

DIRECTIVE 2006/52/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 July 2006

amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs

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 ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

- (1) Food additives may be approved for use in foodstuffs only if they comply with Annex II to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption ⁽³⁾.
- (2) Directive 95/2/EC ⁽⁴⁾ lays down a list of food additives that may be used in the Community and the conditions for their use.
- (3) Directive 94/35/EC ⁽⁵⁾ lays down a list of sweeteners that may be used in the Community and the conditions for their use.

(4) There have been technical developments in the field of food additives since the adoption of Directives 95/2/EC and 94/35/EC. These Directives should be adapted to take account of those developments.

(5) On the basis of an opinion of the European Food Safety Authority (EFSA), expressed on 26 November 2003, changes are made to current authorisations in order to keep the level of nitrosamines as low as possible by bringing down the levels of nitrites and nitrates added to food whilst maintaining the microbiological safety of food products. EFSA recommends that the levels of nitrite and nitrate are set in the legislation as 'added amount'. EFSA is of the opinion that the added amount of nitrite rather than the residual amount contributes to the inhibitory activity against *C. botulinum*. The current provisions should be amended in such a way that the maximum levels permitted, as mentioned by EFSA, in non-heat-treated or heat-treated meat products, in cheese and in fish are expressed as added amounts. Exceptionally, however, for certain traditionally manufactured meat products maximum residual levels should be set, on the condition that the products are adequately specified and identified. The levels set should ensure that the acceptable daily intake (ADI) established by the Scientific Committee on Food in 1990 is not exceeded. Products which are not specifically named in this Directive, but which are traditionally produced in a similar manner (i. e. similar products) can if necessary be categorised in accordance with Articles 5 and 6 of Directive 95/2/EC. For cheese, the level should be expressed as the amount added to the cheese milk. If a process is used where addition of nitrate follows removal of whey and addition of water, this should lead to levels identical to those which would have been obtained had the nitrate been added directly to the cheese milk.

(6) Directive 2003/114/EC amending Directive 95/2/EC required the Commission and EFSA to review the conditions for the use of E 214 to E 219 p-hydroxybenzoates and their sodium salts before 1 July 2004. EFSA assessed the information on the safety of p-hydroxybenzoates and expressed its opinion on 13 July 2004. EFSA established a full-group ADI of 0 to 10 mg/kg body weight for the sum of methyl and ethyl p-hydroxybenzoic acid esters and their sodium salts. EFSA considered that propyl paraben should not be included in this group ADI because propyl paraben, contrary to methyl and ethyl paraben, had effects on sex hormones and the male reproductive organs in juvenile rats. Therefore, EFSA was unable to recommend an ADI for propyl paraben because of the lack of a clear no-observed-adverse-effect-level (NOAEL). It is necessary to withdraw E 216 propyl p-hydroxybenzoate and E 217 sodium propyl p-hydroxybenzoate from Directive 95/2/EC. In addition, it is necessary to withdraw the use of p-hydroxybenzoates in liquid dietary food supplements.

⁽¹⁾ OJ C 255, 14.10.2005, p. 59.

⁽²⁾ Opinion of the European Parliament of 26 October 2005 (not yet published in the Official Journal). Council Decision of 2 June 2006.

⁽³⁾ OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽⁴⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2003/114/EC (OJ L 24, 29.1.2004, p. 58).

⁽⁵⁾ OJ L 237, 10.9.1994, p. 3. Directive as last amended by Directive 2003/115/EC (OJ L 24, 29.1.2004, p. 65).

