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Committee on Industry, Research and Energy

2007/0121(COD)

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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))

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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	(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.	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	(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

level. The same should apply where the supplier chooses to generate new information.	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 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.

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 information by applying the other method or methods described in each section of parts 3 and 4 of Annex I.	However, where that information does not permit the application of the bridging principles ***and expert judgement cannot 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 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 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 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 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 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 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 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