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from: General Secretariat
to: Permanent Representatives Committee/Council

Subject: Proposal for a Directive of the European Parliament and of the Council amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/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
– Outcome of the European Parliament's first reading
(Strasbourg, 3 to 6 February 2014)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure ¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

¹ OJ C 145, 30.6.2007, p.5

In this context, the rapporteur, Sari ESSAYAH (EPP, FI), presented one compromise amendment (amendment 20) to the proposal for Directive, on behalf of the Committee on Employment and Social Affairs. This amendment had been agreed during the informal contacts referred to above.

II. VOTE

When it voted on 4 February 2013, the plenary adopted amendment 20 to the proposal for a Directive. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto¹.

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

¹ The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol "■" indicates deleted text.

Classification, labelling and packaging of substances and mixtures *I**

European Parliament legislative resolution of 4 February 2014 on the 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 (COM(2013)0102 – C7-0047/2013 – 2013/0062(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0102),
 - having regard to Article 294(2) and Article 153(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0047/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 12 March 2008¹,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 4 December 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs (A7-0319/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 204, 9.8.2008, p. 47.

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Position of the European Parliament adopted at first reading on 4 February 2014 with a view to the adoption of Directive 2014/.../EU 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

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 Committee¹,

Having consulted the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure²,

Whereas:

- (1) Pursuant to Article 153 of the Treaty, the European Parliament and the Council may adopt, by means of directives, minimum requirements for encouraging improvements, in particular in the working environment, to ensure a better level of protection of the health and safety of workers. Such directives *should* avoid *holding* back the creation and development of small and medium-sized undertakings *and their potential to create jobs*. *Good health and safety standards should not be considered as constraints, since they are fundamental rights and are to be applied without exception to all sectors of the labour market and all types of undertakings regardless of their size.*
- (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.

¹ OJ C 204, 9.8.2008, p. 47.

² Position of the European Parliament of 4 February 2014.

- (3) Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹ 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 framework of the United Nations Economic Commission for Europe.
- (4) Council Directives 92/58/EEC², 92/85/EEC³, 94/33/EC⁴ and 98/24/EC⁵, and Directive 2004/37/EC of the European Parliament and of the Council⁶ contain references to the previous classification and labelling system. Those Directives should therefore be amended in order to align them to the new system laid down in Regulation (EC) No 1272/2008.

¹ 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 353, 31.12.2008, p. 1).

² 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).

³ 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).

⁴ Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

⁵ 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).

⁶ 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).

- (5) The amendments are necessary to ensure the continued effectiveness of those *Directives*. *The aim of this Directive is not to change the scope of those Directives. This Directive intends to maintain and not reduce the level of protection of workers that is provided by those Directives. However, in view of on-going technological progress, those Directives should be subject to periodic review in accordance with Article 17a of Council Directive 89/391/EEC¹ in order to ensure the coherency of legislation and an appropriate level of health and safety protection when hazardous chemical substances and mixtures are present in the working environment. Particular attention should be paid to employees within professions where there is frequent contact with hazardous substances and mixtures.*

¹ *Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).*

- (6) *The amendments to Directive 92/85/EEC do not address the issue of hazardous substances and mixtures which can adversely affect fertility of pregnant workers or workers who have recently given birth or who are breastfeeding, since the aim of this Directive is only to update references and terminology set out in that Directive. However, taking account of the evolving scientific evidence regarding this issue together with the increased sophistication of classification of these effects, the Commission should consider the most appropriate means for addressing such effects.*
- (7) *The amendments to Directives 92/85/EEC and 94/33/EC should align the approach taken in those Directives to the wording adopted under Directive 98/24/EC in so far as the words "substances labelled", in Section A point 3(a) of Annex I to Directive 92/85/EEC and "substances and preparations classified" in Section I point 3(a) of the Annex to Directive 94/33/EC are replaced by the wording "substances and mixtures which meet the criteria for classification". This Directive does not impose obligations on employers as regards classification, labelling and packaging of substances and mixtures covered by Regulation (EC) No 1272/2008. Regardless of whether or not the substances or mixtures are placed on the market, the employer needs to carry out an assessment of risk of all hazardous chemical agents in accordance with Directive 98/24/EC.*

- (8) Section I point 2 and Section II point 1 of the Annex to Directive 94/33/EC contain references to repealed Council Directives 90/679/EEC¹ and 90/394/EEC². Those references should therefore be replaced by references to the relevant provisions of Directive 2000/54/EC of the European Parliament and of the Council³ and Directive 2004/37/EC.
- (9) In accordance with Article 154 of the Treaty, the Commission consulted the social partners on the possible direction of Union action in this field ***and the social partners indicated that explanatory guidance in particular for small and medium-sized enterprises is useful.***
- (10) 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.
- (11) 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 155 of the Treaty,

HAVE ADOPTED THIS DIRECTIVE:

¹ Council Directive 90/679/EEC of 26 November 1990 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) (OJ L 374, 31.12.1990, p. 1).

² Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 196, 26.7.1990, p. 1).

³ 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) (OJ L 262, 17.10.2000, p. 21).

Article 1
Amendments to Directive 92/58/EEC

Directive 92/58/EEC is amended as follows:

(1) In Article 1, paragraph 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, ■ products and/or equipment, unless other Union provisions make specific reference thereto."

(2) In Annex I, Section 12 ■ is replaced by *the following*:

"12. Areas, rooms or enclosures used for the storage of significant quantities of hazardous substances or mixtures must be indicated by a suitable warning sign taken from Section 3.2 of Annex II, or marked as provided in Section 1 of Annex III, unless the labelling of the individual packages or containers is adequate for this purpose.

If there is no equivalent warning sign in Section 3.2 of Annex II to warn about hazardous chemical substances or mixtures, the relevant hazard pictogram, as laid down in Annex V to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, must be used.*

* *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 353, 31.12.2008, p. 1)."*

(3) *In Annex II, Section 3.2 is amended as follows:*

(a) *warning sign "Harmful or irritant material" is deleted:*



~~*Harmful or irritant material*~~

(b) *the following footnote linked to warning sign “General danger” is added:*

*“*** This warning sign shall not be used to warn about hazardous chemical substances or mixtures, except for cases when the warning sign is used in accordance with the second paragraph of Section 5 of Annex III to indicate the stores of hazardous substances or mixtures.”*

(4) 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 *physical or health* hazard *class* in accordance with Regulation (EC) No 1272/2008, and containers used for the storage of such hazardous substances or mixtures, together with the visible pipes containing or transporting such hazardous substances and mixtures, must be labelled with the relevant hazard pictograms in accordance with that Regulation.

The first paragraph does not apply to containers used at work for brief periods nor to containers whose contents change frequently, provided that alternative adequate measures are taken, in particular for information and/or training, which guarantee the same level of protection.

The labels referred to in the first paragraph may be:

- replaced by warning signs set out in Annex II, using the same pictograms or symbols. If there is no equivalent warning sign in Section 3.2 of Annex II, the relevant hazard pictogram set out in Annex V of Regulation (EC) No 1272/2008 must be used,*
- supplemented by additional information, such as the name and/or formula of the hazardous substance or mixture and the details of the hazard,*
- for the transporting of containers at the place of work, supplemented or replaced by signs that are applicable throughout the Union for the transport of hazardous substances or mixtures."*

- (b) in first and second paragraph of 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 is amended as follows:

- (a) point 2 is replaced by the following:

"2. Biological agents

Biological agents of risk groups 2, 3 and 4 within the meaning of points 2, 3 and 4 of second paragraph of Article 2 of Directive 2000/54/EC of the European Parliament and of the Council*, 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.

* 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) (OJ L 262, 17.10.2000, p. 21).";

(b) point 3 is amended as follows:

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

"(a) *substances and mixtures which meet the criteria for classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council* in one or more of the following hazard classes and hazard categories with one or more of the following hazard statements, in so far as they do not yet appear in Annex II;*

- *germ cell mutagenicity, category 1A, 1B or 2 (H340, H341);*
- *carcinogenicity, category 1A, 1B or 2 (H350, H350i, H351);*

- *reproductive toxicity, category 1A, 1B or 2 or the additional category for effects on or via lactation (H360, H360D, H360FD, H360Fd, H360Df, H361, H361d, H361fd, H362);*
- *specific target organ toxicity after single exposure, category 1 or 2 (H370, H371).*

* *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 353, 31.12.2008, p. 1).";*

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

"(b) chemical agents in Annex I to Directive 2004/37/EC of the European Parliament and of the Council*;

* 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)."

