



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Regulation (EC) No 648/2004  
in order to adapt it to Regulation (EC) No ... 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)

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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 mixtures<sup>1</sup>. 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, 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 Regulation aims to make such changes to such a downstream act, 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 Decision aiming to make changes in order to address the effects of the proposal on classification, labelling and packaging for six existing Directives.

#### **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 Regulation proposes such changes to the provisions of Regulation (EC) No 648/2004.

A proposal for a Regulation concerning the placing on the market of plant protection products is currently under discussion in the European Parliament and the Council. Once this proposal is adopted, the present proposal for a Regulation on amending EU downstream legislation should be revised in order to include also the Plant Protection Products Regulation, or a separate amending proposal should be presented, if appropriate.

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. To the extent this proposal addresses an existing Regulation, it does not require transposition at Member State level.

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<sup>1</sup> 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 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 proposed Regulation on classification, labelling and packaging of substances and mixtures. Regulation (EC) 648/2004 does not base any additional obligation on the classification of substances and mixtures. 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 REACH<sup>2</sup> have been taken into account in drafting this proposal. Further studies were carried out<sup>3</sup> 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 is based on Article 95 of the EC Treaty. This legal basis is appropriate for this proposed Regulation because it adapts an existing Regulation, which is itself based on Article 95 of the EC Treaty, to the proposed Regulation on classification, labelling and packaging of substances and mixtures.

### **Subsidiarity and proportionality**

#### *Subsidiarity*

An existing Regulation in the field of detergents already contains substantive legal provisions. The proposed Regulation will amend the existing Regulation to adapt it 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 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 and the rules on the labelling and packaging of hazardous substances and mixtures are contained in the proposal for a Regulation on classification, labelling and packaging of substances and mixtures. To ensure legal certainty and clarity of the obligations of the operators concerned, the provisions of Regulation (EC) 648/2004 should be amended to reflect the new situation. This is especially important as Regulations are directly applicable in the Member States and operators should be in no doubt as to the obligations which apply to them.

In ensuring this, this proposal for a Regulation is proportionate.

### **Choice of legal instrument**

The choice of a Regulation is justified, as it amends an existing Regulation.

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

<sup>3</sup> 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.

## **INTRODUCTION TO THE PROPOSAL**

This proposed Regulation amends an existing Regulation to the provisions of the proposal for a Regulation on classification, labelling and packaging of substances and mixtures which will repeal and replace Directives 67/548/EEC and 1999/45/EC.

### **1. REASONS AND OBJECTIVES**

The objective of this Regulation is to reflect the introduction of a new Regulation on classification, labelling and packaging of substances and mixtures and of new terminology for a Regulation which refers to classification of substances or mixtures. The term “mixture” is introduced to replace the term “preparation”, in line with the proposal on classification and labelling of substances and mixtures.

### **2. DETAILED PROVISIONS**

Article 1 introduces the required changes to Regulation (EC) No 648/2004 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 in the previous section. As far as Regulation (EC) No 648/2004 makes general references to Directives 67/548/EEC and 1999/45/EC, which will be repealed by the Regulation on classification, labelling and packaging of substances and mixtures, it needs to be updated so as to refer to that Regulation.

The staggered dates of entry into effect of the changes reflect the phased entry into effect of the aforementioned proposal for a Regulation.

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**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission<sup>4</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>5</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>6</sup>,

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 1907/2006<sup>7</sup> 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 substances<sup>8</sup> 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 preparations<sup>9</sup>.
- (2) Regulation (EC) No ... builds on the experience of Directives 67/548/EEC and 1999/45/EC and incorporates the criteria for classification and labelling of substances

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<sup>4</sup> OJ C

<sup>5</sup> OJ C

<sup>6</sup> OJ C

<sup>7</sup> OJ L

<sup>8</sup> OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC (OJ L 396, 30.12.2006, p. 850).

<sup>9</sup> OJ L 200, 30.7.1999, p. 1. Directive as last 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 Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents<sup>10</sup>.
- (4) An analysis of the potential effects of replacing Directives 67/548/EEC and 1999/45/EC and the introduction of the GHS criteria led to the conclusion that by adapting the references to those Directives in Regulation (EC) No 648/2004, the scope of that act should be maintained.
- (5) 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 detergents are manufacturers, importers or downstream users within the meaning of Regulation (EC) No ... and should be given the possibility under this Regulation to adjust to that transition within a similar timeframe as that provided for in Regulation (EC) No ....
- (6) Regulation (EC) No 648/2004 should be amended accordingly.

