

Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Text with EEA relevance)

DIRECTIVE 2008/112/EC OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

of 16 December 2008

amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

(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 and Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽²⁾,

Whereas:

- (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⁽³⁾ 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⁽⁴⁾ as well as 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⁽⁵⁾.
- (2) Regulation (EC) No 1272/2008 builds on the experience with Directives 67/548/EEC and 1999/45/EC and incorporates the criteria for classification and labelling of substances 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 structure of the United Nations.

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- (3) Certain provisions on classification and labelling laid down in Directives 67/548/EEC and 1999/45/EC also serve for the purpose of application of other Community legislation, such as Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products⁽⁶⁾, Council Directive 88/378/EEC of 3 May 1988 on the approximation of laws of the Member States concerning the safety of toys⁽⁷⁾, Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations⁽⁸⁾, Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles⁽⁹⁾, Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)⁽¹⁰⁾ and Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products⁽¹¹⁾.
- (4) The incorporation of the GHS criteria into Community legislation leads to the introduction of new hazard classes and categories only partially corresponding to the classification and labelling arrangements provided for by Directives 67/548/EEC and 1999/45/EC. An analysis of the potential effects of the transition from the old to the new system of classification and labelling has led to the conclusion that, by adapting the references to the classification criteria in Directives 76/768/EEC, 88/378/EEC, 2000/53/EC and 2002/96/EC to the new system introduced by Regulation (EC) No 1272/2008, the scope of the respective acts should be maintained.
- (5) It is also necessary to adapt Directive 76/768/EEC to take into account the adoption of 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⁽¹²⁾.
- (6) It is appropriate to bring Directive 1999/13/EC into line with the replacement of risk phrase R40 by two new risk phrases R40 and R68 under Directive 67/548/EEC, so as to ensure a correct transition to the hazard statements laid down in Regulation (EC) No 1272/2008.
- (7) The transition from the criteria for classification contained in Directives 67/548/EEC and 1999/45/EC should be fully completed on 1 June 2015. Manufacturers of cosmetics, toys, paints, varnishes, vehicle refinishing products, vehicles and electric and electronic equipment are manufacturers, importers or downstream users within the meaning of Regulation (EC) No 1272/2008, as are the operators whose activities are covered by Directive 1999/13/EC. All of them should be enabled to design their transition strategy under this Directive in a similar timeframe as under Regulation (EC) No 1272/2008.
- (8) In accordance with point 34 of the Interinstitutional Agreement on better law-making⁽¹³⁾, Member States are encouraged to draw up, for themselves and in the interests of the

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Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and make them public.

- (9) Directives 76/768/EEC, 88/378/EEC, 1999/13/EC, 2000/53/EC, 2002/96/EC and 2004/42/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 76/768/EEC

Directive 76/768/EEC is hereby amended as follows:

1. the word ‘preparation’ or ‘preparations’ within the meaning of Article 3(2) of Regulation (EC) No 1907/2006, in its version of 30 December 2006, shall be replaced by ‘mixture’ or ‘mixtures’ respectively throughout the text;
2. in Article 4a(1), point d shall be replaced by the following:
 - (d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated methods listed in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)⁽¹⁴⁾ or in Annex IX to this Directive.;

3. from 1 December 2010, Article 4b shall be replaced by the following:

Article 4b

The use in cosmetic products of substances classified as carcinogenic, germ cell mutagenic or toxic for reproduction, of category 1A, 1B and 2, under part 3 of Annex VI to 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⁽¹⁵⁾ shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the regulatory procedure referred to in Article 10(2). A substance classified in category 2 may be used in cosmetics if the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found acceptable for use in cosmetic products.;

4. from 1 December 2010, in Article 7a(1), the last sentence of the second subparagraph of point (h) shall be replaced by the following:

The quantitative information required under (a) to be made publicly accessible shall be limited to substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 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;
- (b) hazard classes 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;
- (c) hazard class 4.1;

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- (d) hazard class 5.1.;
5. in Annex IX, the first sentence shall be replaced by the following:
- ‘This Annex lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Directive and which are not listed in Regulation (EC) No 440/2008.’.

