Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Official Journal L 157, 24/06/1988 P. 0028 - 0033 Finnish special edition: Chapter 13 Volume 17 P. 0066 Swedish special edition: Chapter 13 Volume 17 P. 0066

COUNCIL DIRECTIVE

of 13 June 1988

on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

(88/344/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas differences between national laws relating to extraction solvents hinder the free movement of foodstuffs and may create conditions of unequal competition thereby directly affecting the establishment or functioning of the common market;

Whereas the approximation of those laws is therefore necessary if the free movement of foodstuffs is to be achieved;

Whereas laws relating to extraction solvents for use in foodstuffs should take account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technical needs;

Whereas such approximation must involve the establishment of a single list of extraction solvents for the preparation of foodstuffs or food ingredients; whereas general purity criteria should also be specified;

Whereas the use of an extraction solvent under conditions of good manufacturing practice should result in the removal of all or the major part of the solvent residues from the foodstuff or food ingredient;

Whereas, under such conditions, the presence of residues or derivatives in the final foodstuff or food ingredient may be unintentional but technically unavoidable;

Whereas, although in general a specific limitation is useful, it need not be laid down for substances listed in Part I of the Annex which have been found acceptable from the point of view of safety to the consumer when used under conditions of good manufacturing practice;

Whereas to take account of protection of public health, the conditions of use of other extraction solvents listed in Parts II and III of the Annex and residues permitted in food and food ingredients must be established;

Whereas, pending the adoption of Community rules on flavourings, Member States should not be prevented from authorizing, as extraction solvents for certain flavourings, substances used for diluting and dissolving such materials;

Whereas the provisions on certain extraction solvents should be reviewed within a period of time on the basis of the ongoing scientific and technical research on the acceptability of such solvents and the conditions for their use;

Whereas specific purity criteria for extraction solvents and methods of analysis and sampling of extraction solvents in and on foodstuffs should be established;

Whereas, should the use of an extraction solvent provided for in this Directive appear to constitute a health risk as a result of new information, Member States should be able to suspend or limit such use, or to reduce existing limits, pending a decision at Community level;

Whereas the establishment of sampling procedures and of the methods of analysis required for checking the substances listed and their purity standards constitute technical implementing measures; whereas in order to simplify and expedite these procedures and facilitate their application it is desirable to ensure close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs set up by Council Decision 69/414/EEC (1),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients.

This Directive shall not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives are listed in the Annex.

However, the Member States shall ensure that the use of food additives, vitamins and other nutritional additives does not result in foodstuffs containing extraction solvent residue levels dangerous to human health.

- 2. This Directive does not affect the laws of the Member States relating to the use of methanol, propan-1-ol, propan-2-ol and tricholoroethylene as extraction solvents in the production of foodstuffs or food ingredients.
- 3. For the purposes of this Directive:
- (a) 'solvent' means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff;
- (b) 'extraction solvent' means a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which is removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.

Article 2

1. Member States shall authorize the use as extraction solvents in the manufacture of foodstuffs or food ingredients of those substances and materials listed in the Annex, under the conditions of use and where appropriate within the maximum residue limits therein specified.

Member States may not prohibit, restrict or obstruct the marketing of foodstuffs or food ingredients on grounds relating to the extraction solvents used or their residues if these comply with the provisions of this Directive.

2. Member States shall not authorize the use of other substances and materials as extraction solvents, nor extend the conditions or use or permitted residues of the extraction solvents listed in the Annex beyond those specified therein.

- 3. Until the adoption of Community provisions on substances used for diluting and dissolving flavourings Member States may, on their territory, allow the use, as solvents for the extraction of flavourings from natural flavouring materials, of substances used for diluting or dissolving flavourings.
- 4. Water, to which substances regulating acidity or alkalinity may have been added, other food substances which possess solvent properties and ethanol are authorized as extraction solvent the manufacture of foodstuffs or food ingredients.
- 5. Within two years of the adoption of this Directive, the Commission shall, after consulting the Scientific Committee for Food, re-examine the provisions relating to Part I of the Annex hereto and to the following substances and shall propose any necessary amendments acting in accordance with the procedure laid down in Article 100a of the Treaty:

Butan-1-ol

Butan-2-ol

Methyl-propan-1-ol

Methyl-propan-2-ol

Methyl acetate

Cyclohexane

Dichloromethane

Hexane

Ethylmethylketone

Isobutane

Diethyl ether

As part of this amendment, the Council shall decide whether the residues of the extraction solvents listed in Part III of the Annex should refer to flavourings rather than foodstuffs.

