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Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council , in order to align them to Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures**

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### Grounds for and objectives of the proposal

Article 153(1)(a) of the Treaty on the Functioning of the European Union (hereinafter TFEU) stipulates that ‘the Union shall support and complement the activities of the Member States in improvement of the working environment to protect workers’ health and safety’. Under Article 153(2) of the TFEU, the Commission may propose directives which lay down minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States.

On the basis of these legal provisions, an appropriate occupational safety and health framework has been adopted with a view to protecting workers’ health and safety from risks due to exposure to chemicals at the workplace. Following the adoption of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging (CLP) of substances and mixtures<sup>1</sup>, in order to implement, within the European Union, the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter GHS)<sup>2</sup>, certain aspects of this legal framework need to be adapted.

Directives 92/58/EEC<sup>3</sup>, 92/85/EEC<sup>4</sup>, 94/33/EC<sup>5</sup>, 98/24/EC<sup>6</sup> and 2004/37/EC<sup>7</sup> contain references to EU chemical classification and labelling legislation. If these Directives are to remain effective, they need to be aligned to the new legislation in this area. Thus, the aim of the present Directive is to update references and terminology of the five aforesaid Directives to bring them into line with the applicable EU chemical classification and labelling legislation. In doing so, no changes to the scope or level of protection provided by these Directives are required.

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<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 216, 20.8.1994, p. 12)(hereafter the CLP Regulation).

<sup>2</sup> The Globally Harmonised System of Classification and Labelling of Chemicals provides a harmonised basis for globally uniform physical, environmental and health and safety information on hazardous chemical substances and mixtures. With its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development encouraged countries to implement the harmonised system as soon as possible, with a view to making it fully operational by 2008.

<sup>3</sup> Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 245, 26.8.1992, p. 23).

<sup>4</sup> Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

<sup>5</sup> Council Directive 94/33/EC on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

<sup>6</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

<sup>7</sup> Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

## **General context**

The GHS is a United Nations system for identifying hazardous chemicals and informing users about the related hazards by means of standard symbols and phrases on packaging labels, and safety data sheets.

Following successful negotiations on the Commission's proposal, the European Parliament and the Council adopted the CLP Regulation on 16 December 2008. This Regulation aligns the existing EU legislation to the GHS and was published in the Official Journal on 31 December 2008.

The CLP Regulation entered into force on 20 January 2009. The deadlines for classification in accordance with the new rules are 1 December 2010 for substances and 1 June 2015 for mixtures. The CLP Regulation will ultimately replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC) after the transitional period provided for in its Article 61.

The CLP Regulation is expected to facilitate global trade and harmonised communication of information on hazards posed by chemicals and to promote regulatory efficiency. It will complement the 'REACH Regulation'<sup>8</sup>.

Implementation of the GHS in the European Union via the CLP Regulation will require companies to classify, label and package their substances and mixtures appropriately before placing them on the market after a transitional period during which the two systems, CLP Regulation and the combination of the substances and preparations directives, will apply side by side. The aim is to protect workers, consumers and the environment by means of labelling and indicating any potential hazardous effects of chemicals.

The safety data sheets provided by suppliers of chemicals are a major source of information for employers and workers. Transitional arrangements will also apply to the legislative requirements governing safety data sheets which are now regulated in Article 31 of the REACH Regulation.

The aforementioned five Directives need to be amended in order to update the references to the EU chemical classification and labelling legislation described above, without any changes to the scope or level of protection provided by these Directives.

## **Consistency with other European Union policies and objectives**

This proposal relates to the key action on quality of work and working conditions identified in the Flagship initiative 'An agenda for new skills and jobs'<sup>9</sup>

It is consistent with the objectives of other policies of the European Union, in particular those aiming at improvement of the regulatory framework in order to develop a clear,

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<sup>8</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

<sup>9</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – An Agenda for new skills and jobs: A European contribution towards full employment, COM(2010) 682.

understandable, up-to-date and user-friendly body of secondary EU legislation, in the interests of citizens and economic operators.

## **2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **Consultation of interested parties**

- Consultation of the Advisory Committee on Safety and Health at Work (ACSHW), in accordance with the Council Decision of 22 July 2003 setting up that Committee<sup>10</sup>. The Committee adopted its opinion on 1 December 2011.

