available information for evaluating the intrinsic hazards of these substances and mixtures with the aim of labelling them with this information on the hazards and appropriate precautionary measures to be taken before being placed on the market. REACH, on the other hand, requires that manufacturers and importers of substances assess the risks in relation to identified uses with the aim of providing concrete instructions to downstream users on control of such risks during use, and that this is documented in a registration to the European Chemicals Agency.

Other related proposals

The proposal for this regulation is accompanied by two other Communications which propose technical changes to downstream legislation. These changes are needed to bring this downstream legislation in line with the GHS proposals. COM(2007)0611[2] proposes amendments to a number of directives (cosmetics, toys safety, solvent emissions, end of life vehicles and two paints directives). COM(2007)0613[3] proposes amendments to the Detergent Regulation. The intent of the proposals is to align the terminology with the GHS, as well as to adapt the cross-references between the texts. Your draftsperson will not propose amendments to these two Communications but two separate opinions will be tabled on them.

The annexes of the text

Like the rapporteur in the Committee on the Environment, Public Health and Food Safety, your draftsman is not proposing amendments to the Annexes of the proposal. However, the

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[1] Regulation (EC) No 1907/2006 on the European Parliament and of the Council.

[2] COM(2007)0611 of 16.10.2007 on a Proposal for a decision of the European Parliament and of the Council amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC in order to adapt them to Regulation (EC) ... on Classification, Labelling and Packaging of Substances and Mixtures, and amending Directive 6/548/EEC and Regulation (EC) No 1907/2006.

[3] COM(2007)0613 of 17.10.2007 on a Proposal for a decision of the European Parliament and of the Council amending Regulation (EC) No 648/2004 in order to adapt them to Regulation (EC) ... on Classification, Labelling and Packaging of Substances and Mixtures, and amending Directive 6/548/EEC and Regulation (EC) No 1907/2006.

Commission is requested to ensure consistency between the amendments finally adopted by the European Parliament to the regulation and the annexes to the regulation.

Main concerns of your draftsman
Your draftsman supports the proposal from the Commission but has suggested some amendments in this draft opinion. Your draftsman's main concern has been to strike a balance between properly implementing the European Union's international obligations in the United Nation Economic and Social Council while at the same time avoiding unnecessary burdens on businesses. Moreover, it is important to ensure that overclassification of products does not lead to confusion among consumers or healthcare providers. To this end, your draftsman has proposed several amendments relating to labelling, including amendments to the recitals to clarify the principles relating to supplier classification and information to the public on the risk and safe use of chemicals.

Your draftsman has also proposed amendments aimed at strengthening certain aspects relating to confidentiality and ensuring more workable rules relating to packaging. Finally, your draftsman is suggesting a minimum threshold value of 1 ton per year before the obligation to notify the Agency on the usage of a substance is invoked as well as clarifying the obligations of the supplier to assemble and keep information available.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
	Amendment 1 Recital 16 a (new)
	(16a) The principle of classification by the manufacturer is a fundamental precondition for the uniform EU-wide classification and labelling of substances and mixtures. This principle should therefore be regarded as a matter of key importance for the smooth movement of goods in the internal market and should apply without exception to all substances and mixtures falling within the scope of this Regulation. Member States are required to transpose the principle of

[1] Not yet published in OJ.

classification by the manufacturer in all areas of classification of chemical substances.

Justification

One of the main objectives of the legal act in question is to harmonise the classification and labelling of chemical substances and mixtures so as to prevent distortions of competition in the internal market. Classification by the manufacturer, as laid out in Article 4, constitutes a fundamental principle to ensure uniform classification within the EU. This basic principle should therefore apply without exception to all substances and mixtures falling within the scope of this regulation.

Amendment 2
Recital 23 a (new)

(23a) It is necessary to provide appropriate information to consumers, to avoid the possibility of disproportionate measures such as child-resistant packaging stemming particularly from any over-classification of a mixture, and to avoid duplication of testing. A procedure that helps suppliers, particularly SMEs, in specific product sector groups to establish the appropriate classification and corresponding labelling and packaging for a mixture should be encouraged. Such a procedure would be open to any supplier within the specific sector group.

Justification

Where the manufacturer only has the information provided by the supplier(s) of the substances used in the product (mixture), he will rely on an evaluation of information under the procedure given in Article 9 paragraph 4 to establish the classification of the mixture. This may under- or (particularly) over-estimate the hazardous properties of the mixture. The availability and recognition of a procedure whereby expertise, additional information and data can be made available to evaluate a mixture will ensure a more accurate classification and be of particular value to SMEs.