- 6. The Commission, after consulting the Scientific Committee for Food, shall re-examine the situation with regard to the substances referred to in Article 1 (2) and submit any appropriate proposal to the Council:
- three years after the adoption of this Directive with regard to methanol, propan-1-ol and propan-2-ol,
- seven years after the adoption of this Directive with regard to trichloroethylene.

Article 3

Member States shall take all measures to ensure that the substances and materials listed as extraction solvents in the Annex satisfy the following purity criteria:

- (a) they shall not contain a toxicologically dangerous amount of any element or substance;
- (b) subject to any exceptions deriving from the specific purity criteria referred to in (c), they shall not contain more than 1 mg/kg of arsenic or more than 1 mg/kg of lead;
- (c) they shall satisfy the specific purity criteria determined in accordance with Article 4.

Article 4

The following shall be determined in accordance with the procedure laid down in Article 6:

(a) the methods of analysis necessary to verify compliance with the general and specific purity criteria referred to in Article 3;

- (b) the procedure for taking samples and the methods for qualitative and quantitative analysis of the extraction solvents cited in the Annex used in foodstuffs or food ingredients;
- (c) if necessary, the specific purity criteria for the extraction solvents listed in the Annex, and in particular maximum permitted limits of mercury and cadmium in the extraction solvents; these criteria are to be adopted within three years from the date of adoption of this Directive.

Article 5

- 1. Where a Member State, as a result of new information or of a reassessment of existing information made since the Directive was adopted, has detailed grounds for establishing that the use in foodstuffs of any substance listed in the Annex or the level of one or more of the components referred to in Article 3 contained in such substances might endanger human health although it complies with the conditions laid down in this Directive, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.
- 2. The Commission shall examine as soon as possible the evidence given by the Member State concerned and consult the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures, which may replace the measures referred to in paragraph 1.
- 3. If the Commission considers that amendments to the Directive are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 6 with a view to adopting these amendments. Any Member State which has adopted safeguard measures may in that event retain them until the amendments enter into force in its territory.

Article 6

- 1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee for Foodstuffs.
- 2. The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a period fixed by the chairman according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
- 3. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion.
- (b) Where the intended measures are not in accordance with the opinion of the Committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
- (c) If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures.

Article 7

- 1. Member States shall take all the necessary measures to ensure that the substances listed in the Annex and intended for use as extraction solvents in foodstuffs may not be marketed unless their packaging, containers or labels carry the following information in such a way as to be easily visible, clearly legible and indelible:
- (a) the commercial name as given in the Annex;
- (b) a clear indication that the material is of a quality suitable for use for the extraction of food or food ingredients;

- (c) a reference by which the batch or lot may be identified;
- (d) the name or business name and address of the manufacturer or packer or of a seller established within the Community; (e) the net quantity given as units of volume;
- (f) if necessary, the special storage conditions or conditions of use.
- 2. By way of derogation from paragraph 1, the information specified in points (c), (d), (e) and (f) of that paragraph may appear merely on the trade documents relating to the batch or lot which are to be supplied with or prior to the delivery.
- 3. This Article is without prejudice to more precise or more extensive Community provisions regarding weights and measures or provisions applying to the classification, packaging and labelling or dangerous substances and preparations.
- 4. Member States shall refrain from laying down requirements more detailed than those already contained in this Article concerning the manner in which the particulars provided are to be shown.

Member States shall, however, ensure that the sale of extraction solvents within their own territories is prohibited if the particulars provided for in this Article do not appear in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

Article 8

- 1. This Directive shall apply equally to extraction solvents used or intended for use in the production of foodstuffs or ingredients imported into the Community.
- 2. This Directive shall not apply to extraction solvents, or foodstuffs intended for export outside the Community.