- Consultation of the social partners in accordance with Article 154(2) and (3) of the TFEU. The first-stage consultation (Article 154(2) of the TFEU) took place between 9 December 2009 and 26 March 2010. The second-stage consultation (Article 154(3) of the TFEU) took place between 17 January and 17 March 2011.

The results can be summarised as follows:

- Five out of six social partners which responded agree with the content of the envisaged regulatory initiative.
- The majority of the respondents agree with the approach of a single amending Directive. One of the workers' representatives suggested that the required amendments should be done separately and not by means of a single amending Directive, as two of the five Directives in question are currently under review for other reasons.
- An approach that includes maintaining a formal link to the EU chemical classification system (the CLP Regulation) is commonly preferred.
- The social partners are in favour of additional non-binding measures that can help employers and workers to understand occupational safety and health issues arising from the new requirements for chemical classification, labelling and packaging. Explanatory guidance, in particular for SMEs, would be considered useful. The Commission, in cooperation with the ACSHW, has prepared guidance material which will be published in the near future.
- None of the social partners wished to initiate a dialogue on the matter.

### **Impact assessment**

The proposed amendments to the five aforesaid Directives maintain the current level of worker protection with no additional requirements being introduced. Thus, the proposed changes do not create any significant impact that would require a formal impact assessment to be carried out.

A full impact assessment for the primary piece of legislation, the European Parliament and Council Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, was presented during 2007<sup>11</sup>.

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<sup>10</sup> Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).

<sup>11</sup> Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006. Impact Assessment; COM(2007) 355 final.

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **Summary of the proposed measures**

The proposal amends the relevant articles and annexes of Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and 2004/37/EC, in order to achieve the objectives mentioned under point 1 above.

#### **Legal basis**

Article 153(2) of the TFEU.

#### **Subsidiarity principle**

The subsidiarity principle applies in so far as the proposal concerns a field – protection of the health and safety of workers at work – which does not fall under the exclusive competence of the European Union.

The objectives of the proposal cannot be achieved sufficiently by the Member States themselves, as the provisions of Directives cannot be amended or repealed at national level.

The objectives of the proposal can be achieved only by Union action, entailing amendment of an act of EU law that is currently in force, which cannot be done by the Member States themselves.

The principle of subsidiarity is respected in as much as the proposal amends existing Union legislation.

#### **Proportionality principle**

The proposal complies with the proportionality principle. The minimum EU action necessary to ensure the continued effectiveness of existing policy will be taken, without introducing any additional requirements.

#### **Choice of instrument**

Proposed instrument: Directive.

No other instrument would have been suitable. The aim is to amend five EU Directives and the only way to do this is to adopt another Directive.

### **4. BUDGETARY IMPLICATIONS**

The proposal has no implications for the Union budget.

### **5. ADDITIONAL INFORMATION**

#### **Simplification**

The proposal contributes to the simplification of the legislative framework by introducing appropriate proportionality and flexibility.

#### **Repeal of existing legislation**

Not applicable. This proposal contains only amendments to existing Directives.

#### **European Economic Area**

This draft instrument is concerned with a subject covered by the EEA Agreement and must therefore extend to the European Economic Area.

#### **Detailed explanation of the proposal by article**

Articles 1 to 5 introduce the required changes to the relevant provisions of Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and 2004/37/EC, in order to align them to the references to the European Parliament and Council Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Regarding the non-exhaustive list of agents mentioned in the Annex, Part I, Section 3 of Directive 94/33/EC, an exact correlation between the pre-existing and new chemical classification systems cannot be achieved. The proposal therefore presents an alignment that may result in a limited number of additional substances coming within the scope of the Annex. However, the proposed changes are designed to maintain the policy objective of Article 7 of this Directive, which remains unchanged.

Articles 6 and 7 concern the transposition, entry into force and application of the Directive.

