

II

(Acts whose publication is not obligatory)

COUNCIL

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;

⁽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.

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 trichloroethylene 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.

⁽¹⁾ OJ No L 291, 19. 11. 1969, p. 9.

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

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

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 coffee or tea
Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	10 ⁽²⁾ 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 °C and 70 °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

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 (*)
Methyl-propan-1-ol	1 mg/kg

(*) *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°.