- (7) Commission Decision 2004/374/EC⁽¹⁾ suspended the placing on the market and import of jelly mini-cups containing gel-forming food additives derived from seaweed and certain gums due to the risk of choking on these products. Following a review of that Decision it is necessary to exclude the use of certain gel-forming food additives in jelly mini-cups.
- (8) The Scientific Committee on Food assessed the information on the safety of erythritol and expressed its opinion on 5 March 2003. The Committee concluded that the use of erythritol as a food additive is acceptable. The Committee also notes that erythritol has a laxative effect, but at a higher dose than other polyols. Erythritol has many technological non-sweetening properties that are important in a wide range of foods, from confectionery to dairy products. These include functions such as flavour enhancer, carrier, humectant, stabiliser, thickener, bulking agent and sequestrant. It is necessary to permit the use of erythritol in the same food applications as the other currently permitted polyols. In addition, it is necessary to amend Directive 94/35/EC, as erythritol can also be used for sweetening purposes like the other currently permitted polyols.
- (9) The Scientific Committee on Food assessed the information on the safety of soybean hemicellulose and expressed its opinion on 4 April 2003. The Committee concluded that the use of soybean hemicellulose is acceptable in certain foods in respect of which the request was made and at certain inclusion levels. It is therefore appropriate to permit such use for certain purposes. In order to facilitate matters for allergy sufferers, however, such use should not be permitted for unprocessed foods in which soybean is not expected to be found. At all events, consumers should be informed when products contain hemicellulose derived from soybean in accordance with the provisions of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁽²⁾.
- (10) EFSA assessed the information on the safety of ethyl cellulose and expressed its opinion on 17 February 2004. EFSA decided to include ethyl cellulose in the group ADI 'not specified' for modified celluloses established by the Scientific Committee on Food. The main application of ethyl cellulose is in food supplements and encapsulated flavourings. The use of ethyl cellulose should therefore be permitted in a way similar to that for other celluloses.
- (11) EFSA assessed the information on the safety of pullulan and expressed its opinion on 13 July 2004. EFSA found the use of pullulan acceptable in the coating of food supplements that are in the form of capsules and tablets as well as in breath fresheners in the form of films. It is therefore appropriate to permit these uses.
- (12) EFSA assessed the information on the safety of tertiary butyl hydroquinone (TBHQ) and expressed its opinion on 12 July 2004. EFSA established an ADI of 0 to 0,7 mg/kg body weight for this antioxidant and found that its use would be acceptable in certain foodstuffs at certain inclusion levels. It is therefore appropriate to permit this additive.
- (13) The Scientific Committee on Food assessed the information on the safety of starch aluminium octenyl succinate and expressed its opinion on 21 March 1997. The Committee found that the use of this additive as a component of micro encapsulated vitamins and carotenoids may be regarded as acceptable. It is therefore appropriate to permit this use.
- (14) During the manufacture of sour milk cheese, E 500ii sodium hydrogen carbonate is added to the pasteurised milk in order to buffer the acidity caused by the lactic acid to an appropriate pH value, thereby creating the necessary growth conditions for the ripening cultures. It is, therefore, appropriate to permit the use of sodium hydrogen carbonate in sour milk cheese.
- (15) Currently, the use of a mixture of sorbates (E 200, E 202 and E 203) and benzoates (E 210 to E 213) is authorised in cooked shrimps for preservation. It is appropriate to extend that authorisation to its use in all cooked crustaceans and molluscs.
- (16) E 551 silicon dioxide is permitted as a carrier for food colours at the maximum level of 5 %. The use of silicon dioxide as a carrier for food colours E 171 titanium dioxide and E 172 iron oxides and hydroxides should also be permitted at the level of maximum 90 % relative to the pigment.
- (17) Directive 95/2/EC limits the use of additives listed in Annex I to that Directive in traditional French bread '*Pain courant français*'. The same limitation should apply to similar traditional Hungarian bread. It is also appropriate to authorise use of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium disodium EDTA (E 385) in Hungarian liver patés.
- (18) It is necessary to update the current provisions regarding the use of sulphites (E 220 to E 228) in cooked crustaceans, table grapes and lychees.
- (19) In accordance with a request from a Member State and the opinion of the Scientific Committee on Food of 5 March 2003, 4-hexylresorcinol, which was authorised at national level under Directive 89/107/EEC, should be authorised at Community level.

(1) OJ L 118, 23.4.2004, p. 70.

(2) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(20) The terminology used in Directive 95/2/EC should be adapted to take into account Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses ⁽¹⁾, Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽²⁾ and Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes ⁽³⁾.

(21) Directives 95/2/EC and 94/35/EC should, therefore, be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is hereby amended as follows:

1. Article 1(3)(c) shall be replaced by the following:

‘(c) “carriers”, including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or flavouring without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;’;
2. in Article 3(2) ‘weaning foods’ shall be replaced by ‘processed cereal-based foods and baby foods’;
3. the Annexes shall be amended in accordance with Annex I to this Directive.

Article 2

The Annex to Directive 94/35/EC shall be amended in accordance with Annex II to this Directive.

Article 3

1. Member States shall bring into force by 15 February 2008 the laws, regulations and administrative provisions necessary to comply with this Directive in order to:

- (a) permit trade in and the use of products complying with this Directive by 15 February 2008;
- (b) prohibit trade in and use of products which do not comply with this Directive by 15 August 2008.

However, products placed on the market or labelled before 15 August 2008 which do not comply with this Directive may be marketed until stocks are exhausted.

Member States shall forthwith communicate to the Commission the text of such laws, regulations and administrative provisions, together with a correlation table between them and this Directive.

