



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.7.2003  
COM(2003) 467 final

2003/0181 (COD)

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

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

(Codified version)

(presented by the Commission)

## EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen, thus giving them new opportunities and the chance to make use of the specific rights it gives him.

This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules.

For this reason a codification of rules that have frequently been amended is also essential if Community law is to be clear and transparent.

2. On 1 April 1987 the Commission therefore decided<sup>1</sup> to instruct its staff that all legislative measures should be codified after no more than ten amendments, stressing that this was a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that the Community rules were clear and readily understandable.
3. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this<sup>2</sup>, stressing the importance of codification as it offers certainty as to the law applicable to a given matter at a given time.

Codification must be undertaken in full compliance with the normal Community legislative procedure.

Given that no changes of substance may be made to the instruments affected by codification, the European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast track adoption of codification instruments.

4. The purpose of this proposal is to undertake a codification of 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<sup>3</sup>. The new Directive will supersede the various Directives incorporated in it<sup>4</sup>; their content is fully preserved, and they are brought together with only such formal amendments as are required by the codification exercise itself.

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<sup>1</sup> COM(87) 868 PV.

<sup>2</sup> See Annex 3 to Part A of such Conclusions.

<sup>3</sup> Carried out pursuant to the Communication for the Commission to the European Parliament and the Council – Codification of the Acquis communautaire, COM(2001) 645 final.

<sup>4</sup> Annex II, Part A of this proposal.

5. The codification proposal was drawn up on the basis of a preliminary consolidation, in all official languages, of Directive 88/344/EEC and the instruments amending it, carried out by the Office for Official Publications of the European Communities, by means of a data-processing system. Insofar as the Articles have been given new numbers, the correlation between the old and the new numbers is shown in a table contained in Annex III to the codified Directive.

Proposal for a

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↓ 88/344/EEC (adapted)

**DIRECTIVE .../.../EC ☒ OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ☒**

**of [...]**

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

**☒ (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 ☒ thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

☒ Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>2</sup>, ☒

Whereas:

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- (1) 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<sup>3</sup> has been substantially amended several times<sup>4</sup>. In the interests of clarity and rationality the said Directive should be codified.

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<sup>1</sup> [...]

<sup>2</sup> ☒ [...] ☒

<sup>3</sup> OJ L 157, 24.6.1988, p. 28. Directive as last amended by Directive 97/60/EC of the European Parliament and of the Council (OJ L 331, 3.12.1997, p. 7).

<sup>4</sup> See Annex II, Part A.

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↓ 88/344/EEC Recital 1

- (2) 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 functioning of the common market.

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↓ 88/344/EEC Recital 2

- (3) The approximation of those laws is therefore necessary if the free movement of foodstuffs is to be achieved.

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↓ 88/344/EEC Recital 3

- (4) 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.

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↓ 88/344/EEC Recital 4 (adapted)

- (5) Such approximation  should  involve the establishment of a single list of extraction solvents for the preparation of foodstuffs or food ingredients. General purity criteria should also be specified.

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↓ 88/344/EEC Recital 5

- (6) 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.

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↓ 88/344/EEC Recital 6

- (7) Under such conditions, the presence of residues or derivatives in the final foodstuff or food ingredient may be unintentional but technically unavoidable.

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↓ 88/344/EEC Recital 7 (adapted)

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

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↓ 88/344/EEC Recital 8 (adapted)

- (9) To take account of protection of public health, the conditions of use of other extraction solvents listed in Parts II and III of Annex  I  and residues permitted in food and food ingredients  should  be established.
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↓ 88/344/EEC Recital 9 (adapted)

- (10) Pending the adoption of Community rules on  substances used for diluting and dissolving  flavourings, Member States should not be prevented from authorising, as extraction solvents for certain flavourings, substances used for diluting and dissolving such materials.
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↓ 88/344/EEC Recital 10

- (11) 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.
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↓ 88/344/EEC Recital 11

- (12) Specific purity criteria for extraction solvents and methods of analysis and sampling of extraction solvents in and on foodstuffs should be established.
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↓ 88/344/EEC Recital 12

- (13) 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.
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↓ 88/344/EEC Recital 13  
(adapted)

- (14)  The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>5</sup>.