(2) Section B is replaced by the following:

"B. Processes

Industrial processes listed in Annex I to Directive 2004/37/EC."

Article 3
Amendments to Directive 94/33/EC

The annex to Directive 94/33/EC is amended as follows:

(1) **Section I is amended as follows:**

(a) **in point 2 point (a)** is replaced by the following:

"(a) Biological agents **of risk** groups 3 and 4 within the meaning of points 3 and 4 of second paragraph of Article 2 of Directive 2000/54/EC of the European Parliament and of the Council*.

* 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) (OJ L 262, 17.10.2000, p. 21)."

(b) *point 3* is amended as follows:

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

"(a) Substances and mixtures *which meet the criteria for classification under* Regulation (EC) No 1272/2008 of the European Parliament and of the Council * *in one or more of the following hazard classes and hazard categories with one or more of the following hazard statements:*

- acute toxicity, *category 1, 2 or 3 (H300, H310, H330, H301, H311, H331);*
- skin corrosion, *category 1A, 1B or 1C (H314);*
- flammable gas, *category 1 or 2 (H220, H221);*
- *flammable aerosols, category 1 (H222);*

- flammable liquid, *category 1 or 2 (H224, H225)*;
- *explosives, categories ‘Unstable explosive’, or explosives of Divisions 1.1, 1.2, 1.3, 1.4, 1.5 (H200, H201, H202, H203, H204, H205)*;
- *self-reactive substances and mixtures, type A, B, C or D (H240, H241, H242)*;
- *organic peroxides, type A or B (H240, H241)*;
- specific target organ toxicity *after* single exposure, *category 1 or 2 (H370, H371)*;
- specific target organ toxicity *after repeated* exposure, *category 1 or 2 (H372, H373)*;
- respiratory *sensitisation*, category 1, *subcategory 1A or 1B (H334)*;
- skin *sensitisation*, category 1, *subcategory 1A or 1B (H317)*;

- *carcinogenicity, category 1A, 1B or 2 (H350, H350i, H351);*
- *germ cell mutagenicity, category 1A, 1B or 2 (H340, H341);*
- *reproductive toxicity, category 1A or 1B (H360, H360F, H360FD, H360Fd, H360D, H360Df).*

* 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 353, 31.12.2008, p. 1).";

■
(ii) point (b) is deleted;

(iii) point (c) is deleted;

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

"(d) Substances and mixtures referred to in point (ii) of point (a) of Article 2 of Directive 2004/37/EC of the European Parliament and of the Council*;

* 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)."

(2) In Section II, point 1 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:

(1) In Article 2, point (b) is amended as follows:

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

"(i) any chemical agent which meets the criteria ■ for classification *as hazardous* within any *physical and/or health* hazard classes *laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council**, whether or not that chemical agent is classified under that Regulation;

* **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 353, 31.12.2008, p. 1).";**

(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 *point* (i) of point (b) of this Article may, because of its *physico-chemical*, 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 that is assigned an occupational exposure limit value under Article 3."

(2) In Article 4(1), the 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 Regulation (EC) No 1907/2006 of the European Parliament and of the Council*),

* 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 (OJ L 396, 30.12.2006, p. 1)."

(3) Article 8 is amended as follows:

(a) in paragraph 1, the 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;"

(b) paragraph 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 that is necessary to apply Article 4(1) of this Directive, insofar as *neither Regulation (EC) No 1907/2006, nor* Regulation (EC) No 1272/2008 **■** include any obligation to provide information."

Article 5

Amendments to Directive 2004/37/EC

Directive 2004/37/EC is amended as follows:

(1) In Article 1, paragraph 4 is replaced by the following:

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

* Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)."

(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 of the European Parliament and of the Council*;

- (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;

* 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 353, 31.12.2008, p. 1)."

- (b) point (b) ■ is replaced by the following:

‘(b) "mutagen" means:

■ 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;’

- (3) *In Article 4(1) the word "preparation" is replaced by the word "mixture".*
- (4) *In Article 5(2) the word "preparation" is replaced by the word "mixture".*
- (5) *In point (b) of Article 6, the word "preparations" is replaced by the word "mixtures".*
- (6) *In Annex I, in the heading, the word "preparations" is replaced by the word "mixtures".*

Article 6

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by **1 June 2015**. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures 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

Addressees

This Directive is addressed to the Member States.

Done at

For the European Parliament

The President

For the Council

The President