2. When Member States adopt the laws, regulations and administrative provisions referred to in paragraph 1, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 4

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Strasbourg, 5 July 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

P. LEHTOMÄKI

⁽¹⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.

⁽²⁾ OJ L 183, 12.7.2002, p. 51.

⁽³⁾ OJ L 91, 7.4.1999, p. 29. Directive as amended by the 2003 Act of Accession.

ANNEX I

The Annexes to Directive 95/2/EC are amended as follows:

(1) Annex I is amended as follows:

(a) in the introductory note, the following note is added:

- '4. The substances listed under numbers E 400, E 401, E 402, E 403, E 404, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417, E 418 and E 440 may not be used in jelly mini-cups, defined, for the purpose of this Directive, as jelly confectionery of a firm consistence, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cups or mini-capsule to project the confectionery into the mouth.'

(b) in the table, the following row is inserted:

'E 462	Ethyl cellulose'
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(2) Annex II is amended as follows:

(a) the row for 'ripened cheese' is replaced by the following:

'Ripened cheese	E 170 Calcium carbonate E 504 Magnesium carbonates E 509 Calcium chloride E 575 Glucono-delta-lactone E 500ii Sodium hydrogen carbonate	<i>quantum satis</i> <i>quantum satis (only for sour milk cheese)</i> ;
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(b) in the row for '*Pain courant français*' after the words '*Pain courant français*' the following words are added: '*Friss búzakenyér, fehér és félbarna kenyerek*';

(c) in the row for '*Foie gras, foie gras entier, blocs de foie gras*' after the words '*Foie gras, foie gras entier, blocs de foie gras*' the following words are added: '*Libamáj, libamáj egészben, libamáj tömbben*';

(3) Annex III is amended as follows:

(a) Part A is amended as follows:

(i) in the table 'Sorbates, benzoates and p-hydroxybenzoates', the rows for 'E 216 Propyl p-hydroxybenzoate' and 'E 217 Sodium propyl p-hydroxybenzoate' are deleted;

(ii) the table for foodstuffs is amended as follows:

— the following rows are deleted:

'Shrimps, cooked				2 000		
Crayfish tails, cooked, and pre-packed marinated cooked molluscs	2 000					
Liquid dietary food supplements						2 000';

- the following rows are added:

'Crustaceans and molluscs, cooked		1 000		2 000		
Food supplements as defined in Directive 2002/46/EC (*) supplied in liquid form				2 000		

(*) Directive 2002/46/EC of the European Parliament and of the Council (OJ L 183, 12.7.2002, p. 51).'

- the words 'Dietetic food intended for special medical purposes' are replaced by the words 'Dietary foods for special medical purposes as defined in Directive 1999/21/EC (*)'

(*) Commission Directive 1999/21/EC (OJ L 91, 7.4.1999, p. 29).'

- (b) in Part B the table for foodstuffs is amended as follows:

- the row for 'crustaceans and cephalopods' is replaced by the following:

'Crustaceans and cephalopods:	
— fresh, frozen and deep-frozen	150 ⁽¹⁾
— crustaceans, <i>Penaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family:	
— up to 80 units	150 ⁽¹⁾
— between 80 and 120 units	200 ⁽¹⁾
— over 120 units	300 ⁽¹⁾
Crustaceans and cephalopods	
— cooked	50 ⁽¹⁾
— cooked crustaceans, <i>Penaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family:	
— up to 80 units	135 ⁽¹⁾
— between 80 and 120 units	180 ⁽¹⁾
— over 120 units	270 ⁽¹⁾

⁽¹⁾ In edible parts.'

- the entry 'Starches (excluding starches for weaning foods, follow-on formulae and infant formulae)' is replaced by 'Starches (excluding starches in infant formulae, follow-on formulae and processed cereal-based foods and baby foods)';
- the following rows are added:

'Salsicha fresca	450
Table grapes	10
Fresh lychees	10 (measured on edible parts)';

(c) in Part C the table for E 249, E 250, E 251 and E 252 is replaced by the following:

