



COMMISSION OF THE EUROPEAN COMMUNITIES

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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 67/548/EEC and Regulation (EC) No 1907/2006

(presented by the Commission)

[SEC(2007) 1334]

[SEC(2007) 1335]

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EXPLANATORY MEMORANDUM

BACKGROUND TO THE PROPOSAL

Reasons and objectives

This proposal accompanies the Commission proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures¹. The latter proposal builds on existing chemicals legislation and establishes a new system on classification, labelling and packaging of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nations Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Classification of substances and preparations under the currently applicable Directives 67/548/EEC and 1999/45/EC triggers other obligations in EU legislation, hereinafter referred to as downstream legislation.

The Commission services have assessed the potential effects of the implementation of the GHS criteria on downstream legislation. Their analysis concludes that effects are either minimal or can be minimised by appropriate changes to particular downstream acts. This proposed Decision aims to make such changes to a number of downstream acts, through amendments which take account of the effects of the proposal on classification, labelling and packaging of substances and mixtures. It is presented together with a proposed Regulation aiming to make changes in order to address the effects of the proposal on classification, labelling and packaging for an existing Regulation.

Coherence with other policies

The analysis of the potential effects of the implementation of the GHS criteria on downstream legislation concluded that effects are either minimal or can be minimised by appropriate changes to particular downstream acts. This draft Decision proposes such changes to the provisions of Directives 76/768/EEC, 88/378/EEC, 1999/13/EC, 2000/53/EC, 2002/96/EC and 2004/42/EC.

During the stakeholder consultation which was held on the proposal for a Regulation on classification, labelling and packaging of substances and mixtures and which also addressed potential effects on downstream legislation, some parties mentioned the lack of analysis of national legislation referring to the EU classification criteria. However, the assessment of the effects on national legislation is within the competence of Member States. The Commission would encourage Member States to analyse national downstream acts along the lines of the study on EU legislation.

¹ COM(2007) 355 final.

RESULTS OF PUBLIC CONSULTATIONS AND IMPACT ASSESSMENTS

Public stakeholder consultation

Internet consultation

The Commission launched a public stakeholder consultation on the proposal for a Regulation on classification, labelling and packaging of substances and mixtures on the internet from 21 August to 21 October 2006. All responses were published on the Internet. Some 370 contributions were received. 82% were sent by industry - companies or associations; of the 254 company responses, 45% came from enterprises with less than 250 employees. 10 NGOs responded. One trade union responded.

18 Member State governments and/or public authorities sent comments. Non-EU public authorities (Iceland, Norway, Switzerland, Romania) gave input as well. No international organisation sent comments. **97% of the responses support the implementation of the GHS in the EU.** Overall the draft proposals of the Commission services were well appreciated by Member State authorities and industry.

Issues raised and how they are addressed

Scope: A majority of respondents (59%) supported neither extending nor lowering the level of protection in comparison with the current EU system, except where necessary to ensure consistency with transport legislation or with the GHS. 5% had no opinion, including most of the NGOs. 36% favoured a different approach. Of these, one group (governmental bodies in Denmark, Sweden, Norway, Iceland), wanted to go beyond the scope of the current system; the second group (associations and companies) proposed to include all GHS categories, but not to include the "EU left-overs" which are not yet part of the GHS.

Impact assessments

The Commission's overall impact assessment for the proposed Regulation on classification, labelling and packaging of substances and mixtures and its consequential changes to related downstream legislation made use of the consultant reports prepared by RPA and London Economics as well as the responses to the stakeholder consultation. Specifically, the responses from companies on the costs have led to further efforts to quantify significant cost items. The overall analysis demonstrates that the implementation costs need to be kept in check so as to arrive at the net benefits of the GHS in the foreseeable future.

The measures set out in this proposal provide for an adaptation of the references to the classification rules and terminology according to the proposal for a Regulation on classification, labelling and packaging of substances and mixtures for all downstream acts covered by the current proposed Decision. For Directives 76/768/EEC, 88/378/EEC, 2000/53/EC and 2002/96/EC, potential effects are minimised by covering, in the reference to dangerous substances and mixtures according to the proposed Regulation on classification, labelling and packaging of substances and mixtures, those endpoints which are already referred to under the current EU regime on classification and labelling, while not adding further endpoints.