Article 8 is a standard article reflecting the legal nature of a Directive.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>12</sup>,

Having regard to the opinion of the Committee of the Regions<sup>13</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) According to Article 153 of the Treaty, the European Parliament and the Council may adopt, by means of directives, minimum requirements for encouraging improvements, especially in the working environment, to ensure a better level of protection of the health and safety of workers. Such directives must avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.
- (2) Article 31(1) of the Charter of Fundamental Rights of the European Union provides that every worker has the right to working conditions which respect his or her health, safety and dignity.
- (3) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures<sup>14</sup> established a new system for the classification and labelling of substances and mixtures within the Union, based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) at international level, within the United Nations Economic Commission for Europe structure.
- (4) Council Directives 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work<sup>15</sup>, 92/85/EEC of 19 October 1992 on

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<sup>12</sup> OJ C , , p. .

<sup>13</sup> OJ C , , p. .

<sup>14</sup> OJ L 353, 31.12.2008, p. 1.

<sup>15</sup> OJ L 245, 26.8.1992, p. 23.

the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding<sup>16</sup>, 94/33/EC on the protection of young people at work<sup>17</sup>, and 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work<sup>18</sup>, and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work<sup>19</sup> contain references to the previous classification and labelling system. They should therefore be amended in order to align them to the new system laid down in Regulation (EC) No 1272/2008.

- (5) Those amendments are necessary to ensure the continued effectiveness of the above-mentioned Directives.
- (6) Section I point 2 and Section II point 1 of the Annex to Directive 94/33/EC contain references to repealed Directives 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work<sup>20</sup> and 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work<sup>21</sup>. Those references should therefore be replaced by references to the relevant provisions of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work<sup>22</sup> and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work<sup>23</sup>.
- (7) In accordance with Article 154 of the Treaty, the Commission consulted the social partners on the possible direction of Union action in this field.
- (8) Following this consultation, the Commission considered that Union action was desirable and consulted the social partners on the content of the envisaged proposal, in accordance with Article 154 of the Treaty.
- (9) Following this second phase of consultation, the social partners did not wish to initiate the process which could lead to the conclusion of an agreement, as set out in Article 154 of the Treaty,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*  
*Amendments to Directive 92/58/EEC*

Directive 92/58/EEC is amended as follows:

- (1) Article 1(2) is replaced by the following:

‘2. This Directive shall not apply to signs for the placing on the market of hazardous substances and mixtures, and dangerous products and/or equipment, unless other Union provisions make specific reference thereto.’

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<sup>16</sup> OJ L 348, 28.11.1992, p. 1.

<sup>17</sup> OJ L 216, 20.8.1994, p. 12.

<sup>18</sup> OJ L 131, 5.5.1998, p. 11.

<sup>19</sup> OJ L 158, 30.4.2004, p. 50.

<sup>20</sup> OJ L 374, 31.12.1990, p.1.

<sup>21</sup> OJ L 196, 23.7.1990, p.1.

<sup>22</sup> OJ L 262, 17.10.2000, p. 21.

<sup>23</sup> OJ L 158, 30.4.2004, p. 50.



(2) In Annex I, Section 12, the word ‘dangerous’ is replaced by ‘hazardous’ and the word ‘preparations’ by ‘mixtures’.

(3) Annex III is amended as follows:

(a) Section 1 is replaced by the following:

‘1. Containers used at work for chemical substances or mixtures classified as hazardous according to the criteria for any of the hazard classes or categories 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F, 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and containers used for the storage of such hazardous substances or mixtures, together with the visible pipes containing or transporting hazardous substances and mixtures, must be labelled with appropriate pictograms in accordance with that Regulation.’

(b) In Section 5 the word ‘dangerous’ is replaced by ‘hazardous’ and the word ‘preparations’ by ‘mixtures’.

#### *Article 2*

##### *Amendments to Directive 92/85/EEC*

Annex I to Directive 92/85/EEC is amended as follows:

(1) Section A, point 2, is replaced by the following:

#### *‘2. Biological agents*

Biological agents of risk groups 2, 3 and 4 within the meaning of Article 2 numbers 2, 3 and 4 of Directive 2000/54/EC<sup>24</sup>, in so far as it is known that such agents or the therapeutic measures necessitated by them endanger the health of pregnant women and the unborn child, and in so far as they do not yet appear in Annex II.’

