

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients*COM(83) 626 final**(Submitted by the Commission to the Council on 28 October 1983)*

THE COUNCIL OF THE EUROPEAN
COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas differences between national laws relating to extraction solvents hinder the free movement of foodstuffs and may create unequal conditions of competition thereby 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 there may nevertheless subsist the non-intentional but technically unavoidable presence of residues or derivatives in the final foodstuff or food ingredient;

Whereas no specific limitation need be laid down for substances found acceptable from the point of view of safety to the consumer when used under conditions of good manufacturing practice; whereas such residues, in the case of propane, butane and nitrous oxide at 1 mg/kg; of butyl acetate, propan-2-ol and acetone at 5 mg/kg; and of ethyl acetate, ethanol and methanol at 10 mg/kg of the food or food ingredient represent technically unavoidable maxima attained only in exceptional circumstances;

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

Whereas other substances specified in Community provisions on food additives may also be authorized as extraction solvents; whereas, pending the adoption of Community rules on flavourings presently under discussion, Member States should not be prevented from authorizing, as extraction solvents for certain flavourings, substances used for diluting and dissolving such materials;

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

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

Whereas in order to encourage technical progress Member States should not be prevented from authorizing provisionally under their control the use, in their territory, of extraction solvents not provided

for in this Directive pending a final decision at Community level;

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 the limits provided, pending a decision at Community level;

Whereas amending the conditions of use and the maximum residue limits laid down in the Annex to take account of progress in scientific and technical knowledge and 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 the procedure 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⁾;

Whereas 18 months is sufficient time for Member States to take the necessary measures for the free movement of products complying with the provisions of this Directive, but a longer period seems necessary to prohibit the use of extraction solvents which do not comply therewith so that processes used in the manufacture of foodstuffs containing residues of extraction solvents can be adapted to the new requirements laid down in this Directive,

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.
2. This Directive is without prejudice to specific legislative provisions on vitamins.
3. For the purpose of this Directive, 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 partially or wholly removed but which may result in the non-intentional 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 their 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 of use of permitted residues of the extraction solvents listed in the Annex, beyond those specified therein.

3. By way of derogation from paragraph 2:

- (a) dissolvents and diluents authorized by Community provisions are also authorized as extraction solvents for the production of food additives;
- (b) solvents directly or indirectly taken into account in Community provisions, or in their absence national provisions, on the specific criteria of purity for a particular food additive are authorized as extraction solvents in the production of that food additive; where such solvents are transferred to a food or food ingredient by the use of the additive, the residues specified according to paragraphs 1 and 2 may be exceeded by the amount permitted by the specific criteria of purity in question;
- (c) 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;
- (d) foodstuffs which possess solvent properties are authorized as extraction solvents in the manufacture of foodstuffs or food ingredients.

⁽¹⁾ OJ No L 291, 19. 11. 1969, p. 9.

4. Within five years of the notification of this Directive, the Commission shall re-examine the provisions relating to the following substances and shall propose any necessary amendments acting in accordance with the procedure laid down in Article 100 of the Treaty:

Butan-1-ol,
Butan-2-ol,
2-methyl-propan-2-ol,
Propan-1-ol,
Propan-2-ol,
Methyl acetate,
Butyl acetate,
Cyclohexane,
Dichloromethane,
Trichloroethylene,
Light petroleum,
Ethylmethylketone.

Article 3

1. Notwithstanding Article 2, a Member State may authorize the use within its territory of an extraction solvent not included on the list in the Annex, subject to the condition that the authorization must be limited to a maximum period of three years.

2. The Member State shall forward to the other Member States and to the Commission the text of any authorization drawn up pursuant to paragraph 1 within two months of the date of its taking effect.

3. Before the expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for inclusion on the list in the Annex of the substance or material given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which such substance is intended.

Within 18 months of submission of a request, a decision shall be taken on the basis of information relating to public health and in accordance with the procedure laid down in Article 8 as to whether the substance or material in question may be included on the list in the Annex or whether the national authorization should be withdrawn. If any conditions of use or limits prove necessary, these shall be adopted under the same procedure. Notwithstanding paragraph 1, the national authorization may remain in force until a decision is taken on the request.