Article 9

Member States shall take the measures necessary to comply with this Directive within three years of its adoption, so as to authorize from that date trade in and use of extraction solvents complying with the provisions of this Directive and to prohibit trade in and use of extraction solvents which do not comply therewith. They shall immediately inform the Commission thereof.

Article 10

This Directive is addressed to the Member States.

Done at Luxembourg, 13 June 1988.

For the Council

The President

I. KIECHLE

- (1) OJ No C 312, 17. 11. 1983, p. 3, and
- OJ No C 77, 23. 3. 1985, p. 7.
- (2) OJ No C 12, 14. 1. 1985, p. 152, and
- OJ No C 68, 14. 3. 1988, p. 51.
- (3) OJ No C 206, 6. 8. 1984, p. 7.
- (1) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX

EXTRACTION SOLVENTS WHICH MAY BE USED DURING THE PROCESSING OF RAW MATERIALS, OF FOODSTUFFS, OF FOOD COMPONENTS OR OF FOOD INGREDIENTS

PART I

Extraction solvents to be used in compliance with good manufacturing practice for all uses (1)

Name

Propane

Butane

Butyl acetate

Ethyl acetate

Ethanol

Carbon dioxide

Acetone

Nitrous oxide

(1) An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.

PART II

Extraction solvents for which conditions of use are specified

- 1.2.3 // // // Name // Conditions of use (summary description of extraction) // Maximum residue limits in the extracted foodstuff or food ingredient // // // Hexane (1) // Production or fractionation of fats and oils and production of cocoa butter // 5mg/kg in the fat or oil or cocoa butter // // Preparation of protein products and defatted flours // 10 mg/kg in the food containing the protein products and defatted flours // // Preparation of defatted cereal germs // 5 mg/kg in the defatted cereal germ // // Defatted soya products // 30 mg/kg in the soya product as sold to the final consumer // Methyl acetate // Decaffeination of, or removal of irritants and bitterings from coffee and tea // 20 mg/kg in the coffee or tea // // Production of sugar from molasses // 1 mg/kg in the sugar // Ethylmethylketone // Fractionation of fats and oils // 5 mg/kg in the fat or oil // // Decaffeination of, or removal of irritants and bitterings from coffee and tea // 20 mg/kg in the roasted coffee and 5 mg/kg in the tea // // //
- (1) Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 $^{\circ}$ C und 70 $^{\circ}$ C.
- (2) This level will be reduced to 5 mg/kg three years after adoption of this Directive.

PART III

Extraction solvents for which conditions of use are specified

- 1.2 // // / Name // Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials // // // Diethyl ether // 2 mg/kg // Isobutane // 1 mg/kg // Hexane // 1 mg/kg // Cyclohexane // 1 mg/kg // Methyl acetate // 1 mg/kg // Butan-1-ol // 1 mg/kg // Butan-2-ol // 1 mg/kg // Ethylmethylketone // 1 mg/kg // Dichloromethane // 0,1 mg/kg (1) // Methyl-propan-1-ol // 1 mg/kg // //
- (1) Exception: 1 mg/kg in confectionery and pastry products containing flavourings which are characteristic of the foodstuff and are obtained from extracts of alcoholic beverages of an alcoholic strength of over 35°.

Council Directive 92/115/EEC of 17 December 1992 amending for the first time Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Official Journal L 409, 31/12/1992 P. 0031 - 0032

COUNCIL DIRECTIVE 92/115/EEC of 17 December 1992 amending for the first time Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 2 (5) of Directive 88/344/EEC (4) provides that within two years of the adoption of that Directive the Commission shall, after consulting the Scientific Committee for Food, reexamine the provisions relating to the solvents in the Annex and to Methyl-propan-2-ol and propose any necessary amendments;

Whereas as part of this amendment the Council should decide whether the residues of the extraction solvents in Part III of the Annex should refer to flavourings rather than foodstuffs;

Whereas, three years after the adoption of Directive 88/344/EEC, the Commission should submit any appropriate proposal to the Council for some of the solvents in Article 2 (6), regulated so far only by national legislations;