(2) Section A, point 3(a), is replaced by the following:

‘(a) chemical agents labelled as carcinogen category 1A, 1B, germ cell mutagen category 1A or 1B, toxic to reproduction category 1A or 1B, or toxic to reproduction with effects on or via lactation in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in so far as they do not yet appear in Annex II;’

(3) Section A, point 3(b), is replaced by the following:

‘(b) chemical agents in Annex I to Directive 2004/37/EC’

(4) Section B is replaced by the following:

#### *‘B PROCESSES*

Industrial processes listed in Annex 1 to Directive 2004/37/EC.’

#### *Article 3*

##### *Amendments to Directive 94/33/EC*

Directive 94/33/EC is amended as follows:

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<sup>24</sup> OJ L 262, 17.10.2000, p. 21.

(1) Point (a) of Section I.2 of the Annex is replaced by the following:

‘Biological agents belonging to groups 3 and 4 within the meaning of Article 2, second paragraph of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>25</sup>,

(2) Section I.3 of the Annex is amended as follows:

(a) point (a) is replaced by the following:

‘(a) substances and mixtures classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures:

- acute toxicity, category 1, 2, 3
- skin corrosion, category 1A, 1B, 1C
- flammable gas, category 1, 2
- flammable liquid, category 1, 2
- explosive, category ‘unstable explosive’, or divisions 1.1, 1.2, 1.3, 1.5
- specific target organ toxicity (single exposure), category 1, 2
- specific target organ toxicity (repeat exposure), category 1
- respiratory sensitiser, category 1
- skin sensitiser, category 1
- carcinogen, category 1A, 1B
- germ cell mutagen, category 1A, 1B
- toxic to reproduction, category 1A, 1B
- eye damage, category 1’

(b) point (b) is deleted.

(c) point (c) is deleted.

(d) point (d) is replaced by the following:

‘(d) Substances and mixtures referred to in Article 2(a)(ii) of Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC);’

(3) Section II.1 of the Annex is replaced by the following:

‘1. Processes at work referred to in Annex I to Directive 2004/37/EC.’

#### *Article 4* *Amendments to Directive 98/24/EC*

Directive 98/24/EC is amended as follows:

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<sup>25</sup> OJ, L 262, 17.10.2000, p.21.

(1) Article 2b is amended as follows:

(a) Point (i) is replaced by the following:

‘(i) any chemical agent which meets the criteria laid down in Regulation 1272/2008 for classification within any of the hazard classes or categories 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F, 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10, whether or not that chemical agent is classified under that Regulation;’

(b) Point (ii) is deleted.

(c) Point (iii) is replaced by the following:

‘(iii) any chemical agent which, whilst not meeting the criteria for classification as hazardous in accordance with (i) may, because of its physical, chemical or toxicological properties and the way it is used or is present in the workplace, present a risk to the safety and health of workers, including any chemical agent assigned an occupational exposure limit value under Article 3.’

(2) Article 4(1), second indent is replaced by the following:

‘— information on safety and health that shall be provided by the supplier (e.g. the relevant safety data sheet in accordance with the provisions of Regulation (EC) No 1907/2006<sup>26</sup>),’

(3) Article 8 (1), fourth indent is replaced by the following:

‘— access to any safety data sheet provided by the supplier in accordance with Article 31 of Regulation (EC) No 1907/2006;’

(4) Article 8(3) is replaced by the following:

‘3. Member States may take measures necessary to ensure that employers are able to obtain on request, preferably from the producer or supplier, all information on hazardous chemical agents needed to apply Article 4(1) of this Directive, insofar as Regulation (EC) No 1272/2008 does not include any obligation to provide information.’

#### *Article 5*

#### *Amendments to Directive 2004/37/EC*

Directive 2004/37/EC is amended as follows:

(1) Article 1(4) is replaced by the following:

‘4. As regards asbestos, which is dealt with by Directive 2009/148/EC, the provisions of this Directive shall apply whenever they are more favourable to health and safety at work.’

(2) Article 2 is amended as follows:

a) point (a) is replaced by the following:

‘(a) carcinogen means:

(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008;

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<sup>26</sup> OJ L 396, 30.12.2006, p. 1

(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;'

b) point (b) (i) is replaced by the following:

'(b) mutagen means:

(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008;'

*Article 6*  
*Transposition*

(1) Member States shall bring into force, by [...] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

(2) Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 7*  
*Entry into force and application*

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

*Article 8*

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*