



**COUNCIL OF
THE EUROPEAN UNION**

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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Common Position adopted by the Council with a view to the adoption of a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No .../2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

COMMON GUIDELINES

Consultation deadline for Bulgaria and Romania: 20.6.2006

DIRECTIVE 2006/.../EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

**amending Council Directive 67/548/EEC
on the approximation of laws, regulations and administrative
provisions relating to the classification, packaging and labelling of
dangerous substances in order to adapt it to Regulation (EC) No .../2006*
concerning the Registration, Evaluation, Authorisation and Restriction
of Chemicals (REACH) and establishing a European Chemicals Agency**

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,

Having regard to the Opinion of the European Economic and Social Committee¹,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty²,

* OJ: Please insert the number of the REACH Regulation.

¹ OJ C 294, 25.11.2005, p. 38.

² Opinion of the European Parliament of 17 November 2005 (not yet published in the Official Journal), Council Common Position of ... (not yet published in the Official Journal) and Position of the European Parliament of ... (not yet published in the Official Journal).

Whereas:

In view of the adoption of Regulation (EC) No .../2006^{†1}, Directive 67/548/EEC² should be adapted and its rules on the notification and risk assessment of chemicals deleted,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 67/548/EEC is hereby amended as follows:

- 1) in Article 1, paragraph 1, points (a), (b) and (c) shall be deleted;
- 2) in Article 2, paragraph 1, points (c), (d), (f) and (g) shall be deleted;
- 3) Article 3 shall be replaced by the following:

"Article 3

Testing and assessment of the properties of substances

Tests on substances carried out within the framework of this Directive shall be conducted according to the requirements of Article 13 of Regulation (EC) No .../2006 of the European Parliament and of the Council of ... concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency^{*††}.

* OJ L";

† OJ: Please insert the number of the REACH Regulation.

1 OJ L

2 OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1). Corrected in OJ L 216, 16.6.2004, p. 3.

†† OJ: Please insert the number and date of the REACH Regulation.

4) Article 5 shall be amended as follows:

(a) in paragraph 1, the first subparagraph shall be replaced by the following:

"Member States shall take all the necessary measures to ensure that substances cannot be placed on the market on their own or in preparations unless they have been packaged and labelled in accordance with Articles 22 to 25 of this Directive and with the criteria in Annex VI of this Directive, and, for registered substances, in accordance with the information obtained through the application of Articles 12 and 13 of Regulation (EC) No .../2006*, save in the case of preparations where provisions exist in other Directives.";

(b) paragraph 2 shall be replaced by the following:

"2. The measures referred to in the first subparagraph of paragraph 1 shall apply until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 29.";

5) Articles 7 to 15 shall be deleted;

6) Article 16 shall be deleted;

7) Articles 17 to 20 shall be deleted;

8) Article 27 shall be deleted;

* OJ: Please insert the number of the REACH Regulation.

9) Article 32 shall be replaced by the following:

"Article 32

References

References to Annexes VIIA, VIIB, VIIC, VIID and VIII of this Directive shall be construed as references to the corresponding Annexes VI, VII, VIII, IX, X and XI of Regulation (EC) No .../2006*.";

10) Annex V shall be deleted;

11) Annex VI shall be amended as follows:

(a) in sections 1.6.2, 1.7.2, 1.7.3, 2.1, 2.2.1, 2.2.2, 2.2.2.1, 2.2.3, 2.2.4, 2.2.5, 3.1.1, 3.1.5.1, 3.1.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.5, 3.2.6.1, 3.2.6.2, 3.2.7.2, 4.2.3.3, 5.1.3, 9.1.1.1, 9.1.1.2, 9.3 and 9.5 of this Annex, the words "Annex V" and "Annex V to this Directive", shall be replaced by the words "the Commission Regulation on test methods as specified in Article 13(2) of Regulation (EC) No .../2006*";

* OJ: Please insert the number of the REACH Regulation.

(b) section 1.6.1, point (a) shall be replaced by the following:

"(a) as regards substances for which the information specified in Annexes VI, VII and VIII of Regulation (EC) No .../2006* is required, most of the necessary data for classification and labelling appear in the base set. This classification and labelling must be reviewed, if necessary, when further information is available (Annexes IX and X of Regulation (EC) No .../2006*);";

(c) in section 5.1, the second paragraph shall be replaced by the following:

"The criteria set out below follow directly from the test methods set out in the Commission Regulation on test methods as specified in Article 13(2) of Regulation (EC) No .../2006* in so far as they are mentioned. The test methods required for the base set referred to in Annexes VII and VIII of Regulation (EC) No .../2006* are limited and the information derived from them may be insufficient for an appropriate classification. Classification may require additional data derived from Annexes IX or X of Regulation (EC) No .../2006* or other equivalent studies. Furthermore, classified substances may be subject to review in the light of other new data.";

* OJ: Please insert the number of the REACH Regulation.

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- (d) in section 5.2.1.2, second paragraph, the second sentence shall be replaced by the following:

"Such additional scientific evidence should normally be based on the studies required by Annex IX of Regulation (EC) No .../2006^{*}, or studies of equivalent value, and could include:";

- 12) Annexes VIIA, VIIB, VIIC, VIID and VIII shall be deleted.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive with effect from ...^{**}. They shall forthwith inform the Commission thereof.

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

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.

* OJ: Please insert the number of the REACH Regulation.

** 12 months after entry into force of the REACH Regulation.

Article 3

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

It shall apply from ...*.

Notwithstanding the second paragraph of this Article, Article 1 point 6 shall apply from ...**.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

* 12 months after entry into force of the REACH Regulation.

** 14 months after entry into force of the REACH Regulation.