Amendment 3
Recital 35

(35) ***The*** two components used to	(35) Two ***important*** 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.	communicate the hazards of substances and mixtures are labels and the safety data sheets provided for in Regulation (EC) No 1907/2006. ***Of these only*** the label is ***readily available*** for communication to consumers ***and it therefore needs to be sufficiently detailed and relevant to the use of the product. It is thus essential that, as provided for in Regulation (EC) No 1907/2006, the Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, should provide guidance for the communication of information to general public consumers on the risks and safe use of chemical substances and mixtures. The label*** may also serve to draw ***the*** attention of workers to the more comprehensive information on substances or mixtures provided in safety data sheets. Since the provisions on safety data sheets are included in Regulation (EC) No 1907/2006 which uses the safety data sheet as the main communication tool within the supply chain of substances, it is appropriate not to duplicate the same provisions in this Regulation.

Justification

An appropriate and consistent communication system will provide consumers with the necessary information and advice to enable them to manage their risk safely and effectively when using a substance, preparation or product containing chemicals. This is also consistent with GHS (Para 1.4.3.4) where the label for consumers needs to be "sufficiently detailed and relevant to the use of the product".

Amendment 4
Recital 41

(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 ***and*** Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products	(41) The labelling rules in this Regulation should be without prejudice to Council Directive 91/414/EEC *of 15 July 1991* concerning the placing of plant protection products on the market**,** Directive 98/8/EC of the European Parliament and of the Council *of 16 February 1998* concerning the

on the market.	placing of biocidal products on the market ***and Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents[1].***
	[1] OJ L 104, 8.4.2004, p. 1. Regulation as amended by Commission Regulation (EC) No 907/2006 (OJ L 168, 21.6.2006, p. 5).

Justification

The Detergent Regulation contains specific labelling provisions for detergent products that have to be complied with.

Amendment 5
Article 9, paragraph 4 a (new)

	4a. Where a specific product sector group has established a Hazard and Classification Centre, which brings together expertise in the evaluation of information, test data, weight of evidence determinations, and bridging principles, any supplier within the product sector may rely on an evaluation from that centre for the ascertainment of the hazards associated with, and the corresponding classification of, the mixture.

Justification

Where the manufacturer only has the information provided by the supplier(s) of the substances used in the product (mixture), he will rely on an evaluation of information under the procedure given in Article 9 paragraph 4 to establish the classification of the mixture. This may under- or (particularly) over-estimate the hazardous properties of the mixture. The availability and recognition of a procedure whereby expertise, additional information and data can be made available to evaluate a mixture will ensure a more accurate classification and be of particular value to SMEs.

Amendment 6
Article 18, paragraph 3, subparagraph 1 a (new)

	In the case of natural materials, a designation such as 'essential oil from ...' or ' ... extract' may be used instead of the

	names of the components of this essential oil or extract*.*

Justification

To list all the names of substances in a mixture would mean a disproportionate amount of effort for flavouring or perfume manufacturers, given the small amounts of such substances which end up in the final product.

Amendment 7
Article 26, paragraph 1

1. The supplier of a substance or 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 common name, where he can demonstrate that the disclosure ***on the label*** of the chemical identity of a substance or mixture puts the confidential nature of his business, in particular his intellectual property rights, at risk.	1. The supplier of a substance or 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 common name, where he can demonstrate that the disclosure of the chemical identity of a substance or mixture puts the confidential nature of his business, in particular his intellectual property rights, at risk.

Justification

It should be possible to use the generic name also on the safety data sheet (SDS). Confidentiality does make no sense. In the SDS only the clear name is replaced by a generic name, not the classification and relevant danger information.

Amendment 8
Article 26, paragraph 2

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

Justification

Reference to fees deleted in line with Dangerous Preparations Directive Article 15.

Amendment 9
Article 26, paragraph 3

3. The Agency may require further information from the supplier making the request if such information is necessary to take a decision. The Agency shall notify the person making the request of its decision 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.	3. The Agency may require further information from the supplier making the request if such information is necessary to take a decision. The Agency shall notify the person making the request of its decision 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. ***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, in accordance with Articles 92 and 93 of Regulation (EC) No 1907/2006, against the decision not to accept the request. This appeal shall have a suspensive effect and the data shall not be published.***

Justification

The proposal is table to ensure a right of appeal and the protection of confidential business information (CBI)

Amendment 10
Article 31, paragraph 1, point k

(k) Chronically Aquatic Hazardous of category 1***,2, 3 and 4***.	(k) Chronically Aquatic Hazardous of category 1 ***and 2***.

Justification

Chronically Aquatic Hazardous categories 3 and 4 are not associated with a hazard pictogram; if the hazard statement is omitted from the package then users would not be aware of this particular hazard. This proposed amendment reflects current practice in the DPD for mixtures classified as R10 or R52/53 i.e. classifications not associated with a hazard symbol. Associated with Amendment 27.

Amendment 11

Article 31, paragraph 1 a (new)

1a. For packaging containing 125 ml or less, precautionary statements need not be indicated on the label if the substance or mixture is classified as Chronically Aquatic Hazardous of category 3 or 4.

Justification

Associated with Amendment 26. Chronically Aquatic Hazardous categories 3 and 4 are not associated with a hazard pictogram; if the hazard statement is omitted from the package then users would not be aware of this particular hazard. This proposed amendment reflects current practice in the DPD for mixtures classified as R10 or R52/53 i.e. classifications not associated with a hazard symbol.

