



EUROPEAN PARLIAMENT

2009 - 2014

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*Plenary sitting*

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**A7-0391/2012**

3.12.2012

**\*\*\*I**  
**REPORT**

on the proposal for a directive of the European Parliament and of the Council  
on the classification, packaging and labelling of dangerous preparations  
(recast)  
(COM(2012)0008 – C7-0021/2012 – 2012/0007(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Eija-Riitta Korhola

(Recast – Rule 87 of the Rules of Procedure)

### *Symbols for procedures*

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### *Amendments to a draft act*

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a directive of the European Parliament and of the Council on the classification, packaging and labelling of dangerous preparations (recast)  
(COM(2012)0008 – C7-0021/2012 – 2012/0007(COD))**

**(Ordinary legislative procedure – recast)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0008),
  - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0021/2012),
  - 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 28 March 2012<sup>1</sup>,
  - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>2</sup>,
  - having regard to the letter of 9 November 2012 from the Committee on Legal Affairs to the Committee on the Environment, Public Health and Food Safety in accordance with Rule 87(3) of its Rules of Procedure,
  - having regard to Rules 87 and 55 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0391/2012),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
1. Adopts its position at first reading hereinafter set out, taking account of the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
  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;

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<sup>1</sup> OJ C 181, 21.6.2012, p. 203.

<sup>2</sup> OJ C 77, 28.3.2002, p. 1.

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

## **Amendment 1**

### **Proposal for a directive Article 20 – paragraph 5**

#### *Text proposed by the Commission*

5. A delegated act adopted pursuant to Article 10(4), Article 12(4) and Article 19 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by **one month** at the initiative of the European Parliament or of the Council.

#### *Amendment*

5. A delegated act adopted pursuant to Article 10(4), Article 12(4) and Article 19 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by **two months** at the initiative of the European Parliament or of the Council.

#### *Justification*

*According to the common understanding on delegated acts between the Commission, the European Parliament and the Council, the institutions "undertake to refer as far as possible to the standard clauses annexed". The standard clauses foresee an extension of two months, not only one month. The 2+2 formula has been an important victory of Parliament to ensure that there is enough time in case it wants to object. The two other COM proposals in this "package" also have an extension of two months.*

## EXPLANATORY STATEMENT

The recast of the Dangerous Preparations Directive (1999/45/EC) is proposed in order to codify amending acts and to align provisions regarding the Commission's power to adopt delegated and implementing acts to the Lisbon Treaty. The directive represents a bridging piece of legislation ensuring the legal continuity within the legal sectoral framework, currently under fundamental reform due to the adoption of REACH (Regulation (EC) No 1907/2006).

The Dangerous Preparations Directive (DPD) regulates the classification, packaging and labelling of preparations, i.e. mixtures or solutions of two or more substances (chemical elements and their compounds). It remains applicable until 1 June 2015 within the transitional provisions of the CLP-Regulation (EC) No 1272/2008 as the EU's new system on the classification and labelling of hazardous substances and mixtures, including the UN's Globally Harmonised System, since 20 January 2009. Further on, mixtures already placed on the market may be continued to be supplied under the DPD rules until 1 June 2017. For substances the CLP rules apply already since 1 December 2010. The recast thus refers to an act that is about to be phased out.

The changes made by the recast to the Directive 1999/45/EC are all motivated either by the need to update the proposal under the Lisbon Treaty to replace the old obsolete provisions with new ones, (including the update of the legal basis, i.e. Article 114 TFEU which corresponds to the old Article 95 of the TEC) or the adoption of REACH and some further amendments (introduced by the latter directly or through its implementing acts) that necessitate a codification of Directive 1999/45/EC to ensure the clarity and precision of applicable rules. While no political choices have been exercised within the recast proposal, the substantive changes resulted from the treaty law or new EU legislation concerning the same topic matter.

The most notable adaptations and modifications which have resulted in this recast proposal are:

- Articles 10(4) and 12(4) replace the previous provisions for regulatory procedure with parliamentary scrutiny with provisions for the adoption of delegated acts. This necessitated modifications in Art. 19 and new provisions of Art. 21-23, making possible the exercise of those delegated powers.
- The last paragraph of Article 14 of the original Directive (on dealing with confidential information) contained a reference to Art. 19(4) of Directive 67/548/EC (Dangerous Substances Directive) which was deleted by Art. 1(7) of Directive 2006/121/EC, adapting the sectoral legislation to Regulation (EC) No 1907/2006 (REACH). This resulted in a specific gap concerning the conditions for safeguarding the confidentiality of critical technical information enjoying intellectual property rights protection. The recast closes this gap.
- In Article 1 of the consolidated version there was a reference to Article 14 of the

Directive 1999/45/EC (Safety Data Sheets), which had been deleted by Article 140 of REACH as the regulation of that subject matter was taken on board by the latter act in its capacity as the foundational act for the whole sector of chemical legislation.