Article 2

Amendments to Directive 88/378/EEC

Directive 88/378/EEC is hereby amended as follows:

1. the word ‘preparation’ or ‘preparations’ within the meaning of Article 3(2) of Regulation (EC) No 1907/2006, in its version of 30 December 2006, shall be replaced by ‘mixture’ or ‘mixtures’ respectively throughout the text;
2. from 1 December 2010, in section 2 of part II of Annex II, point (b) shall be replaced by the following:
 - (b) Toys must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components if, for reasons essential to their functioning, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, such toys contain mixtures which are dangerous as defined in Directive 67/548/EEC or substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to 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⁽¹⁶⁾:
 - (i) hazard classes 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;
 - (ii) hazard classes 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;
 - (iii) hazard class 4.1;
 - (iv) hazard class 5.1.;
3. from 1 June 2015, in section 2 of part II of Annex II, point (b) shall be replaced by the following:
 - (b) Toys must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components if, for reasons essential to their functioning, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, such toys contain substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008 of

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the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁽¹⁷⁾:

- (i) hazard classes 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;
- (ii) hazard classes 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;
- (iii) hazard class 4.1;
- (iv) hazard class 5.1.;

4. from 1 December 2010, in section 3 of part II of Annex II, the first paragraph of point 3 shall be replaced by the following:

3. Toys must not contain mixtures which are dangerous within the meaning of 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⁽¹⁸⁾ or substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 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;
- (b) hazard classes 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;
- (c) hazard class 4.1;
- (d) hazard class 5.1,

in amounts which may harm the health of children using them. In any event it is strictly forbidden to include, in a toy, such substances or mixtures if they are intended to be used as such while the toy is being used.;

5. from 1 June 2015, in section 3 of part II of Annex II, the first paragraph of point 3 shall be replaced by the following:

3. Toys must not contain substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 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;
- (b) hazard classes 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;
- (c) hazard class 4.1;

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(d) hazard class 5.1;

in amounts which may harm the health of children using them. In any event it is strictly forbidden to include, in a toy, such substances or mixtures if they are intended to be used as such while the toy is being used.;

6. from 1 December 2010, in section 4 of Annex IV, the title and point (a) shall be replaced by the following:

4. Toys containing inherently dangerous substances or mixtures. Chemical toys

(a) Without prejudice to the application of the provisions laid down in Regulation (EC) No 1272/2008, the instructions for use of toys containing mixtures which are inherently dangerous or substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(i) hazard classes 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;

(ii) hazard classes 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;

(iii) hazard class 4.1;

(iv) hazard class 5.1;

shall bear a warning of the hazardous nature of these substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toys must be kept out of reach of very young children.;

7. from 1 June 2015, in section 4 of Annex IV, the title and point (a) shall be replaced by the following:

4. Toys containing inherently dangerous substances or mixtures. Chemical toys

(a) Without prejudice to the application of the provisions laid down in Regulation (EC) No 1272/2008, the instructions for use of toys containing substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to that Regulation:

(i) hazard classes 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;

(ii) hazard classes 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;

(iii) hazard class 4.1;

(iv) hazard class 5.1;

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shall bear a warning of the hazardous nature of these substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toys must be kept out of reach of very young children..

Article 3

Amendments to Directive 1999/13/EC

Directive 1999/13/EC is hereby amended as follows:

1. the word ‘preparation’ or ‘preparations’ within the meaning of Article 3(2) of Regulation (EC) No 1907/2006, in its version of 30 December 2006, shall be replaced by ‘mixture’ or ‘mixtures’ respectively throughout the text;
2. Article 5 shall be amended as follows:
 - (a) from 1 December 2010, paragraph 6 shall be replaced by the following:
 6. Substances or mixtures which, because of their content of VOCs classified as carcinogens, mutagens or toxic to reproduction under 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⁽¹⁹⁾ are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F or the risk phrases R45, R46, R49, R60 or R61 shall be replaced, as far as possible and by taking into account the guidance referred to in Article 7(1), by less harmful substances or mixtures within the shortest possible time.;
 - (b) from 1 June 2015, paragraph 6 shall be replaced by the following:
 6. Substances or mixtures which, because of their content of VOCs classified as carcinogens, mutagens or toxic to reproduction under 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⁽²⁰⁾ are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F shall be replaced, as far as possible and by taking into account the guidance as mentioned in Article 7(1), by less harmful substances or mixtures within the shortest possible time.;
 - (c) paragraph 8 shall be amended as follows:
 - (i) the words ‘the risk phrase R40’ shall be replaced by ‘the risk phrases R40 or R68’;
 - (ii) the words ‘the labelling R40’ shall be replaced by ‘the labelling R40 or R68’;
 - (iii) from 1 June 2015, the words ‘the risk phrases R40 or R68’ shall be replaced by ‘the hazard statements H341 or H351’;

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- (iv) from 1 June 2015, the words ‘the labelling R40 or R68’ shall be replaced by ‘the hazard statements H341 or H351’;
- (d) from 1 June 2015, in paragraph 9, the words ‘risk phrases’ shall be replaced by ‘hazard statements’;
- (e) paragraph 13 shall be amended as follows:
 - (i) the words ‘the labelling R40, R60 or R61’ shall be replaced by ‘the risk phrases R40, R68, R60 or R61’;
 - (ii) from 1 June 2015, the words ‘the risk phrases R40, R68, R60 or R61’ are replaced by ‘the hazard statements H341, H351, H360F or H360D’.