Amendment 12
Article 31, paragraph 2 a (new)

2a. Packaging for single use (or one-way packaging, portion-packaging or single-dose packaging), which is contained in outer packaging labelled in accordance with this Regulation, is removed only for uses in accordance with the instructions for use and is used up immediately, shall not be subject to the labelling requirement.

Justification

To clarify the situation where mixtures are involved that are supplied as a single dose, when the product, such as a tablet, (a) is intended only for a single use, (b) is removed before use direct from the outer packaging, and (c) all the instructions (and further labelling) are on the outer packaging. This amendment replaces existing Amendment 8 to Article 26, paragraph 4a (new) by the rapporteur and thus corrects a technical error.

Amendment 13
Article 32

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,***	***When substances or mixtures supplied to*** the general public ***are*** classified ***as*** acute toxicity category 1, 2 or 3***,*** specific target organ toxicity (STOT) – single exposure category 1*,* specific target organ toxicity (STOT) – repeated exposure category 1 ***or*** skin corrosion category 1 ***and where it is physically impossible to apply a label on the***

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.

package itself, then packages containing such substances or mixtures shall be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the disposal of the empty package.

Justification

The change is proposed to further clarify the text.

Amendment 14
Article 32, paragraph 1 a (new)

1a. Packaging of substances and mixtures destined for the general public and fulfilling the criteria for Hazard Class 2.16 shall be exempted from the obligation to bear a label relating to this hazard, provided that, where both an outer and an inner packaging are used, the outer packaging bears a pictogram in accordance with 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.

Justification

Corrosive to metals is not relevant for supply. Hazard class 2.16 is a new requirement that is not included in the dangerous substances directive or dangerous preparations directive, but only in the transport regulations. This property is only relevant for transport and storage of bulk quantities, i.e. not relevant for individual consumer packs. This hazard class is assigned a corrosive pictogram - for consumers using the symbol will lead to confusion with skin corrosion and serious eye damage.

Amendment 15

Article 32, paragraph 1 b (new)

	1b. For certain mixtures classified as hazardous to the environment, exemptions to certain provisions on environmental labelling or specific provisions relating to environmental labelling may be determined in accordance with the procedure referred to in Article 53, where it can be demonstrated that there would be a reduction in the environmental impact. These exemptions or specific provisions are defined in Part 2 of Annex II.

Justification

In line with the current dangerous preparations directive, cf. Article 10 (3) of this directive.

Amendment 16
Article 33, paragraph 3

This Article shall be without prejudice to Directives 91/414/EEC ***and*** 98/8/EC.	This Article shall be without prejudice to Directives 91/414/EEC*,* 98/8/EC ***and Article 4 of this Regulation***.

Justification

The changes in Annex I of the Dangerous Substances Directive 67/548/EEC come into effect normally with a transitional period of at least 12 months. These transitional periods should also apply in this regulation, since they would ensure that suppliers of substances and mixtures can feasibly put them into effect. Classification by manufacturers, as laid down in Article 4, ensures uniform classification. This basic principle should therefore apply without exception to all substances and mixtures falling within the scope of the regulation.

Amendment 17
Article 35, paragraph 3

3. The supplemental information shall be placed in the supplemental information section as referred to in Article 27 and the location of that section shall not make it more difficult to identify the elements specified in Article 17 (1).	3. The supplemental information shall be placed in the supplemental information section as referred to in Article 27 and the location of that section shall not make it more difficult to identify the elements specified in Article 17 (1). ***The supplier may decide to place all labelling information according to Chapter 1 on one area of the packaging.***

Justification

The supplier should be allowed to put all hazard communication, including supplemental information in one area together in close proximity.

Amendment 18
Article 36, paragraph 1

1. Where both an outer and an inner packaging ***is*** used ***and the outer packaging does not bear a pictogram*** in accordance with 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 packaging shall be*** labelled in accordance with this Regulation.	1. Where both an outer and an inner packaging ***are*** used***, the labelling requirements shall be deemed to be satisfied if the outer packaging is labelled*** in accordance with 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, ***and if the inner packaging is*** labelled in accordance with this Regulation.
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.	

Justification

paragraph 1: In line with DPD Article 11.6(a).

Amendment 19
Article 36, paragraph 2 a (new)

	2a. Where labelling on the inner packaging is clearly visible due to transparency of the outer packaging, for instance a shrink wrap, additional labelling of the outer packaging shall not be obligatory.

Justification

See the justification to Amendment 18.

Amendment 20
Article 36 a (new)

	Article 36a
	1. The labelling rules provided for in Title III shall be without prejudice to Regulation (EC) No 648/2004.
	2. Notwithstanding the labelling rules provided for in Title III, the supplier of a substance or a mixture intended for use by ordinary consumers shall label in accordance with the guidance provided by the Agency for the communication of information to ordinary consumers on the risks and safe use of chemical substances and mixtures, as provided for in Regulation (EC) No 1907/2006
	3. The Agency shall produce the guidance referred to in paragraph 2 in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice. It shall be available within x years of the entry into force of this Regulation.