As to Directive 1999/13/EC, no further adaptation of reference to the classification criteria is made because potential effects are deemed irrelevant for the scope of the Directive.

Directive 2004/42/EC does not base any additional obligation on the classification of substances and mixtures.

For each of the EU downstream Directives which are proposed for amendment by the current proposed Decision, there is therefore no need for further analysis beyond that set out in the overall impact assessment referred to above.

Collection and use of expertise

The GHS was developed by international organisations, with participation of a variety of stakeholders. Similarly, in the EU there have been continuous technical discussions with Member States and other stakeholders over the past years. Following the publication of the White Paper “Strategy for a future Chemicals Policy”, the Commission consulted widely with experts. The results of the technical working group on classification and labelling convened by the Commission in preparation for REACH² have been taken into account in drafting this proposal. Further studies were carried out³ and an informal stakeholder discussion on the implementation of the GHS in the EU took place on 18 November 2005.

LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

This proposal has a double legal basis consisting of both Article 95 and Article 175 (1) of the EC Treaty. This double legal basis is the appropriate legal basis for this proposed Decision because it minimises the effects for six existing Directives which would result from the proposal for a Regulation on classification, labelling and packaging of substances and mixtures. Three of those Directives are based on Article 175 (1) of the EC Treaty, three of them are based on Article 95 of the EC Treaty. Both legal bases rely on the co-decision procedure laid down in Article 251 of the EC Treaty and they are therefore compatible from a procedural viewpoint. A double legal basis comprising both aforementioned Articles was recently used by the European Parliament and the Council for the Regulation on certain fluorinated greenhouse gases⁴.

Subsidiarity and proportionality

Subsidiarity

Six existing Directives in the fields of cosmetic products, safety of toys, emissions of volatile organic compounds, end-of-life vehicles and waste electric and electronic equipment already contain substantive legal provisions. The proposed Decision will amend the existing Directives to adapt them to the classification rules set forth in the proposal for a Regulation on classification, labelling and packaging of substances and mixtures. Those amendments need to

² ECBI/03/02: White Paper Working Group on Classification and Labelling: Summary of Recommendations from Technical Working Group on Tasks 1 and 2.

³ Final report: Technical Assistance to the Commission on the implementation of the GHS. Ökopol Institute for Environmental Strategies, July 2004.

Final project report: Technical support for the preparation of Annexes for the draft legislation implementing the Globally Harmonised System for Classification and Labelling of Chemicals (GHS). Milieu Environmental Law & Policy, January 2006.

⁴ OJ L 161, 14.6.2006, p. 1.

be exactly the same in all Member States, and should therefore be regulated at Community level.

Proportionality

The criteria for the classification of substances and mixtures as hazardous are contained in the proposal for a Regulation on classification, labelling and packaging of substances and mixtures. In that proposal, some hazard classes and categories are added in comparison to the current EU system, leading to classification of substances and mixtures which previously were not classified. To ensure proportionality, there should be no change in the scope of downstream legislation, so as not to trigger new obligations. The proposed Decision aims to ensure this, by including in six Directives a reference to the concept of “dangerous” which is found in Article 3 (2) of the proposal for a Regulation on classification and labelling of substances and mixtures and which is in line with the current EU system.

Therefore this proposal for a Decision is proportionate.

Choice of legal instrument

The choice of a Decision is justified. On the one hand, this proposal amends six existing Directives which have been transposed into Member State legislation and whose legal nature is not affected by the proposal for a Regulation on classification, labelling and packaging of substances and mixtures. The amendments introduced by this Decision in turn will have to be transposed in Member State legislation. It is therefore appropriate to choose an instrument that is not directly applicable, but that is addressed to the Member States instead. On the other hand, the majority of the amendments contained in this proposal are only intended to become applicable several years from the adoption of the amending act, namely from 1 December 2010 and from 1 June 2015 respectively. This would either require different transposition dates to be set for the different provisions depending on the relevant dates, which is unorthodox wording for a Directive from a legal perspective, or a single date of transposition, which would require Member States to adopt national legislation with a deferred applicability for some provisions, which is unusual for a Directive. A Decision is more efficient in laying down clearly the obligations of Member States in this regard and is therefore to be preferred.

INTRODUCTION TO THE PROPOSAL

This Decision amends six existing Directives to adapt them to the criteria for the classification and labelling of substances and mixtures laid down in the proposal for a Regulation on classification, labelling and packaging of substances and mixtures.

