Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (Recast) (Text with EEA relevance)

#### DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 23 April 2009

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

(Recast)

### (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:

- (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>. Since further amendments are to be made, it should be recast in the interests of clarity.
- (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 internal market.
- (3) The approximation of those laws is therefore necessary if the free movement of foodstuffs is to be achieved.
- (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.
- (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.
- (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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- (7) Under such conditions, the presence of residues or derivatives in the final foodstuff or food ingredient may be unintentional but technically unavoidable.
- (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.
- (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 maximum residue values permitted in food and food ingredients should be established.
- (10) Specific purity criteria for extraction solvents and methods of analysis and sampling of extraction solvents in and on foodstuffs should be established.
- (11) 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.
- (12) 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>.
- (13) In particular, the Commission should be empowered to amend the list of extraction solvents which may be used during the processing of the raw materials, of foodstuffs, of food components or of food ingredients, and the specification of their conditions of use and maximum residue limits, and to adopt specific purity criteria for extraction solvents and the methods of analysis necessary to verify compliance with the general and specific purity criteria as well as methods of analysis and sampling of extraction solvents in and on foodstuffs. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (14) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of amendments of the list of extraction solvents which may be used during the processing of the raw materials, of foodstuffs, of food components or of food ingredients, and the specification of their conditions of use and maximum residue limits, and for the adoption of specific purity criteria for extraction solvents.
- (15) When, on imperative grounds of urgency, in particular where a risk to human health exists, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of the list of extraction solvents which may be used during the processing of the raw materials, of foodstuffs, of food components or of food ingredients, and the specification of their conditions of use and maximum residue limits, and for the adoption of specific purity criteria for extraction solvents, as well as for the adoption of amendments to

this Directive when it is established 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.

- (16) The new elements introduced into this Directive only concern the committee procedures. They therefore do not need to be transposed by the Member States.
- (17) 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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- (1) OJ C 224, 30.8.2008, p. 87.
- (2) Opinion of the European Parliament of 23 September 2008 (not yet published in the Official Journal) and Council Decision of 23 March 2009.
- (**3**) OJ L 157, 24.6.1988, p. 28.
- (4) See Annex II, Part A.
- (5) OJ L 184, 17.7.1999, p. 23.