Justification

The amendment is linked to Recital 35 and 41. The Detergent Regulation contains specific labelling provisions for detergent products that have to be complied with. An appropriate and consistent communication system will provide consumers with the necessary information and advice to enable them to manage their risk safely and effectively when using a substance, preparation or product containing chemicals.

Amendment 21
Article 37, paragraph 1

1. Substances and mixtures classified as hazardous shall be contained in packaging that shall satisfy the following requirements:	1. Substances and mixtures classified as hazardous shall be contained in packaging that shall satisfy the following requirements:
(a) the packaging shall be so designed and constructed that its contents cannot escape, except in cases where other more specific safety devices are prescribed;	(a) the packaging shall be so designed and constructed that its contents cannot escape ***during normal handling and use***, except in cases where other more specific safety devices are prescribed
(b) the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form dangerous compounds with the contents;	(b) the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form dangerous 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;	(c) the packaging and fastenings shall be strong and solid throughout 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 that the container can be refastened repeatedly without the contents escaping.	(d) packaging in the form of containers fitted with replaceable fastening devices shall be so designed that the container can be refastened repeatedly without the contents escaping.

Justification

The aim of the amendment is to increase the clarity of the text.

Amendment 22
Article 37, paragraph 2

2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products.	2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products ***which would mislead the consumer***.
Where ***such*** 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.	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 Directive or Regulation.***
Where ***such*** 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.	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 Directive or Regulation.***

Justification

Avoids overlap with provisions provided for in other EU Directives or Regulations

Amendment 23
Article 38, paragraph 1, point (d)

(d) reproductive toxicity, section 3.7, category 1A, 1B or 2;	(d) reproductive toxicity, section 3.7, category 1A, 1B or 2 ***excluding effects on or via lactation;***

Justification

The aim is to improve the clarity of the text.

Amendment 24
Article 41, paragraph 1, subparagraphs 1 and 2

1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market 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 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 to the Agency the following information in order for it to be included in the inventory referred to in Article 43:	1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market in ***a quantity of 1 ton per year either*** a substance subject to registration in accordance with Regulation (EC) No 1907/2006 or a substance ***that is*** classified as hazardous on its own or in a mixture 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 to the Agency the following information in order for it to be included in the inventory referred to in Article 43:
(a) the identity of the notifier or notifiers responsible for placing the substance or substances on the market as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006;	(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;	(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;	(c) the classification of the substance or substances in accordance with Article 13;
(d) where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although	(d) where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although

insufficient for classification;	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;	(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.	(f) the labelling elements for the substance or substances in accordance with Title III of this Regulation.
The information referred to in (a) to ***(e)*** shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006. The manufacturer or importer shall submit this information in the format specified pursuant to Article 111 of Regulation (EC) No 1907/2006.	The information referred to in (a) to ***(f)*** shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006. The manufacturer or importer shall submit this information in the format specified pursuant to Article 111 of Regulation (EC) No 1907/2006.

Justification

The paragraph requires notification to the inventory of substances that are placed on the market and subject to registration under (EC) No 1907/2006 (REACH) i.e. at a quantity above 1 ton/year, or substances classified as hazardous on their own or in a mixture resulting in that mixture being classified as hazardous, i.e. irrespective of quantity. In accordance with REACH, substances placed on the market below a threshold value of 1 ton/year are not subject to registration and should not be notified to the Inventory. Otherwise, the costs of compliance would exceed the costs of the market.

Amendment 25
Article 41, paragraph 3

3. For substances placed on the market before 1 December 2010, notifications shall be made in accordance with paragraph 1 before that date.	3. For substances ***classified as hazardous on their own or in a mixture 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,*** placed on the market ***at 1 MT/annum per manufacturer or importer*** before 1 December 2010, notifications shall be made in accordance with paragraph 1 before that date.

Justification

The paragraph requires notification to the inventory of substances that are placed on the

market and subject to registration under (EC) No 1907/2006 (REACH) i.e. at a quantity above 1 ton/year, or substances classified as hazardous on their own or in a mixture resulting in that mixture being classified as hazardous, i.e. irrespective of quantity. In accordance with REACH substances placed on the market below a threshold value of 1 ton/year are not subject to registration and should not be notified to the Inventory. Otherwise, the costs of compliance would exceed the costs of the market.

Amendment 26
Article 45, paragraph 3 a (new)

3a. The Commission shall submit a legislative proposal no later than 1 December 2010 with the aim of harmonising the information referred to in paragraph 1.

Justification

A recent study has shown that this provision is being implemented in different ways in different Member States. The regulation's purpose is to safeguard the free circulation of chemical substances and mixtures. This justifies the further harmonisation of emergency response procedures in the EU.