1. REASONS AND OBJECTIVES

The main objective of this Decision is to address the effects of the introduction of new classification criteria for substances and mixtures for six Directives which refer to classification of substances or mixtures, so as to prevent undesired changes in scope and obligations. Where necessary, it adapts the provisions of those Directives to the new terminology resulting from the new criteria and the new hazard statements introduced by the proposal on classification, labelling and packaging. The term “mixture” is introduced to replace the term “preparation”, in line with the proposal on classification, labelling and packaging of substances and mixtures.

Where the Directives refer in general to the test methods laid down in Directive 67/548/EEC, this proposal updates this reference in line with the recently adopted Regulation 1907/2006 (REACH) which foresees a Commission Regulation containing these methods.

For Directive 1999/13/EC, this proposal contains a change which is consequential to the replacement of the former risk phrase R40 by two new risk phrases called R40 and R68, operated by Directive 2001/59/EC. This replacement had until now not been reflected in the wording of Directive 1999/13/EEC. It is appropriate to make this change now to ensure a correct transition to the corresponding hazard phrases foreseen in the proposal on classification, labelling and packaging of substances and mixtures.

2. DETAILED PROVISIONS

Articles 1 to 6 introduce the required changes to Directives 76/768/EEC, 88/378/EEC, 1999/13/EC, 2000/53/EC, 2002/96/EC and 2004/42/EC in line with the findings of the analysis of the potential effects of the proposal for a Regulation on classification, labelling and packaging of substances and mixtures on EU downstream legislation and the objectives discussed under the previous section.

The staggered dates of entry into effect of the changes reflect the phased entry into effect of the aforementioned proposal for a Regulation. This is logical, as the Decision introduces changes which are consequential to the adoption of that Regulation.

Article 7 is a standard article which is required due to the legal nature of a Decision.

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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 67/548/EEC and Regulation (EC) No 1907/2006

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 and Article 175(1) thereof,

Having regard to the proposal from the Commission⁵,

Having regard to the opinion of the European Economic and Social Committee⁶,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁷,

Whereas:

- (1) Regulation (EC) No ... 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 1907/2006⁸ provides for the harmonisation of the classification and labelling of substances and mixtures within the Community. That Regulation will replace Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁹ as well as Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations¹⁰.
- (2) Regulation (EC) ... builds on the experience of Directives 67/548/EEC and 1999/45/EC and incorporates the criteria for classification and labelling of substances

⁵ OJ C

⁶ OJ C

⁷ OJ C

⁸ OJ L

⁹ OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC (OJ L 396, 30.12.2006, p. 850).

¹⁰ OJ L 200, 30.7.1999, p. 1. Directive as amended by Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006, p. 1).

and mixtures provided for by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which has been adopted at the international level, within the United Nations structure.

- (3) Certain provisions on classification and labelling laid down in Directives 67/548/EEC and 1999/45/EC also serve for the purpose of the application of other Community legislation, such as Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products¹¹, Council Directive 88/378/EEC of 3 May 1988 on the approximation of laws of the Member States concerning the safety of toys¹², Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations¹³, Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles¹⁴, Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment¹⁵ and Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC¹⁶.
- (4) The incorporation of the GHS criteria into Community legislation leads to the introduction of new hazard classes and categories only partially corresponding to the classification and labelling arrangements provided for by Directives 67/548/EEC and 1999/45/EC. An analysis on the potential effects of the transition from the old to the new system of classification and labelling has led to the conclusion that by adapting the references to the classification criteria in Directives 76/768/EEC, 88/378/EEC, 2000/53/EC and 2002/96/EC to the new system introduced by Regulation (EC) No ..., the scope of the respective acts should be maintained.
- (5) It is also necessary to adapt Directive 76/768/EEC to take into account the adoption of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency, amending Directive 1999/45/EC 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/EC¹⁷.

¹¹ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2007/22/EC (OJ L 101, 18.4.2007, p. 11).

¹² OJ L 187, 16.7.1988, p. 1. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

¹³ OJ L 85, 29.3.1999, p. 1. Directive as last amended by Directive 2004/42/EC (OJ L 143, 30.4.2004, p. 87).

¹⁴ OJ L 269, 21.10.2000, p. 34. Directive as last amended by Decision 2005/673/EC (OJ L 254, 30.9.2005, p. 69).