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<sup>5</sup>  OJ L 184, 17.7.1999, p. 23.



- (15) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B,

HAVE ADOPTED THIS DIRECTIVE:

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↓ 88/344/EEC (adapted)

*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 Annex  I .

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.

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↓ 92/115/EEC Art.1 pt.1

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

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↓ 88/344/EEC (adapted)

2.  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 authorise the use as extraction solvents in the manufacture of foodstuffs or food ingredients of those substances and materials listed in Annex  I  , under the conditions of use and where appropriate within the maximum residue limits specified  therein.

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 authorise the use of other substances and materials as extraction solvents, nor extend the conditions of use or permitted residues of the extraction solvents listed in Annex  I  beyond those specified therein.

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88/344/EEC

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 authorised as extraction solvents in the manufacture of foodstuffs or food ingredients.

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88/344/EEC (adapted)

### *Article 3*

Member States shall take all measures to ensure that the substances and materials listed as extraction solvents in Annex  I  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  (d) .

### *Article 4*

The following shall be determined in accordance with the procedure  referred to  in Article 6  (2) .

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97/60/EC Art.1 pt.1 (adapted)

- (a) The necessary amendments to Annex  I  in the light of scientific and technical progress in the field of the use of solvents, their conditions of use and maximum residue limits;

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↓ 88/344/EEC (adapted) → <sub>1</sub> 97/60/EC Art.1 pt. 1
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- <sub>1</sub> (b) ← the methods of analysis necessary to verify compliance with the general and specific purity criteria referred to in Article 3;
- <sub>1</sub> (c) ← the procedure for taking samples and the methods for qualitative and quantitative analysis of the extraction solvents cited in Annex  I  used in foodstuffs or food ingredients;
- <sub>1</sub> (d) ← if necessary, the specific purity criteria for the extraction solvents listed in Annex  I  , and in particular maximum permitted limits of mercury and cadmium in the extraction solvents.

#### *Article 5*

1. Where a Member State, as a result of new information or of a reassessment of existing information made since  this  Directive was adopted, has detailed grounds for establishing that the use in foodstuffs of any substance listed in Annex  I  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 Committee  referred to in Article 6(1)  , 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  this  Directive are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall  adopt  these amendments  in accordance with the procedure referred to in Article 6(2)  . 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.  The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, instituted by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>6</sup>, hereinafter referred to as “the Committee”.

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<sup>6</sup>  OJ L 31, 1.2.2002, p. 1.

2.  Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

3.  The Committee shall adopt its rules of procedure.

#### *Article 7*

1. Member States shall take all the necessary measures to ensure that the substances listed in Annex  I  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 Annex  I  ;
  - (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 of 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  also  apply 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*

Directive 88/344/EEC, as amended by the Directives listed in Annex II, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

*Article 10*

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

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 88/344/EEC Art. 10

*Article 11*

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*  
[\[...\]](#)

*For the Council*  
*The President*  
[\[...\]](#)

**ANNEX I**

**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<sup>1</sup>**

Name:

Propane

Butane

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↓ 88/344/EEC (adapted)  
→<sub>1</sub> 92/115/EEC Art.1 pt.3  
→<sub>2</sub> 97/60/EC Art.1 pt.2  
→<sub>3</sub> 94/52/EC Art.1

Ethyl acetate

Ethanol

Carbon dioxide

Acetone →<sub>1</sub> <sup>2</sup> ←

Nitrous oxide

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<sup>1</sup> 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.

<sup>2</sup> The use of Acetone in the refining of olive-pomace oil is forbidden.