Amendment 27
Article 49, paragraph 1, subparagraph 1

1. Any supplier of a substance or mixture shall assemble and keep available all the information ***required*** for the purposes of classification and labelling under this Regulation for a period of at least 10 years after he last supplied the substance or the mixture.	1. Any supplier of a substance or mixture shall assemble and keep available all the information ***that he requires*** for the purposes of classification and labelling under this Regulation for a period of at least 10 years after he last supplied the substance or the mixture.

Justification

The aim is to ensure the clarity of the rules.

Amendment 28
Article 58 a (new)

Article 58a

The Commission shall submit a report no later than 1 December 2010 on the effectiveness of this Regulation with

regard to Article 45, with the aim of proposing amendments if necessary, in accordance with the regulatory procedure with scrutiny referred to in Article 54(3), aimed at further harmonisation.

Justification

A recent study has shown that this provision is being implemented in different ways in different Member States. The regulation's purpose is to safeguard the free circulation of chemical substances and mixtures. This justifies the further harmonisation of emergency response procedures in the EU.

PROCEDURE

Title	Classification, labelling and packaging of substances and mixtures
References	COM(2007)0355 – C6-0197/2007 – 2007/0121(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 9.7.2007
Associated committee(s) - date announced in plenary	27.9.2007
Drafts(wo)man Date appointed	Andreas Schwab 16.7.2007
Discussed in committee	2.10.2007 27.11.2007 22.1.2008
Date adopted	26.3.2008
Result of final vote	+: 37 –: 0 0: 0
Members present for the final vote	Cristian Silviu Buşoi, Charlotte Cederschiöld, Gabriela Creţu, Mia De Vits, Janelly Fourtou, Vicente Miguel Garcés Ramón, Evelyne Gebhardt, Małgorzata Handzlik, Malcolm Harbour, Edit Herczog, Iliana Malinova Iotova, Pierre Jonckheer, Alexander Lambsdorff, Kurt Lechner, Lasse Lehtinen, Toine Manders, Arlene McCarthy, Catherine Neris, Zita Pleštinská, Giovanni Rivera, Zuzana Roithová, Luisa Fernanda Rudi Ubeda, Heide Rühle, Christel Schaldemose, Andreas Schwab, Bernadette Vergnaud, Barbara Weiler, Marian Zlotea
Substitute(s) present for the final vote	Emmanouil Angelakas, Šarūnas Birutis, Giovanna Corda, Benoît Hamon, Joel Hasse Ferreira, Filip Kaczmarek, Othmar Karas, Joseph Muscat, Gary Titley

6.3.2008

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EEC) No 1907/2006
(COM(2007)0355 – C6-0197/2007 – 2007/0121(COD))

Draftswoman: Anne Laperrouze

SHORT JUSTIFICATION

The proposal, as amended below, marks an important stage in a process launched in the 1980s by the International Labour Organisation and taken over, and later expanded, by the United Nations Conference on Environment and Development.

The aims of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) cover harmonised criteria for classifying substances and mixtures, according to the physical, health, or environmental hazards that they pose, and harmonised means of communicating those hazards, including provisions on labelling and safety data sheets.

Your draftswoman can only applaud this initiative: it is entirely appropriate to adopt a global approach aimed at protecting health and the environment more effectively while allowing for international trade in the products concerned.

The Commission proposal harmonises the rules on classification, labelling, and packaging of substances and mixtures. It imposes an obligation on firms to classify their substances and mixtures on their own initiative and notify the classifications. It lays down a harmonised list of substances classified at Community level (in Annex VI). Finally, it establishes a classification and labelling inventory encompassing all of the notifications and harmonised classifications mentioned above.

It would be desirable for the proposal to be consistent with REACH as regards both time-frames and a tonnage-based approach or where the annexes are concerned, not least Annex VI.

According to the Commission proposal, part 3 of Annex VI is binding. The only thing that

this part should contain is the classifications which, by virtue of REACH and Article 38 of the draft regulation, will remain harmonised at Community level, that is to say, carcinogenicity, mutagenicity, reproductive toxicity (c/m/r), and respiratory sensitisation, along with justified specific cases (Article 38(2)).

It is proposed to add a part 4 to Annex VI to cover classifications and labelling provisions for hazardous substances which have already been the subject of Community harmonisation under Directive 67/548/EEC in connection with hazard categories other than those specified in Article 38(1); these classifications and forms of labelling will be transferred taking into account the classification and labelling criteria set out in Annex I.

The Commission is proposing to incorporate the latter classifications in part 3 of Annex VI, alongside those which will remain harmonised under Article 38, applying the procedures set out in Articles 39 and 40. This approach entails several drawbacks:

- the 'translation', whereby 'Directive 67/548/EEC, Annex I' classifications have been converted into 'GHS' classifications, has been done without consultation;

- bearing in mind that, as far as many substances are concerned, the present criteria and the GHS criteria do not correspond exactly, it will be permitted to depart from the classification laid down in Annex VI, part 3;

- the requirement in Article 4(6) to 'complete' classifications entered in Annex VI, part 3, can apply only to 'partial' classifications as referred to in Article 38;

- since classifications will not be revised or updated, they will gradually become obsolete. If they are binding, it will be impossible to take new data into account, in particular data generated by applying the REACH regulation.