¹⁵ OJ L 37, 13.2.2003, p. 24. Directive as amended by Directive 2003/108/EC (OJ L 345, 31.12.2003, p. 106).

¹⁶ OJ L 143, 30.4.2004, p. 87.

¹⁷ OJ L 396, 30.12.2006, p. 1.

- (6) It is appropriate to bring Directive 1999/13/EC into line with the replacement of risk phrase R40 by two new risk phrases R40 and R68 under Directive 67/548/EEC, so as to ensure the correct transition to the hazard statements laid down in Regulation (EC) No ...
- (7) The transition from the criteria for classification contained in Directives 67/548/EEC and 1999/45/EC will be fully completed on 1 June 2015. Manufacturers of cosmetics, toys, paints, varnishes, vehicles refinishing products, vehicles and electric and electronic equipment are manufacturers, importers or downstream users within the meaning of Regulation (EC) No ..., as are the operators whose activities are covered by Council Directive 1999/13/EC. All of them should be enabled to design their transition strategy under this Decision in a similar timeframe as under Regulation (EC) No
- (8) Directives 76/768/EEC, 88/178/EEC, 1999/13/EC, 2000/53/EC, 2002/96/EC and 2004/42/EC should be amended accordingly.

HAVE ADOPTED THIS DECISION:

Article 1
Amendment to Directive 76/768/EEC

Directive 76/768/EEC is amended as follows:

- (1) the word « preparation » or “preparations” within the meaning of Article 3(2) of Regulation (EC) No 1907/2006 in its version of 30 December 2006 is replaced by the word « mixture » or “mixtures” respectively throughout the text;
- (2) in Article 4a, point d of paragraph 1 is replaced by the following:

“(d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated methods listed in Commission Regulation [...* on test methods]**, or in Annex IX to this Directive.

* OJ L ...

** OJ L 396, 30.12.2006, p. 1.”

- (3) from 1 December 2010, Article 4b of Directive 76/768/EEC is replaced by the following:

“Article 4b

The use in cosmetic products of substances classified as carcinogenic, germ cell mutagenic or toxic for reproduction, of category 1A, 1B and 2, under part 3 of Annex VI of Regulation (EC) No ... of the European Parliament and of the Council of ... on Classification and Labelling of Substances and Mixtures*** shall be prohibited. To that end the Commission shall adopt the necessary measures in

accordance with the procedure referred to in Article 10 (2). A substance classified in category 2 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.

*** OJ L ...”

- (4) from 1 December 2010, in Article 7a(1), the last sentence of the second subparagraph of point (h) is replaced by the following:

“The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances within the meaning of Article 3(2) of Regulation (EC) No”;

- (5) in Annex IX, the first sentence is replaced by the following:

“This Annex lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Directive and which are not listed in Regulation [..].”

Article 2
Amendment to Directive 88/378/EEC

Directive 88/378/EEC is amended as follows:

- (1) the word « preparation » or “preparations” within the meaning of Article 3(2) of Regulation (EC) No 1907/2006 in its version of 30 December 2006 is replaced by the word « mixture » or “mixtures” respectively throughout the text;
- (2) from 1 June 2015, in section 2 of part II of Annex II, point (b) is replaced by the following:

“(b) Toys which, for reasons essential to their functioning, contain dangerous substances or mixtures within the meaning of Article 3 (2) of Regulation (EC) No ... of the European Parliament and of the Council of ... on Classification and Labelling of Substances and Mixtures*, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.”

* OJ L ...”

- (3) from 1 June 2015, in section 3 of part II of Annex II, the first paragraph of point 3 is replaced by the following:

“3. Toys must not contain dangerous substances or mixtures within the meaning of Article 3(2) of Regulation (EC) No ... in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, such dangerous substances or mixtures if they are intended to be used as such while the toy is being used.”

- (4) from 1 June 2015, in section 4 of Annex IV, the title and point (a) are replaced by the following:

“4. Toys containing inherently dangerous substances or mixtures. Chemical toys

(a) Without prejudice to the application of the provisions laid down in Regulation (EC) No ..., the instructions for use of toys containing inherently dangerous substances or mixtures within the meaning of Article 3 (2) of that Regulation shall bear a warning of the dangerous nature of these substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toys must be kept out of reach of very young children.”