- In Article 3(2) of the consolidated version there are references to Articles 7, 8 and 13 of Directive 67/548/EC, all of them had been deleted by Article 1(5) of Directive 2006/121/EC.
- In the consolidated version there are also numerous references to Part A of Annex V to Directive 67/548/EEC (Test Methods); these references have been replaced by Regulation (EC) 440/2008 (laying down test methods pursuant to Regulation (EC) No 1907/2006 (REACH)) that took the subject matter on board after the repeal of the respective Annex in Directive 67/548/EEC.

It is due to the nature of these adaptations and modifications that the rapporteur proposes no further amendments to the recast proposal on Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations.



## ANNEX: LETTER FROM THE COMMITTEE ON LEGAL AFFAIRS

Ms Matthias GROOTE  
Chair of the Environment, Public Health  
and Food Safety Committee  
ASP 12G201  
Brussels

*Subject: Proposal for a directive of the European Parliament and of the Council on the classification, packaging and labelling of dangerous preparations (recast) (COM(2012)0008 – C7-0021/2012 – 2012/0007(COD))*

Dear Chairman,

The Committee on Legal Affairs, which I am honoured to chair, has examined the proposal referred to above, pursuant to Rule 87 on Recasting, as introduced into the Parliament's Rules of Procedure.

Paragraph 3 of that Rule reads as follows:

*"If the committee responsible for legal affairs considers that the proposal does not entail any substantive changes other than those identified as such in the proposal, it shall inform the committee responsible.*

*In such a case, over and above the conditions laid down in Rules 156 and 157, amendments shall be admissible within the committee responsible only if they concern those parts of the proposal which contain changes.*

However, if in accordance with point 8 of the Interinstitutional Agreement, the committee responsible intends also to submit amendments to the codified parts of the proposal, it shall immediately notify its intention to the Council and to the Commission, and the latter should inform the committee, prior to the vote pursuant to Rule 54, of its position on the amendments and whether or not it intends to withdraw the recast proposal."

Following the opinion of the Legal Service, whose representatives participated in the meetings of the Consultative Working Party examining the recast proposal, and in keeping with the recommendations of the draftsperson, the Committee on Legal Affairs considers that the proposal in question does not include any substantive changes other than those identified as such in the proposal and that, as regards the codification of the unchanged provisions of the earlier acts with those changes, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

Concerning the alignment of comitology provisions to Articles 290-291 TFEU within the context of a recast procedure, the Committee on Legal Affairs nevertheless stresses that the legislator must always remain free to make the final determinations concerning the delegation of legislative powers and implementing powers and must never be limited by how the codification of existing texts on these issues is presented in the proposal.

In conclusion, after discussing it at its meeting of 6 November 2012, the Committee on Legal Affairs, by 23 votes in favour and no abstentions<sup>1</sup>, recommends that your Committee, as the committee responsible, proceed to examine the above proposal in accordance with Rule 87.

Yours faithfully,

Klaus-Heiner LEHNE

*Encl.: Opinion of the Consultative Working Party*

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<sup>1</sup> Members present: Luigi Berlinguer, Françoise Castex, Christian Engström, Marielle Gallo, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sylvie Guillaume, Sajjad Karim, Eva Lichtenberger, Antonio López-Istúriz White, Antonio Masip Hidalgo, Jiří Maštálka, Alajos Mészáros, Evelyn Regner, Francesco Enrico Speroni, József Szájer, Rebecca Taylor, Alexandra Thein, Axel Voss, Rainer Wieland, Cecilia Wikström, Zbigniew Ziobro, Tadeusz Zwiefka.

**ANNEX: OPINION OF THE CONSULTATIVE WORKING PARTY OF THE LEGAL SERVICES OF THE EUROPEAN PARLIAMENT, THE COUNCIL, AND THE COMMISSION**



CONSULTATIVE WORKING PARTY  
OF THE LEGAL SERVICES

Brussels, 8 October 2012

**OPINION**

**FOR THE ATTENTION OF THE EUROPEAN PARLIAMENT  
THE COUNCIL  
THE COMMISSION**

**Proposal for a directive of the European Parliament and of the Council on the classification, packaging and labelling of dangerous preparations  
COM(2012) 8 of 26.1.2012 – 2012/0007(COD)**

Having regard to the Inter-institutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts, and in particular to point 9 thereof, the Consultative Working Party consisting of the respective legal services of the European Parliament, the Council and the Commission met on 15 March, 24 May and 5 July 2012 for the purpose of examining, among others, the aforementioned proposal submitted by the Commission.