Part 4 of Annex VI should thus be viewed as a non-binding reference tool that will be extensively used by industry and the authorities.

The decades of work by Commission experts, Member States, and industry to compile Annex I to Directive 67/548/EEC will consequently not 'go to waste', and the GHS criteria will, moreover, be possible to apply in full.

If they were to use classifications and forms of labelling different from those specified in Annex VI, part 4, suppliers would be required, under Article 49, to prove to the proper authorities that they had duly observed the criteria set out in parts 2 to 5 of Annex I.

A non-binding Annex VI, excepting part 3, would also present a twofold advantage in that it would avert confusion, inconsistencies, ambiguities, and the like in relation to the classification and labelling inventory, dealt with in Title V, Chapter 2, and would not impede international trade.

As regards the information affixed to finished products, given that the Commission has chosen to include post-manufacturing, the paramount consideration has to be the quality and relevance of information and not its quantity.

Lastly, since what is involved is a global system, the future regulation must not subject

European firms to constraints that their international rivals would escape.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission	Amendments by Parliament
Amendment 1 RECITAL 7	
(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.	(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 ***and in particular to small and medium-sized enterprises (SMEs)***.
Justification	
The Commission's online consultation of 21 August to 21 October 2006 received 370 replies from enterprises, of which 45% had a workforce of less than 250 employees.	
Amendment 2 RECITAL 19	
(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.	(19) To ensure information on ***and protection from*** 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.

Justification

Classification, labelling and packaging is not done for information purposes alone but for consumer health and environmental protection purposes.

Amendment 3
RECITAL 21

(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.	(21) ***The*** classification of any substance or mixture may be carried out on the basis of available information, ***which should*** be used for the purposes of this Regulation ***and*** 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.

Justification

It must be made clear that any relevant information available can be taken into consideration in the classification of a substance or mixture.

Amendment 4
RECITAL 25

(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.	(25) ***Tests to determine the*** physical hazards ***of a substance or mixture*** should always be necessary, except if the ***necessary reliable*** data are already available or if a derogation is *provided for* in part 2.

Amendment 5
RECITAL 44

(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	(44) Resources of the authorities should be focused on substances of the highest concern ***with regard to health and the environment***. Provision should therefore be made to

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.	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.

Amendment 6
RECITAL 52 A (new)

	(52a) In the interests of providing consumers with appropriate information, of avoiding disproportionate measures, such as child resistant packaging, which may arise from the over-classification of substances and mixtures, and of avoiding the duplication of testing, the Member States should introduce a procedure to assist all suppliers, and particularly SMEs in certain specific product groups to determine the appropriate classification, labelling and packaging for such substances and mixtures.

Justification

Where the manufacturer only has the information provided by the supplier(s) of the substances used in the product (mixture), he will rely on the establishment of the classification of the mixture from an evaluation of information by the procedure given in Article 9 paragraph 4. This may under or (particularly) over estimate the hazardous properties of the mixture. The availability and recognition of a procedure whereby expertise, additional information and data can be made available to evaluate a mixture will ensure a more accurate classification and be of particular value to SME's.

Amendment 7
ARTICLE 9, PARAGRAPH 4, SUBPARAGRAPH 2

However, where that information does not permit the application of the bridging principles, the supplier shall evaluate the	However, where that information does not permit the application of the bridging principles ***and expert judgement cannot***

information by applying the other method or methods described in each section of parts 3 and 4 of Annex I.	***justify latitude beyond the bridging principles***, the supplier shall evaluate the information by applying the other method or methods described in each section of parts 3 and 4 of Annex I.

Justification

To make for consistency with the wording of the UN GHS on expert judgement (point 1.3.2.4.8 of the Mauve Paper): 'The approach to classifying mixtures includes the application of expert judgement in a number of areas in order to ensure existing information can be used for as many mixtures as possible to provide protection for human health and the environment'.

Amendment 8
ARTICLE 9, PARAGRAPH 4 A (new)

	4a. Where a hazard and classification centre has been established for a specific group of products which brings together expertise in the evaluation of information, test data, weight of evidence determinations and bridging principles relating to substances and mixtures in that group of products, a supplier of such substances and mixtures may rely on an evaluation provided by that centre for the purpose of ascertaining the hazards associated with the substance or mixture.

Justification

Where the manufacturer only has the information provided by the supplier(s) of the substances used in the product (mixture), he will rely on the establishment of the classification of the mixture from an evaluation of information by the procedure given in Article 9 paragraph 4. This may under or (particularly) over estimate the hazardous properties of the mixture. The availability and recognition of a procedure whereby expertise, additional information and data can be made available to evaluate a mixture will ensure a more accurate classification and be of particular value to SME's.