Whereas the Scientific Committee for Food reconsidered all the extraction solvents mentioned in that Directive in 1990 and in 1991 with the aim of replacing the temporary acceptable daily intakes (ADIs) established in 1981 with permanent assessments; whereas this has not always been possible, as appropriate information, although requested, has not been provided; whereas on the basis of the information received, the Scientific Committee for Food decided to confirm its acceptance or to retain the temporary status or to withdraw its previous temporary approval, depending on the substance concerned,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 88/344/EEC is hereby amended as follows:

- 1. in Article 1:
- (a) the following subparagraph shall be added to paragraph 1:

'This Directive shall apply without prejudice to the provisions adopted under more specific Community rules.`;

- (b) Paragraph 2 shall be deleted;
- 2. in Article 2, paragraphs 5 and 6 shall be deleted;
- 3. the Annex shall be amended as follows:
- (a) IN PART I:

- the following footnote 2 shall be added to Acetone:
- '(2) The use of Acetone in the refining of olive-pomace oil is forbidden.';
- (b) IN PART II:
- the solvents methanol and Propan-2-ol shall be added for all uses with a maximum residue content of 10 mg/kg,
- footnote 1 shall be completed with the following sentence:

'The combined use of Hexane and Ethylmethylketone is forbidden.',

- footnote 2 shall be deleted. In the third column, the presence of 10 mg/kg in respect of Dichlormethane in roasted coffee, shall be replaced by the presence of '2 mg/kg',
- the following footnote 2 shall be added to Ethylmethylketone:
- '(2) The presence of n-Hexane in this solvent should not exceed 50 mg/kg. This solvent may not be used in combination with Hexane.`;
- (c) IN PART III:
- Cyclohexane, Isobutane, and the footnote shall be deleted,
- the presence of 0.1 mg/kg in respect of Dichloromethane shall be replaced by the presence of 0.02 mg/kg,
- Propan-1-ol shall be added, with a maximum residue limit of 1 mg/kg,
- a footnote shall be added to Hexane and Ethylmethylketone on the following page:
- '(1)The combined use of these two solvents is forbidden.`

Article 2

- 1. Member States shall amend their laws, regulations and administrative provisions in such a way as to:
- permit trade in products complying with this Directive at the latest by 1 July 1993,
- prohibit trade in products not complying with this Directive with effect from 1 January 1994.

They shall forthwith inform the Commission thereof.

2. When Member States adopt the measures referred to in paragraph 1, 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 a reference shall be laid down by the Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992,

For the Council

The President

- R. NEEDHAM
- (1) OJ No C 11, 17. 1. 1992, p. 5.
- (2) OJ No C 94, 13. 4. 1992, p. 158, and
- OJ No C 337, 21. 12. 1992.
- (3) OJ No C 223, 31. 8. 1992, p. 23.

(4) OJ No L 157, 24. 6. 1988, p. 28.

Directive 94/52/EC of the European Parliament and of the Council of 7 December 1994 amending for the second time Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Official Journal L 331, 21/12/1994 P. 0010 - 0010 Finnish special edition: Chapter 13 Volume 27 P. 0056 Swedish special edition: Chapter 13 Volume 27 P. 0056

DIRECTIVE 94/52/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 December 1994 amending for the second time Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure referred to in Article 189b of the Treaty (3),

Whereas Directive 88/344/EEC (4), deleted from Part III of the Annex, as from 1 January 1994 the solvent cyclohexane, used in the preparation of flavourings;

Whereas, on the basis of complementary information meanwhile received, the Scientific Committee for Food has decided to re-instate its previous temporary acceptance for this substance; whereas the use of the solvent can therefore be continued, pending the definitive opinion of that Committee,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 88/344/EEC is hereby amended as follows:

in Part III: The solvent cyclohexane shall be reinstated with a maximum residue limit of 1mg/kg.

Article 2

1. Member States shall amend their laws, regulations and administrative provisions in such a way as to permit trade in products complying with this Directive at the latest by 7 December 1995.

They shall forthwith inform the Commission thereof.

2. When Member States adopt the measures referred to in paragraph 1, 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 a reference shall be laid down by the Member States.

Article 3

This Directive shall enter into force on the seventh day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 7 December 1994.