Should it be decided pursuant to the preceding subparagraph that the national authorization should be withdrawn, that decision shall apply to any other national authorization in respect of the substance in question.

Article 4

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

- (a) they shall not contain a toxicologically dangerous amount of any element or substance, in particular heavy metals;
- (b) subject to any exception deriving from the specific criteria of purity 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 criteria of purity laid down in accordance with Article 5.

Article 5

The following shall be determined in accordance with the procedure laid down in Article 8:

- (a) the methods of analysis necessary to verify compliance with the general and specific criteria of purity referred to in Article 4;
- (b) the procedure for taking samples and the methods for qualitative and quantitative analysis of the extraction solvents referred to in the Annex in foodstuffs or food ingredients;
- (c) the specific criteria of purity for the extraction solvents listed in the Annex.

Article 6

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 4 contained in such substances might endanger human health although it complies with the provisions of 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 grounds given by the Member State concerned and consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

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 8 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 7

Technical amendments to the conditions of use and maximum residue limits laid down in the Annex necessary to take account of progress in scientific and technical knowledge on the use of the solvents therein specified shall be adopted in accordance with the procedure provided for in Article 8.

Article 8

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Committee for Foodstuffs set up by Decision 69/414/EEC (hereinafter called 'the Committee') by its chairman, either on his own initiative or at the request of a representative of a Member State.

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. A qualified majority of votes as laid down in Article 148 (2) of the Treaty shall be required before the Committee can deliver its opinion.

The chairman shall not vote.

3. (a) The Commission shall adopt the proposed measures where they are in accordance with the opinion of the Committee.

(b) Where the proposed measures are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall submit to the Council without delay a proposal on the measures to be adopted. The Council shall decide by a qualified majority.

(c) If the Council has not acted within three months of the date on which the proposal was submitted, the proposed measures shall be adopted by the Commission.

Article 9

1. Member States shall take all necessary measures to ensure that the substances listed in the Annex and intended for use in foodstuffs may be marketed only

if their packagings or containers bear the following information:

(a) the name, and where appropriate its EEC number, of the substance given in the Annex;

(b) in the case of substances listed in the Annex when mixed with each other, or with other substances or materials or with food ingredients, the name of each component, and where appropriate its EEC number, in descending order by weight;

(c) a clear indication that the material is of a quality suitable for use in the manufacture of food or food ingredients;

(d) an identifying batch number;

(e) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;

(f) the net quantity;

(g) any special storage conditions or conditions of use;

(h) an indication of the percentage of any component which is subject to a quantitative limitation in a food in the Member State in which the product will be sold or used or adequate information to enable compliance with such a limitation. Where the same quantitative limitation applies to components used singly or in combination, the combined percentage may be given as a single figure.

2. The provisions of this Article are 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.

3. 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 solvents within their own territories is prohibited if the particulars provided 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, and it may not result in a customs check on imported solvents.

4. By way of derogation from paragraph 1, the information required by points (a), (b), (f) and (h) of that paragraph may appear on the relevant trade documents relating to the consignment, provided that the statement 'not for retail sale' appears in a prominent position on the packagings or container of the product in question.

Article 10

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, foodstuffs or ingredients intended for export outside the Community.

Article 11

Member States shall take the measures necessary to comply with this Directive not later than ... ⁽¹⁾, 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 not later than ... ⁽²⁾. They shall immediately inform the Commission thereof.

Article 12

This Directive is addressed to the Member States.

⁽¹⁾ 18 months after notification.

⁽²⁾ Three years after notification.