Article 3
Amendment to Directive 1999/13/EC

Directive 1999/13/EC is amended as follows:

- (1) the word « preparation » or “preparations” within the meaning of Article 3(2) of Regulation (EC) No 1907/2006 in its version of 30 December 2006 is replaced by the word « mixture » or “mixtures” respectively throughout the text;

- (2) Article 5 is amended as follows:

- (a) from 1 June 2015, paragraph 6 is replaced by the following:

“6. Substances or mixtures which, because of their content of VOCs classified as carcinogens, mutagens or toxic to reproduction under Regulation (EC) No ... of the European Parliament and of the Council* are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F shall be replaced, as far as possible and by taking into account the guidance as mentioned in Article 7 (1), by less harmful substances or mixtures within the shortest possible time.

* OJ L ...”

- (b) paragraph 8 is amended as follows:

- (i) the words “the risk phrase R40” are replaced by “the risk phrases R40 or R68”;
- (ii) the words “the labelling R40” are replaced by “the labelling R40 or R68”;
- (iii) from 1 June 2015, the words “the risk phrases R40 or R68” are replaced by “the hazard statements H341 or H351”;

- (iv) from 1 June 2015, the words “the labelling R40 or R68” are replaced by “the hazard statements H341 or H351”;
- (c) from 1 June 2015, in paragraph 9, the words “risk phrases” are replaced by the words “hazard statements”;
- (d) paragraph 13 is amended as follows:
 - (i) the words “the labelling R40, R60 or R61” are replaced by “the risk phrases R40, R68, R60 or R61”;
 - (ii) from 1 June 2015, the words “the risk phrases R40, R68, R60 or R61” are replaced by “the hazard statements H341, H351, H360F or H360D”.

Article 4
Amendment to Directive 2000/53/EC

From 1 December 2010, in Article 2 of Directive 2000/53/EC, paragraph 11 is replaced by the following:

“11. ‘hazardous substance’ means any substance which is considered to be dangerous within the meaning of Article 3(2) of Regulation (EC) No ... of the European Parliament and of the Council*;

* OJ L ...”

Article 5
Amendment to Directive 2002/96/EC

Directive 2002/96/EC is amended as follows:

- (1) from 1 June 2015, the word “preparation” or “preparations” within the meaning of Article 3(2) of Regulation (EC) No 1907/2006 in its version of 30 December 2006 is replaced by the word “mixture” or “mixtures” respectively throughout the text;
- (2) from 1 June 2015, in Article 3, point (l) is replaced by the following:

“ (l) ‘dangerous substance or mixture’ means any substance or mixture which has to be considered dangerous within the meaning of Article 3(2) of Regulation (EC) No ... of the European Parliament and of the Council*;

* OJ L...”

- (3) in section 1 of Annex II, the thirteenth indent is replaced by the following:

“- components containing refractory ceramic fibres as described in part 3 of Annex VI to Regulation (EC) No ... of the European Parliament and of the Council*;

* OJ L ...”

Article 6
Amendment to Directive 2004/42/EC

Article 2 of Directive 2004/42/EC is amended as follows:

- (a) in paragraph 3, the word « preparation » is replaced by « mixture »;
- (b) in paragraph 8, the word “preparation” is replaced by “mixture”.

Article 7

This Decision is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): 02 – ENTERPRISE

Activit(y/ies): 04 – GETTING STILL MORE FROM THE INTERNAL MARKET

TITLE OF ACTION: PROPOSAL FOR A GLOBALLY HARMONISED SYSTEM FOR CLASSIFICATION AND LABELLING OF CHEMICALS

1. PART 1: BUDGET LINES

1.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B.A lines)) including headings:

Not applicable.

1.2. Duration of the action and of the financial impact:

Not applicable

For reasons explained under Section 3.1 of this document, there are no direct additional costs related to this legislative proposal on the Community budget.

Costs, which relate to the work with Technical Committees required for this legislation will be borne by the European Chemicals Agency (budget line 02 03 03), to be established under Commission proposal COM (2003) 644.

These costs, however, will not be different from the costs related to the management of existing legislation for the classification and labelling of substances and preparations. This regulation replaces two other pieces of Legislation¹⁸ at no additional costs to the Community budget.