For the European Parliament The President K. HAENSCH For the Council The President G. $\ensuremath{\mathsf{REXRODT}}$

- (1) OJ No C 15, 18. 1. 1994, p. 17.
- (2) OJ No C 133, 16. 5. 1994, p. 21.
- (3) Opinion of the European Parliament of 9 February 1994. (OJ No C 61, 28. 2. 1994, p. 101), Council common position of 10 March 1994 (OJ No C 172, 24. 6. 1994, p. 1) and Decision of the European Parliament of 15 September 1994 (OJ No C 276, 3. 10. 1994, p. 13).
- (4) OJ No L 157, 24. 6. 1988, p. 28. Directive as amended by Directive 92/115/EEC, (OJ No L 409, 31. 12. 1992, p. 31).

Directive 97/60/EC of the European Parliament and of the Council of 27 October 1997 amending for the third time Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Official Journal L 331, 03/12/1997 P. 0007 - 0009

DIRECTIVE 97/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1997 amending for the third time Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the Opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

Whereas the Scientific Committee for Food has reexamined all the extraction solvents listed in Directive 88/344/EEC (4), with a view to replacing the provisional acceptable daily intakes (ADIs) set in 1981 by definitive figures; whereas this has not always been possible because the information needed, although requested from the industry, has not been communicated; whereas, on the basis of the information received, the Scientific Committee for Food has been able to confirm its agreement for the majority of the solvents; whereas the maximum residues of the solvents in certain foodstuffs can be reduced;

Whereas some solvents are no longer used and should thus be taken off the list;

Whereas as a result of scientific progress other substances have been developed which can be added to the Directive; whereas a new solvent which has received a favourable opinion from the Scientific Committee should be authorized;

Whereas this new solvent, namely 1, 1, 1, 2-tetrafluoroethane, is used solely for the extraction of flavourings and whereas residues in foodstuffs do not exceed 0,02 mg/kg; whereas, apart from those residues, the solvent is fully recycled, so that its use under these conditions has no impact on global warming of the atmosphere;

Whereas the amendments needed, in the light of technical and scientific progress, amount to measures of a technical nature; whereas to simplify and speed up the procedure, adoption of these measures should be entrusted to the Commission;

Whereas a procedure of this kind makes for quicker placing on the market of innovations, which is to the benefit of both industry and the consumer,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 88/344/EEC is hereby amended as follows:

- (1) The following paragraph shall be added to Article 4:
- '(a) The necessary amendments to the Annex in the light of scientific and technical progress in the field of the use of solvents, their conditions of use and maximum residue limits.`

Former paragraphs (a), (b) and (c) become paragraphs (b), (c), and (d) respectively.

- (2) The Annex shall be amended as follows:
- (a) PART I

The substance 'Butyl acetate' shall be deleted.

(b) PART II

The entry for hexane shall be amended as follows:

>TABLE>

- (c) PART III
- The substance 'methyl-propan-1-ol` shall be deleted.
- The following substance shall be added:
- >TABLE>

Article 2

- 1. Member States shall amend their laws, regulations and administrative provisions so as to:
- authorize trade in products complying with Directive 88/344/EEC, as amended by this Directive by 27 October 1998 at the latest;
- ban trade in products not complying with Directive 88/344/EEC, as amended by this Directive, as from 27 April 1999. However, products placed on the market or labelled before that date and not complying with Directive 88/344/EEC, as amended by this Directive, may be marketed until stocks are used up.

They shall forthwith inform the Commission thereof.

2. 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 Member States.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 October 1997.

For the European Parliament

The President

J.M. GIL-ROBLES

For the Council

The President

R. GOEBBELS

- (1) OJ C 278, 24. 9. 1996, p. 25.
- (2) OJ C 66, 3. 3. 1997, p. 3.
- (3) Opinion of the European Parliament of 23 October 1996 (OJ C 347, 18. 11. 1996, p. 58), Council Common Position of 24 March 1997 (OJ C 157, 24. 5. 1997, p. 4) and Decision of the

European Parliament of 15 July 1997 (OJ C 286, 22. 9. 1997). Council Decision of 7 October 1997.

(4) OJ L 157, 24. 6. 1988, p. 28. Directive as last amended by Directive of the European Parliament and of the Council 94/52/EC (OJ L 331, 21. 12. 1994, p. 10).