Article 4

Amendment to Directive 2000/53/EC

From 1 December 2010, in Article 2 of Directive 2000/53/EC, point 11 shall be replaced by the following:

11. “hazardous substance” means any substance which fulfils the criteria for any of the following hazard classes or categories set out in Annex I of 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⁽²¹⁾;
- (a) hazard classes 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;
 - (b) hazard classes 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;
 - (c) hazard class 4.1;
 - (d) hazard class 5.1..

Article 5

Amendments to Directive 2002/96/EC

Directive 2002/96/EC is hereby amended as follows:

1. the word ‘preparation’ or ‘preparations’ within the meaning of Article 3(2) of Regulation (EC) No 1907/2006, in its version of 30 December 2006, shall be replaced by ‘mixture’ or ‘mixtures’ respectively throughout the text;
2. from 1 December 2010, in Article 3, point (l) shall be replaced by the following:
 - (l) “dangerous substance or mixture” means any mixture which has to be considered dangerous under 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⁽²²⁾ or any substance which fulfils the criteria for any of the

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following hazard classes or categories set out in Annex I of 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⁽²³⁾:

- (i) hazard classes 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;
- (ii) hazard classes 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;
- (iii) hazard class 4.1;
- (iv) hazard class 5.1.;

3. from 1 June 2015, in Article 3, point (l) shall be replaced by the following:

(l) “dangerous substance or mixture” means any substance or mixture which fulfils the criteria for any of the following hazard classes or categories set out in Annex I to 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⁽²⁴⁾:

- (i) hazard classes 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;
- (ii) hazard classes 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;
- (iii) hazard class 4.1;
- (iv) hazard class 5.1.;

4. in section 1 of Annex II, the thirteenth indent shall be replaced by the following:

— components containing refractory ceramic fibres as described in part 3 of Annex VI to Regulation (EC) No 1272/2008.

Article 6

Amendment to Directive 2004/42/EC

Article 2 of Directive 2004/42/EC is hereby amended as follows:

- (a) in paragraph 3, the word ‘preparation’ shall be replaced by ‘mixture’;
- (b) in paragraph 8, the word ‘preparation’ shall be replaced by ‘mixture’.

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Article 7

Transposition

1 Member States shall adopt and publish by 1 April 2010, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 June 2010.

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 8

Entry into Force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 9

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 16 December 2008.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

B. LE MAIRE

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- (1) OJ C 120, 16.5.2008, p. 50.
- (2) Opinion of the European Parliament of 3 September 2008 (not yet published in the Official Journal) and Council Decision of 28 November 2008.
- (3) OJ L 353, 31.12.2008, p. 1.
- (4) OJ 196, 16.8.1967, p. 1.
- (5) OJ L 200, 30.7.1999, p. 1.
- (6) OJ L 262, 27.9.1976, p. 169.
- (7) OJ L 187, 16.7.1988, p. 1.
- (8) OJ L 85, 29.3.1999, p. 1.
- (9) OJ L 269, 21.10.2000, p. 34.
- (10) OJ L 37, 13.2.2003, p. 24.
- (11) OJ L 143, 30.4.2004, p. 87.
- (12) OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3.
- (13) OJ C 321, 31.12.2003, p. 1.
- (14) OJ L 142, 31.5.2008, p. 1.?
- (15) OJ L 353, 31.12.2008, p. 1.?
- (16) OJ L 353, 31.12.2008, p. 1.?
- (17) OJ L 353, 31.12.2008, p. 1.?
- (18) OJ L 200, 30.7.1999, p. 1.?
- (19) OJ L 353, 31.12.2008, p. 1.?
- (20) OJ L 353, 31.12.2008, p. 1.?
- (21) OJ L 353, 31.12.2008, p. 1.?
- (22) OJ L 200, 30.7.1999, p. 1.
- (23) OJ L 353, 31.12.2008, p. 1.?
- (24) OJ L 353, 31.12.2008, p. 1.?