1.3. Budgetary characteristics (add rows if necessary)

Budget line	Type of expenditure	New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
<i>Not applicable</i>					

¹⁸ Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended [OJ 196, 16.8.1967, p.1] and Council Directive 1999/45/EEC relating to the classification, packaging and labelling of dangerous preparations, as amended [OJL 200, 30.7.1999, p.1]

2. PART 2: SUMMARY OF RESOURCES

2.1. Financial Resources

2.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
Operational expenditure									
Commitment Appropriations (CA)	6.1	a	<i>Not applicable</i>						
Payment Appropriations (PA)		b							
Administrative expenditure within reference amount									
Technical & administrative assistance (NDA)	6.2.4	c	<i>Not applicable</i>						
TOTAL REFERENCE AMOUNT									
Commitment Appropriations		a+c	<i>Not applicable</i>						
Payment Appropriations		b+c							

Administrative expenditure not included in reference amount

Human resources and associated expenditure (NDA)	6.2.5	d	0.351	0.351	0.351	0.351	0.351	0.351	2.106
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	6.2.6	e	--	--	--	--	--	--	--

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c +d+ e	0.351	0.351	0.351	0.351	0.351	0.351	2.106
TOTAL PA including cost of Human Resources		b+c +d+ e	--	--	--	--	--	--	--

Co-financing details

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

EUR million (to 3 decimal places)

Co-financing body		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
	f							
TOTAL CA including co-financing	a+c +d+ e+f	<i>Not applicable</i>						

2.1.2. Compatibility with Financial Programming

- Proposal is compatible with existing financial programming.
- Proposal will entail reprogramming of the relevant heading in the financial perspective.
- Proposal may require application of the provisions of the Interinstitutional Agreement (i.e. flexibility instrument or revision of the financial perspective).

2.1.3. Financial impact on Revenue

- Proposal has no financial implications on revenue
- Proposal has financial impact – the effect on revenue is as follows:

EUR million (to one decimal place)

Budget line	Revenue	Prior to action [Year n-1]	Situation following action					
			[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5] 19
	a) Revenue in absolute terms		<i>Not applicable</i>					
	b) Change in revenue	Δ						

(Please specify each revenue budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)

¹⁹ Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.

2.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 6.2.1.

Annual requirements	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later
Total number of human resources	3	3	3	3	3	3

The needs for human and administrative resources shall be covered within the allocation granted to the managing DGs (co-responsibility of ENTR and ENV) in the framework of the annual allocation procedure.

3. PART 3: CHARACTERISTICS AND OBJECTIVES

Details of the context of the proposal are required in the Explanatory Memorandum. This section of the Legislative Financial Statement should include the following specific complementary information:

3.1. Need to be met in the short or long term

As explained in 3.2 below, this proposal replaces existing legislation with almost the same scope.

DG ENV is responsible for the existing legislation on the classification of dangerous substances which is largely managed by the European Chemicals Bureau (ECB) in Ispra under a special agreement with DG ENV; whereas DG ENTR has the responsibility to manage the existing legislation on dangerous preparations. While the ECB runs most of the complex Technical Committees, which are responsible for the preparatory work, it is the Commission's task to take the recommendations from the Technical Committees and manage the associated Comitology procedure. For this purpose, staff is maintained in DG ENV and DG ENTR.

Under the new proposal, the work with the Technical Committees will be transferred from the ECB to the new European Chemicals Agency in Helsinki. The opinions, which the Committees of the Agency will produce, will be forwarded to the Commission which will then manage the associated Comitology procedure.

Estimates are that the human resources requirements at the Commission will not change with the introduction of the new legislation. Therefore, this legislative proposal does not trigger any additional (compared to existing legislation) resource requirements.

3.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

Currently, there are a large number of different classification and labelling (C&L) systems for chemicals (substances and preparations, GHS term: mixtures) in force in different jurisdictions across the world (e.g. European Union, USA, Canada, Japan, China, Korea, Australia). As a consequence, C&L systems are different and so is the resulting Health and Safety (H&S) information for the same type of substances and mixtures that originate in different countries.

In 1992, the UN Conference on Environment and Development (UNCED) in Rio de Janeiro identified the harmonisation of classification and labelling systems for chemicals as one of its action programmes.

As a result, a new system has been developed in co-operation with various international organisations. EU Member States, the Commission and stakeholders were heavily involved in this development work.

In December 2002, this new system, the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), was agreed by the UN Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals (CETDG/GHS) in Geneva. The GHS was then formally adopted by UN ECOSOC²⁰ in July 2003 and became available for implementation.