## PART II

### Extraction solvents for which conditions of use are specified

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
→ <sub>2</sub> Hexane <sup>1</sup> ←	→ <sub>2</sub> Production or fractionation of fats and oils and production of cocoa butter ←	→ <sub>2</sub> 1 mg/kg in the fat or oil or cocoa butter ←
	→ <sub>2</sub> Preparation of defatted protein products and defatted flours ←	→ <sub>2</sub> 10 mg/kg in the food containing the defatted protein products and the defatted flours ←
		→ <sub>2</sub> 30 mg/kg in the defatted soya products as sold to the final consumer ←
	→ <sub>2</sub> Preparation of defatted cereal germs ←	→ <sub>2</sub> 5 mg/kg in the defatted cereal germs ←
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 → <sub>1</sub> <sup>2</sup> ←	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 coffee or tea

<sup>1</sup> Hexane means a commercial product consisting essentially of ☒ acyclic ☒ saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. →<sub>1</sub> The combined use of Hexane and Ethylmethylketone is forbidden. ←

<sup>2</sup> →<sub>1</sub> The presence of n-Hexane in this solvent should not exceed 50 mg/kg. This solvent may not be used in combination with Hexane. ←

Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	→ <sub>1</sub> 2 mg/kg ← in the roasted coffee and 5 mg/kg in the tea
→ <sub>1</sub> Methanol ←	→ <sub>1</sub> For all uses ←	→ <sub>1</sub> 10 mg/kg ←
→ <sub>1</sub> Propan-2-ol ←	→ <sub>1</sub> For all uses ←	→ <sub>1</sub> 10 mg/kg ←

### PART III

#### Extraction solvents for which conditions of use are specified

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
Hexane → <sub>1</sub> <sup>1</sup> ←	1 mg/kg
→ <sub>3</sub> Cyclohexane ←	→ <sub>3</sub> 1 mg/kg ←
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone → <sub>1</sub> <sup>1</sup> ←	1 mg/kg
Dichloromethane	→ <sub>1</sub> 0,02 mg/kg ←
→ <sub>1</sub> Propan-1-ol ←	→ <sub>1</sub> 1 mg/kg ←
→ <sub>2</sub> 1,1,1,2-tetrafluoroethane ←	→ <sub>2</sub> 0,02 mg/kg ←

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<sup>1</sup> →<sub>1</sub> The combined use of these two solvents is forbidden. ←



## **ANNEX II**

### **Part A**

#### **Repealed Directive with its successive amendments** (referred to in Article 9)

Council Directive 88/344/EEC (OJ L 157, 24.6.1988, p. 28)

Council Directive 92/115/EEC (OJ L 409, 31.12.1992, p. 31)

Directive 94/52/EC of the European Parliament and of the Council (OJ L 331, 21.12.1994, p. 10)

Directive 97/60/EC of the European Parliament and of the Council (OJ L 331, 3.12.1997, p. 7)

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## Part B

### List of time limits for transposition into national law (referred to in Article 9)

Directive	Time-limit for transposition
Directive 88/344/EEC	13 June 1991
Directive 92/115/EEC	<b>a.</b> 1 July 1993 <b>b.</b> 1 January 1994 <sup>1</sup>
Directive 94/52/EC	7 December 1995
Directive 97/60/EC	<b>a.</b> 27 October 1998 <b>b.</b> 27 April 1999 <sup>2</sup>

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<sup>1</sup> In accordance with Article 2(1) of Directive 92/115/EEC:  
“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.”

<sup>2</sup> In accordance with Article 2(1) of Directive 97/60/EC:

“1. Member States shall amend their laws, regulations and administrative provisions so as to:

- authorise trade in products complying with Directive 88/344/EEC, as amended by this Directive by 27 October 1998 by 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.”

### ANNEX III

#### Correlation Table

Directive 88/344/EEC	This Directive
Article 1(1)	Article 1(1)
Article 1(3)	Article 1(2)
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	-
-	Article 9
-	Article 10
Article 10	Article 11
Annex	Annex I
-	Annex II
-	Annex III