Amendment 9
ARTICLE 12, POINT (C)

(c) where adequate and reliable information demonstrates the potential occurrence of synergistic or antagonistic effects ***among*** the	(c) where adequate and reliable information demonstrates the potential occurrence of synergistic or antagonistic effects ***between***

substances in a mixture ***for which the evaluation was decided on the basis of the information for the substances in the mixture***.	the substances in a mixture.

Amendment 10
ARTICLE 17, PARAGRAPH 1, INTRODUCTORY PART

1. A substance or mixture classified as hazardous shall bear a label including the following elements:	1. A substance or mixture classified as hazardous shall bear a label ***on the packaging*** including the following elements:

Justification

Labelling can only be done on the packaging. Indication on the packaging of the neutralising substance to be used is an emergency safety measure, as is the indication of the emergency number (112).

Amendment 11
ARTICLE 31, PARAGRAPH 1, POINT (K)

(k) Chronically Aquatic Hazardous of ***category 1, 2, 3 and 4***.	(k) Chronically Aquatic Hazardous of ***category 1 and 2***.

Justification

Chronically Aquatic Hazardous categories 3 and 4 are not associated with a hazard pictogram; if the hazard statement is omitted from the package then users would not be aware of this particular hazard. This proposed amendment reflects current practice in the DPD for mixtures classified as R10 or R52/53 i.e. classifications not associated with a hazard symbol. Associated with the amendment on Article 31, paragraph 1 a (new).

Amendment 12
ARTICLE 31, PARAGRAPH 1 A (new)

	1a. For packaging containing 125 ml or less, precautionary statements need not be indicated on the label if the substance or mixture is classified as Chronically Aquatic Hazardous of category 3 or 4.

Justification

Associated with the amendment on article 31, paragraph 1, point k). Chronically Aquatic

Hazardous categories 3 and 4 are not associated with a hazard pictogram; if the hazard statement is omitted from the package then users would not be aware of this particular hazard. This proposed amendment reflects current practice in the DPD for mixtures classified as R10 or R52/53 i.e. classifications not associated with a hazard symbol.

Amendment 13
ARTICLE 31, PARAGRAPH 2 A (new)

	2a. Single application, or single service, single portion or unit dose packs which are kept in packaging labelled pursuant to this Regulation and are removed only for single use in accordance with user instructions accompanying the packaging shall be exempted from the obligation to bear a label.

Justification

Clarifies the situation regarding mixtures supplied in unit dose format where the product (e.g. tablet) is intended a) for a single use only and b) shall be removed from the outer pack directly before use and c) all instructions (and further labelling) is on the outer pack.

Amendment 14
ARTICLE 36, PARAGRAPH 1, SUBPARAGRAPH 1

1. Where both an outer and an inner packaging ***is*** used and the outer packaging ***does not bear a pictogram*** in accordance with 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 packaging shall be labelled in accordance with this Regulation.	1. Where both an outer and an inner packaging ***are*** used and the outer packaging ***is labelled*** in accordance with 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, the inner packaging shall be labelled in accordance with this Regulation.

Justification

In line with DPD Article 11.6(a).

Amendment 15
ARTICLE 37, PARAGRAPH 2

2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products.	2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products.
Where such 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.	Where such 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 there are specific provisions on packaging applying to the mixture in another EU Directive or Regulation, in particular Regulations (EC) Nos 648/2004 and 907/2006***.
Where such 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.	Where such 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 there are specific provisions on packaging applying to the mixture in another EU Directive or Regulation, in particular Regulations (EC) Nos 648/2004 and 907/2006***.

Justification

This amendment avoids overlapping with provisions of other EU directives or regulations.

Amendment 16
ARTICLE 41, PARAGRAPH 1, SUBPARAGRAPH 1

1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market 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 above the concentration limits specified in	1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market a substance ***classified as hazardous and*** subject to registration in accordance with Regulation (EC) No 1907/2006 or***, where the quantity exceeds one tonne per annum,*** a substance classified as hazardous on its

Directive 1999/45/EC or in this Regulation, where relevant, which results in the classification of the mixture as hazardous, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 43:	own or in a mixture 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 to the Agency the following information in order for it to be included in the inventory referred to in Article 43:

Justification

The obligation, starting from 1 December 2010, to notify the Agency for the purposes of the classification inventory should not apply to every case in which a substance subject to registration is to be placed on the market, but only to substances classified as hazardous, including where REACH is concerned. In the last two cases mentioned (a substance classified as hazardous on its own or in a mixture ...), a threshold (1 tonne a year) should be laid down. Failure to do so would undermine legal certainty and adversely affect R & D activities.