Despite the non-binding nature of the agreement the new GHS system is a *de facto* international standard. Besides participating in the work to develop the GHS at UN level, the Commission has announced on several occasions its aim to implement the GHS into Community legislation. On 29 October 2003, the Commission stated in the explanatory memorandum to the amendment to 67/548/EC, adopted at the same time as the REACH proposal, that:

“it is the intention of the Commission to propose inclusion of the internationally agreed GHS into Community law as soon as possible”

and, more specifically that:

“the Commission will come forward with the necessary proposals for having it adopted at the same time as the final adoption of the REACH legislation”.

The current proposal will replace 2 existing European Directives²¹ including more than 10 Amendments and 30 Adaptations to Technical Progress. As this

²⁰ Economic and Social Committee of the United Nations

²¹ Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended [OJ 196, 16.8.1967, p.1] and Council Directive 1999/45/EEC relating to

area was already legislated at European level and it is related to the introduction of an international standard with the objective of achieving a high level of harmonisation, the Community involvement is justified.

3.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

The objective of the proposal is to contribute not only to the harmonisation of the internal market but to better protect human health and the environment and at the same time promote sustainable development and facilitate international trade.

In this context it must be stated that the existing situation, namely having different hazard descriptions for the same substance, does not contribute to the protection of human health nor does it facilitate international trade as industry has to apply different labels for the same substance depending on the region to which it wants to export.

For the expected results of the proposal, see the final Report of the Impact Assessment of this proposal which has made extensive use of the detailed studies of RPA and London Economics and also of the responses to the Stakeholder Consultation. Specifically, the responses from companies on the costs have led to further efforts to quantify significant cost items. The overall analysis demonstrates that the implementation costs need to be kept in check so as to arrive at the net benefits of the GHS in the foreseeable future. This requires a transition period of appropriate length, viz. for substances 3 years to align with the deadline of the classification and labelling inventory, and for mixtures of around 4.5 years so as to avoid the costs and risks of significant workability bottleneck related with overly short and too long periods.

Any additional studies regarding the establishment of a base-line scenario or the definition of indicators to measure the impact of the proposed legislation are deemed to be not proportionate and are therefore not being carried out. The reasons why such studies are deemed to be not proportionate are the following:

- This legislative proposal relates to the implementation of an international agreement. Even a negative ex-ante evaluation would not result in the Commission not putting forward such a legislative proposal since other policy options do not exist
- A negative ex-post evaluation would not induce the Commission to withdraw from its commitment to implement the internationally agreed system of Classification and Labelling

the classification, packaging and labelling of dangerous preparations, as amended [OJL 200, 30.7.1999, p.1]

3.4. Method of Implementation (indicative)

Show below the method(s) chosen for the implementation of the action.

- X Centralised Management
 - X Directly by the Commission (in co-operation with the European Chemicals Agency, please see below)
 - † Indirectly by delegation to:
 - † Executive Agencies
 - X Bodies set up by the Communities as referred to in Art. 185 of the Financial Regulation (European Chemicals Agency to be set up under Commission proposal COM (2003) 644)
 - † National public-sector bodies/bodies with public-service mission
- † Shared or decentralised management
 - † With Member states
 - † With Third countries
- † Joint management with international organisations (please specify)

Relevant comments:

4. PART 4: MONITORING AND EVALUATION

4.1. Monitoring system

The Commission services will align the monitoring and evaluation activities on the Regulation with the corresponding efforts at UN level and those for REACH.

UNITAR and OECD will review the extent of convergence of the C&L systems over the world as realised by the GHS, firstly to see whether the expected benefits of harmonisation are realized and also to identify the appropriate next steps towards even more uniform C&L requirements. The Commission services will provide their expert input to this review work, based on the GHS classifications as registered in the REACH classification and labelling inventory.

4.2. Evaluation

4.2.1. Ex-ante evaluation

Based on the five-yearly reports from the Member States (as required by Article 46 of the Regulation), the Commission will evaluate to which extent the Regulation is applied correctly and whether there are bottlenecks in the application.

The first evaluation (i.e. the one after five years) will focus on the transition of substance classifications towards GHS with a view on the then ongoing transition of mixture classifications and also informing the review of REACH foreseen at seven years after entry into force.