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 for which conditions of use are unspecified

EEC No	Name
E 290	Propane
	Butane
	Buryl acetate
	Ethyl acetate
	Methanol
	Ethanol
	Propan-2-ol
	Carbon dioxide
	Acetone
	Nitrous oxide

PART II

Extraction solvents for which conditions of use and maximum residue limits are specified

EEC No	Name	Conditions of use (summary description of extraction)	Maximum residues in the extracted food or food ingredient
	Diethyl ether	Preparation of flavourings from natural flavouring materials	2 mg/kg in the food containing the flavouring
	Iso-butane	Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
	Light petroleum ⁽¹⁾	Production or fractionation of fats and oils and cocoa butter	5 mg/kg in the fat or oil or cocoa butter
		Preparation of protein products and defatted flours	20 mg/kg in the protein product or flour
		Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germ
		Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
	Cyclohexane	Fractionation of fats and oils	5 mg/kg in the fat or oil
		Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
	Methyl acetate	Decaffeination of, or removal of, irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
		Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
		Production of sugar from molasses	1 mg/kg in the sugar
	Propan-1-ol	Preparation of protein products and defatted flours	20 mg/kg in the protein product or flour
		Production of fats and oils	5 mg/kg in the fat or oil
	Butan-1-ol	Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
	Butan-2-ol	Preparation of protein products and defatted flours	20 mg/kg in the protein product or flour
	2-methyl-propan-2-ol	Production or fractionation of fats and oils	5 mg/kg in the fat or oil
	Ethylmethyl-ketone	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
		Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring

⁽¹⁾ Light petroleum means a product consisting essentially of acyclic saturated hydrocarbons containing five, six, seven or eight carbon atoms or mixtures thereof, distilling completely between 25 °C and 120 °C.

EEC No	Name	Conditions of use (summary description of extraction)	Maximum residues in the extracted food or food ingredient
	Dichloromethane	Decaffeination of, or removal of, irritants and bitterings from coffee and tea	10 mg/kg in the coffee or tea
		Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
	Trichloroethylene	Production or fractionation of fats and oils	5 mg/kg in the fat or oil
		Production of cocoa butter	5 mg/kg in the cocoa butter
		Decaffeination of, or removal of, irritants and bitterings from coffee and tea	5 mg/kg in the coffee or tea
		Preparation of flavourings from natural flavouring materials	1 mg/kg in the food containing the flavouring
	Anhydrous solution of ammonia in methanol, ethanol, propan-1-ol, propan-2-ol or butan-2-ol	Preparation of protein products and defatted wheat flour	20 mg/kg of the alcohol in the protein product or flour

Amendment to the Amended proposal for a Council Directive on containers of liquids for human consumption ⁽¹⁾

COM(83) 638 final

(Submitted by the Commission to the Council pursuant to Article 149 (2) of the EEC Treaty on 3 November 1983)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas the first action programme of the European Communities on the environment ⁽²⁾ recognizes the need for Community action relating to certain types of waste, including used containers; whereas the second action programme of the European Communities on the environment ⁽³⁾ emphasizes *inter*

alia the importance of re-using or recycling the various materials contained in waste;

Whereas Article 3 of Council Directive 75/442/EEC of 15 July 1975 on waste ⁽⁴⁾ calls for the implementation of measures to encourage the prevention, recycling and processing of waste;

Whereas, at its meeting of 9 April 1979, when examining the communication from the Commission on the tightening-up of the Community's environmental policy ⁽⁵⁾, the Council called on the Commission to propose appropriate measures to promote *inter alia* the standardization of containers of liquids for human consumption ⁽⁶⁾;

Whereas containers of liquids for human consumption account for a significant proportion of urban waste and are a source of litter; whereas the cost of collecting and disposing of household waste is a matter of growing concern to local authorities and Governments in the Member States;

⁽¹⁾ OJ No C 204, 13. 8. 1981, p. 6.

⁽²⁾ OJ No C 112, 20. 12. 1973, p. 1.

⁽³⁾ OJ No C 139, 13. 6. 1977, p. 33.

⁽⁴⁾ OJ No L 194, 25. 7. 1975, p. 47.

⁽⁵⁾ COM(79)144 final, 22. 3. 1979.

⁽⁶⁾ Document 6755/79 (ENV/73), 29. 5. 1979.