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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⁽¹⁾

Name:

Propane
Butane
Ethyl acetate
Ethanol
Carbon dioxide
Acetone⁽²⁾
Nitrous oxide

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 ^a	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or cocoa butter
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
a	Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. The combined use of Hexane and Ethylmethylketone is forbidden.	
b	The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.	
c	[¹ ‘Gelatine’ means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004.	
d	‘Collagen’ means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.]	

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	Preparation of defatted cereal germs	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 ^b	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	2 mg/kg in the roasted coffee and 5 mg/kg in the tea
Methanol	For all uses	10 mg/kg
Propan-2-ol	For all uses	10 mg/kg
[^{F2} Dimethyl ether	Preparation of defatted animal protein products including gelatine ^c	0,009 mg/kg in the defatted animal protein products including gelatine
	Preparation of collagen ^d and collagen derivatives, except gelatine]	3 mg/kg in the collagen and collagen derivatives, except gelatine]

a Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. The combined use of Hexane and Ethylmethylketone is forbidden.

b The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.

c [^{F1}‘Gelatine’ means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004.

d ‘Collagen’ means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.]

Textual Amendments

- F1** Inserted by [Commission Directive \(EU\) 2016/1855 of 19 October 2016 amending Directive 2009/32/EC 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 \(Text with EEA relevance\).](#)
- F2** Substituted by [Commission Directive \(EU\) 2016/1855 of 19 October 2016 amending Directive 2009/32/EC 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 \(Text with EEA relevance\).](#)

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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 ^a	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 ^a	1 mg/kg
Dichloromethane	0,02 mg/kg
Propan-1-ol	1 mg/kg
1,1,1,2-tetrafluoroethane	0,02 mg/kg
[^{F3} Methanol	1,5 mg/kg
Propan-2-ol	1 mg/kg]

a The combined use of Hexane and Ethylmethylketone is forbidden.

Textual Amendments

F3 Inserted by [Commission Directive 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC 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 \(Text with EEA relevance\).](#)

ANNEX II

PART A

REPEALED DIRECTIVE WITH LIST OF 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)	

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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)	
Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)	Point 9 of Annex III only

PART B

TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW

(referred to in Article 9)

Directive	Time-limit for transposition
88/344/EEC	13 June 1991
92/115/EEC	a. 1 July 1993 b. 1 January 1994 ^a
94/52/EC	7 December 1995
97/60/EC	a. 27 October 1998 b. 27 April 1999 ^b
a	In accordance with Article 2(1) of Directive 92/115/EEC: Member States shall amend their laws, regulations and administrative provisions in such a way as to: <ul style="list-style-type: none"> — 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.
b	In accordance with Article 2(1) of Directive 97/60/EC: Member States shall amend their laws, regulations and administrative provisions so as to: <ul style="list-style-type: none"> — authorise 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.

ANNEX III

CORRELATION TABLE

Directive 88/344/EEC	This Directive
Article 1(1)	Article 1(1)
Article 1(3)	Article 1(2)

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Article 2(1)	Article 2(1)
Article 2(2)	Article 2(2)
Article 2(3)	—
Article 2(4)	Article 2(3)
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6(1)	Article 6(1)
Article 6(2)	—
Article 6(3)	—
—	Article 6(2)
—	Article 6(3)
—	Article 6(4)
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

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- (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.
- (2) The use of Acetone in the refining of olive-pomace oil is forbidden.