The second evaluation (i.e. the one after ten years) will be able to assess the complete transition period. Both evaluations can use a sample of chemicals with their “old” and “new” classifications so as to check whether any significant change of scope has occurred, and to assess the (change in) quality of the classifications and labelling.

4.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

Not applicable.

4.2.3. Terms and frequency of future evaluation

Please see 4.2.1

5. PART 5: ANTI-FRAUD MEASURES

As this proposal does not contain or result in the management of financial resources this section is not applicable.

6. PART 6: DETAILS OF RESOURCES

6.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year n		Year n+1		Year n+2		Year n+3		Year n+4		Year n+5 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 ²²			<i>Not applicable</i>													
Action 1																
- Output 1																
- Output 2																
Action 2																
- Output 1																
Sub-total Objective 1																
OPERATIONAL OBJECTIVE No.2 ¹																
Action 1																
- Output 1																
Sub-total Objective 2																
OPERATIONAL OBJECTIVE No.n ¹																

²² As described under Section 5.3

Sub-total Objective n			
TOTAL COST			

6.2. Administrative Expenditure

6.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs)					
		Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5
Officials or temporary staff ²³ (XX 01 01)	A*/AD	3*	3*	3*	3*	3*	3*
	B*, C*/AST	<i>Not applicable</i>					
Staff financed ²⁴ by Art. XX 01 02							
Other staff ²⁵ financed by Art. XX 01 04/05							
TOTAL		3	3	3	3	3	3

* Currently one person DG ENV and two persons DG ENTR

6.2.2. Description of tasks deriving from the action

Under the new legislation the opinions regarding the classification and labelling formulated by the Committees of the Agency will be forwarded to the Commission. It will then be the task of the Commission to manage the related Comitology work.

In addition, the Commission will continue to participate in the evolutive work on the GHS system on the level of the United Nations.

6.2.3. Sources of human resources (statutory)

- Posts currently allocated to the management of the programme to be replaced or extended
- Posts pre-allocated within the APS/PDB exercise for year n
- Posts to be requested in the next APS/PDB procedure
- Posts to be redeployed using existing resources within the managing service (internal redeployment)

²³ Cost of which is NOT covered by the reference amount

²⁴ Cost of which is NOT covered by the reference amount

²⁵ Cost of which is included within the reference amount

- Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

6.2.4. *Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)*

EUR million (to 3 decimal places)

Budget line (number and heading)	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
1. Technical and administrative assistance (including related staff costs)	<i>Not applicable</i>						
Executive agencies ²⁶							
Other technical and administrative assistance							
- <i>Intra muros</i>							
- <i>Extra muros</i>							
Total Technical and administrative assistance							

6.2.5. *Financial cost of human resources and associated costs not included in the reference amount*

EUR million (to 3 decimal places)

Type of human resources	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later
Officials and temporary staff (XX 01 01)	0.351	0.351	0.351	0.351	0.351	0.351
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	--	--	--	--	--	--
Total cost of Human Resources and associated costs (NOT in reference amount)	0.351	0.351	0.351	0.351	0.351	0.351

²⁶ Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

Calculation – *Officials and Temporary agents*

Reference should be made to Point 6.2.1, if applicable.

It is assumed that the average cost for an AD official or temporary agent is € 117.000 per year.

Calculation – *Staff financed under Art. XX 01 02*

Reference should be made to Point 6.2.1, if applicable.

6.2.6 Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
XX 01 02 11 01 – Missions	<i>Not applicable</i>						
XX 01 02 11 02 – Meetings & Conferences							
XX 01 02 11 03 – Committees*							
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
2. Total Other Management Expenditure (XX 01 02 11)							
3. Other expenditure of an administrative nature (specify including reference to budget line)							
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)							

* The Technical Committees required for this legislative proposal are Committees established at the level of the new European Chemicals Agency. Their tasks include *inter alia* work related to Classification and Labelling. All costs for these Technical Committees will be borne by the budget of the Chemicals Agency.

- * The Comitology Committee required for the management of the new legislation will most likely be the same Committee as the one required for the REACH legislation. Therefore, no additional costs will occur for Committee work.
- * The needs for human and administrative resources shall be covered within the allocation granted to the managing DGs (co-responsibility of ENTR and ENV) in the framework of the annual allocation procedure.

Calculation - *Other administrative expenditure not included in reference amount*