HAVE ADOPTED THIS REGULATION:

*Article 1*  
***Amendment to Regulation (EC) No 648/2004***

Regulation (EC) No 648/2004 is amended as follows:

- (1) the word “preparation” or “preparations” within the meaning of Article 3(2) of Regulation (EC) 1907/2006 of the European Parliament and of the Council<sup>11</sup>, in its version of 30 December 2006, is replaced by the word « mixture » or “mixtures” respectively throughout the text;
- (2) in paragraph 1 of Article 9, the introductory phrase is replaced by the following:

“Without prejudice to Article 45 of Regulation (EC) No ... of the European Parliament and of the Council\*, manufacturers placing on the market the substances and/or mixtures covered by this Regulation shall hold at the disposal of the competent authorities of the Member States;

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\* OJ L ...”

- (3) in Article 11, paragraph 1 is replaced by the following:

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<sup>10</sup> 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).

<sup>11</sup> OJ L 396, 30.12.2006, p. 1.



“1. Paragraphs 2 to 6 are without prejudice to the provisions relating to the classification, labelling and packaging of substances and mixtures in Regulation (EC) No ....”.

*Article 2*

***Entry into force and application***

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

Points (2) and (3) of Article 1 shall apply from 1 June 2015.

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

Done at Brussels,

*For the European Parliament*  
*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 Legislation<sup>12</sup> 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>					

<sup>12</sup> 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	Not applicable						
Payment Appropriations (PA)		b							
Administrative expenditure within reference amount									
Technical & administrative assistance (NDA)	6.2.4	c	Not applicable						
TOTAL REFERENCE AMOUNT									
Commitment Appropriations		a+c	Not applicable						
Payment Appropriations		b+c							
Administrative expenditure <u>not</u> 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

<b>TOTAL CA including cost of Human Resources</b>		a+c+d+e	0.351	0.351	0.351	0.351	0.351	0.351	2.106
<b>TOTAL PA including cost of Human Resources</b>		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)

		Prior to action [Year n-1]	Situation following action					
Budget line	Revenue		[Year n]	[n+1]	[n+2]	[n+3 ]	[n+4]	[n+5] 13
	a) Revenue in absolute terms		<i>Not applicable</i>					
	b) Change in revenue	Δ						

<sup>13</sup> Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.

*(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.)*

**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 ECOSOC<sup>14</sup> 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 Directives<sup>15</sup> including more than 10 Amendments and 30 Adaptations to Technical Progress. As this area was already legislated at European level and it is related to the

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<sup>14</sup> Economic and Social Committee of the United Nations

<sup>15</sup> 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]

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

### **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 <sup>16</sup>	<i>Not applicable</i>															
Action 1																
- Output 1																
- Output 2																
Action 2																
- Output 1																
Sub-total Objective 1																
OPERATIONAL OBJECTIVE No.2 <sup>1</sup> .....																
Action 1																
- Output 1																
Sub-total Objective 2																
OPERATIONAL OBJECTIVE No.n <sup>1</sup>																

<sup>16</sup> As described under Section 5.3

Sub-total Objective n			
<b>TOTAL COST</b>			

## 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 ( <b>number of posts/FTEs</b> )					
		Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5
Officials or temporary staff <sup>17</sup> (XX 01 01)	A*/AD	3*	3*	3*	3*	3*	3*
	B*, C*/AST	<i>Not applicable</i>					
	Staff financed <sup>18</sup> by Art. XX 01 02						
	Other staff <sup>19</sup> financed by Art. XX 01 04/05						
<b>TOTAL</b>		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)

<sup>17</sup> Cost of which is NOT covered by the reference amount

<sup>18</sup> Cost of which is NOT covered by the reference amount

<sup>19</sup> 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
<b>1. Technical and administrative assistance (including related staff costs)</b>	<b><i>Not applicable</i></b>						
Executive agencies <sup>20</sup>							
Other technical and administrative assistance							
- <i>Intra muros</i>							
- <i>Extra muros</i>							
<b>Total Technical and administrative assistance</b>							

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)	--	--	--	--	--	--
<b>Total cost of Human Resources and associated costs (NOT in reference amount)</b>	0.351	0.351	0.351	0.351	0.351	0.351

<sup>20</sup> 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							
<b>2. Total Other Management Expenditure (XX 01 02 11)</b>							
<b>3. Other expenditure of an administrative nature</b> (specify including reference to budget line)							
<b>Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)</b>							

- \* 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 - <i><b>Other administrative expenditure <u>not</u> included in reference amount</b></i>
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