Amendment 17
ARTICLE 45

1. Member States shall appoint a body or bodies responsible for receiving information by the suppliers***, including chemical composition of*** the mixtures placed on the market and classified or considered as hazardous on the basis of their health effects or on the basis of their physical effects.	1. Member States shall appoint a body or bodies responsible for receiving information by the suppliers ***on*** the mixtures placed on the market and classified or considered as hazardous on the basis of their health effects or on the basis of their physical effects.
	1a. The information referred to in paragraph 1 shall be presented in the format laid down in Annex VIIa[1] and shall be sufficient to meet medical needs for the purpose of determining preventive and curative measures, including in case of emergency.
2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet medical ***demand by formulating preventative and curative measures, in particular in case of emergency***.	2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet ***the*** medical ***needs referred to in paragraph 2 and*** shall not be used for other purposes.
The information shall not be used for other purposes.	
3. The appointed bodies shall have at their disposal all the information required from	3. The appointed bodies shall have at their disposal all the information required from

the suppliers responsible for marketing to carry out the tasks for which they are responsible.	the suppliers responsible for marketing to carry out the tasks for which they are responsible.
	3a. Every year Member States shall submit data, based on the European accident database set up under the EHLASS programme (European Home and Leisure Accident Surveillance System), detailing the number of accidents and those mixtures involved in respect of which appointed bodies have received requests for medical information concerning treatment and curative measures.
	[1]The information requirements laid down in the entire body of directions issued by the EACCPT shall form the basis of Annex VIIa.

Justification

Given that each Member State has different arrangements regarding requests for information and prescribed formats, a Community procedure will encourage transparency and facilitate the practical aspects of enforcement.

The European Association of Poisons Centres and Clinical Toxicologists has published information requirements that would form the basis of a new Annex VIIa. The accident database set up by the Health and Consumer Protection DG would provide a vehicle for reporting data gathered by appointed bodies on mixtures and accidents in which these were involved.

Amendment 18
ARTICLE 52, PARAGRAPH 1

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 risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.	1. Where***, in the event of a dispute with a supplier,*** a Member State has justifiable grounds for believing that a substance or a mixture, ***whether or not it satisfies*** the requirements of this Regulation, constitutes a risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.

Justification

It would be desirable to allow both for the possibility that disputes might arise between suppliers and Member States over the interpretation of requirements under the regulation and for the need to have a procedure for achieving a harmonised classification in the event of such a dispute.

PROCEDURE

Title	Classification, labelling and packaging of substances and mixtures
References	COM(2007)0355 – C6-0197/2007 – 2007/0121(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ITRE 9.7.2007
Drafts(wo)man Date appointed	Anne Laperrouze 9.10.2007
Discussed in committee	19.12.2007 29.1.2008
Date adopted	6.3.2008
Result of final vote	+: 35 –: 3 0: 0
Members present for the final vote	Šarūnas Birutis, Philippe Busquin, Jerzy Buzek, Giles Chichester, Dragoş Florin David, Den Dover, Lena Ek, Nicole Fontaine, Norbert Glante, András Gyürk, Fiona Hall, David Hammerstein, Rebecca Harms, Ján Hudacký, Romana Jordan Cizelj, Pia Elda Locatelli, Eluned Morgan, Reino Paasilinna, Francisca Pleguezuelos Aguilar, Anni Podimata, Paul Rübig, Andres Tarand, Patrizia Toia, Catherine Trautmann, Nikolaos Vakalis
Substitute(s) present for the final vote	Etelka Barsi-Pataky, Ivo Belet, Danutė Budreikaitė, Zdzisław Kazimierz Chmielewski, Malcolm Harbour, John Purvis, Bernhard Rapkay, Esko Seppänen, Vladimir Urutchev
Substitute(s) under Rule 178(2) present for the final vote	Chris Davies, Andrew Duff, Ruth Hieronymi, Jacques Toubon

PROCEDURE

Title	Classification, labelling and packaging of substances and mixtures
References	COM(2007)0355 – C6-0197/2007 – 2007/0121(COD)
Date submitted to Parliament	27.6.2007
Committee responsible Date announced in plenary	ENVI 9.7.2007
Committee(s) asked for opinion(s) Date announced in plenary	ITRE IMCO 9.7.2007 9.7.2007
Associated committee(s) Date announced in plenary	IMCO 27.9.2007
Rapporteur(s) Date appointed	Amalia Sartori 13.9.2007
Discussed in committee	27.11.2007 28.1.2008 26.3.2008
Date adopted	2.4.2008
Result of final vote	+: 50 –: 5 0: 3
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Liam Aylward, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Karl-Heinz Florenz, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Jens Holm, Marie Anne Isler Béguin, Caroline Jackson, Dan Jørgensen, Christa Klaß, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Peter Liese, Jules Maaten, Marios Matsakis, Roberto Musacchio, Riitta Myller, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Guido Sacconi, Amalia Sartori, Karin Scheele, Horst Schnellhardt, Richard Seeber, Kathy Sinnott, Bogusław Sonik, Antonios Trakatellis, Evangelia Tzampazi, Thomas Ulmer, Marcello Vernola, Anja Weisgerber, Åsa Westlund, Anders Wijkman, Glenis Willmott
Substitute(s) present for the final vote	Antonio De Blasio, Ambroise Guellec, Johannes Lebech, Kartika Tamara Liotard, Miroslav Mikolášik, Bart Staes, Andres Tarand, Lambert van Nistelrooij