At those meetings<sup>1</sup>, an examination of the proposal for a directive of the European Parliament and of the Council recasting Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations resulted in the Consultative Working Party's establishing by common accord that, as regards the explanatory memorandum accompanying the proposal, in order to be drafted in full compliance with the relevant requirements laid down by the Inter-institutional Agreement such a document should have stated the reasons for each proposed substantive amendment, as is provided for under point 6(a)(ii) of that agreement, and should have specified which provisions of the earlier act remain unchanged in the proposal, as is provided for under point 6(a)(iii).

As far as Articles 10(4), 12(4) and 19 of the draft recast act are concerned, it was discussed on

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<sup>1</sup> The Consultative Working Party had at its disposal the English, French and German language versions of the proposal and worked on the basis of the English version, being the master-copy language version of the text under discussion.

whether or not those texts should have been entirely identified with the grey-shaded type generally used for marking substantive changes. On the one hand, the Legal Services of the European Parliament and of the Commission considered that the presentation used for identifying the replacements of certain wordings currently contained in Articles 10, point 3, 12(4) and 20 of Directive 1999/45/EC with new wordings, taken from standard texts agreed between the three institutions, sufficiently describes the substantive amendments proposed for those existing provisions. On the other hand, the Legal Service of the Council considered that the change in procedure cannot be separated from the substantive issues to which that procedure relates and that the entire texts of Articles 10(4), 12(4) and 19 should therefore have been identified by using that grey-shaded type. Nevertheless, the three legal services shared the view that the draft texts submitted by the Commission for Articles 10(4), 12(4) and 19 should be understood as meaning that the Commission had intended to propose only that the references to the regulatory procedure with scrutiny currently contained in Articles 10, point 3, 12(4) and 20 of Directive 1999/45/EC be replaced with delegations to the Commission of the power to adopt acts in accordance with Article 290 TFEU. In that respect, it was also the common understanding of the three legal services that, as part of the recast exercise, the legislator could lay down a delegation of powers in relation to the said provisions, or alternatively opt, with regard to one or more of those provisions, for not delegating its powers to the Commission (therefore rendering the ordinary legislative procedure applicable to the said amendments) or for conferring implementing powers on that institution or on the Council in accordance with Article 291 TFEU and Regulation (EU) No 182/2011.

In consequence, examination of the proposal has enabled the Consultative Working Party to conclude, without dissent, that the proposal does not comprise any substantive amendments other than those identified as such therein or in the present opinion. The Working Party also concluded, as regards the codification of the unchanged provisions of the earlier act with those substantive amendments, that the proposal contains a straightforward codification of the existing text, without any change in its substance.

C. PENNERA  
Jurisconsult

H. LEGAL  
Jurisconsult

L. ROMERO REQUENA  
Director General

## PROCEDURE

<b>Title</b>	Classification, packaging and labelling of dangerous preparations
<b>References</b>	COM(2012)0008 – C7-0021/2012 – 2012/0007(COD)
<b>Date submitted to Parliament</b>	26.1.2012
<b>Committee responsible</b> Date announced in plenary	ENVI 2.2.2012
<b>Committee(s) asked for opinion(s)</b> Date announced in plenary	JURI 2.2.2012
<b>Rapporteur(s)</b> Date appointed	Eija-Riitta Korhola 13.3.2012
<b>Discussed in committee</b>	10.7.2012
<b>Date adopted</b>	28.11.2012
<b>Result of final vote</b>	+: 53 -: 0 0: 0
<b>Members present for the final vote</b>	Kriton Arsenis, Sophie Auconie, Lajos Bokros, Nessa Childers, Chris Davies, Anne Delvaux, Bas Eickhout, Edite Estrela, Elisabetta Gardini, Matthias Groote, Françoise Grossetête, Satu Hassi, Jolanta Emilia Hibner, Dan Jørgensen, Karin Kadenbach, Christa Kläß, Eija-Riitta Korhola, Jo Leinen, Corinne Lepage, Peter Liese, Zofija Mazej Kukovič, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Vladko Todorov Panayotov, Antonyia Parvanova, Andres Perello Rodriguez, Mario Pirillo, Pavel Poc, Oreste Rossi, Dagmar Roth-Behrendt, Richard Seeber, Salvatore Tatarella, Thomas Ulmer, Åsa Westlund, Glenis Willmott, Sabine Wils
<b>Substitute(s) present for the final vote</b>	Cristian Silviu Buşoi, Nikos Chrysogelos, Christofer Fjellner, Vicky Ford, Julie Girling, Mairead McGuinness, James Nicholson, Alojz Peterle, Britta Reimers, Birgit Schnieber-Jastram, Bart Staes, Rebecca Taylor, Marita Ulvskog, Vladimir Urutchev, Andrea Zannoni
<b>Substitute(s) under Rule 187(2) present for the final vote</b>	Ashley Fox, Emma McClarkin
<b>Date tabled</b>	3.12.2012