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO ₂)	Maximum residual level (expressed as NaNO ₂)
E 249	Potassium nitrite (*)	Meat products	150 mg/kg	
E 250	Sodium nitrite (*)	Sterilised meat products (Fo > 3,00) (*)	100 mg/kg	
		Traditional immersion cured meat products (1): <i>Wiltshire bacon</i> (1.1); <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)</i> <i>Toucinho fumado</i> (1.2); and similar products		175 mg/kg
		<i>Wiltshire ham</i> (1.1); and similar products		100 mg/kg
		<i>Rohschinken, nassgepökelt</i> (1.6); and similar products		50 mg/kg
		<i>Cured tongue</i> (1.3)		
		Traditional dry cured meat products (2): <i>Dry cured bacon</i> (2.1); and similar products		175 mg/kg
		<i>Dry cured ham</i> (2.1); <i>Jamón curado, paleta curada, lomo embuchado y cecina</i> (2.2); <i>Presunto, presunto da pá and paio do lombo</i> (2.3); and similar products		100 mg/kg
		<i>Rohschinken, trocken-/nassgepökelt</i> (2.5); and similar products		50 mg/kg
		Other traditionally cured meat products (3): <i>Vysočina</i> <i>Selský salám</i> <i>Turistický trvanlivý salám</i> <i>Poličan</i> <i>Herkules</i> <i>Lovecký salám</i> <i>Dunajská klobása</i> <i>Paprikáš</i> (3.5); and similar products	180 mg/kg	
		<i>Rohschinken, trocken-/nassgepökelt</i> (3.1); and similar products <i>Jellied veal and brisket</i> (3.2)		50 mg/kg

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO ₂)	Maximum residual level (expressed as NaNO ₂)
E 251 E 252	Potassium nitrate ^(?) Sodium nitrate ^(?)	Non-heat-treated meat products	150 mg/kg	
		<p>Traditional immersion cured meat products (1):</p> <p><i>Kylmäsavustettu poronliha/ Kallrökt renkött</i> (1.4);</p> <p>Wiltshire bacon and Wiltshire ham (1.1); <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados), Toucinho fumado</i> (1.2); <i>Rohschinken, nassgepökelt</i> (1.6); and similar products</p> <p>Bacon, <i>Filet de bacon</i> (1.5); and similar products</p> <p><i>Cured tongue</i> (1.3)</p> <p>Traditional dry cured meat products (2): <i>Dry cured bacon and Dry cured ham</i> (2.1); <i>Jamón curado, paleta curada, lomo embuchado y cecina</i> (2.2);</p> <p><i>Presunto, presunto da pá and paio do lombo</i> (2.3); <i>Rohschinken, trockengepökelt</i> (2.5); and similar products</p> <p><i>Jambon sec, jambon sel sec et autres pièces maturées séchées similaires</i> (2.4)</p>	<p>300 mg/kg</p>	<p>250 mg/kg</p> <p>250 mg/kg without added E 249 or E 250</p> <p>10 mg/kg</p> <p>250 mg/kg</p>
		<p>Other traditionally cured meat products (3): <i>Rohwürste (Salami and Kantwurst)</i> (3.3);</p> <p><i>Rohschinken, trocken-/nassgepökelt</i> (3.1); and similar products</p> <p><i>Salchichón y chorizo tradicionales de larga curación</i> (3.4); <i>Saucissons secs</i> (3.6); and similar products</p> <p><i>Jellied veal and brisket</i> (3.2);</p>	<p>300 mg/kg (without added E 249 or E 250)</p> <p>250 mg/kg</p> <p>250 mg/kg (without added E 249 or E 250)</p>	<p>250 mg/kg without added E 249 or E 250</p> <p>10 mg/kg</p>

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO ₂)	Maximum residual level (expressed as NaNO ₂)
		Hard, semi-hard and semi-soft cheese	150 mg/kg in the cheese milk or equivalent level if added after removal of whey and addition of water	
		Dairy-based cheese analogue		
		Pickled herring and sprat	500 mg/kg	

- (*) When labelled "for food use", nitrite may be sold only in a mixture with salt or a salt substitute.
- (†) Fo-value 3 is equivalent to 3 minutes heating at 121 °C (reduction of the bacterial load of one billion spores in each 1 000 cans to one spore in a thousand cans).
- (‡) Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment.
- 1 Meat products are immersed in curing solution containing nitrites and/or nitrates, salt and other components. The meat products may undergo further treatments e.g. smoking.
 - 1.1 Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures.
 - 1.2 Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity.
 - 1.3 Immersion cured for at least 4 days and pre-cooked.
 - 1.4 Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks.
 - 1.5 Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24 hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C.
 - 1.6 Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation.
 - 2 Dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation. The meat products may undergo further treatments e.g. smoking.
 - 2.1 Dry curing followed by maturation for at least 4 days.
 - 2.2 Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days.
 - 2.3 Dry cured for 10 to 15 days followed by a 30 to 45 day stabilisation period and a maturation period of at least 2 months.
 - 2.4 Dry cured for 3 days + 1 day/kg followed by a 1 week post-salting period and an ageing/ripening period of 45 days to 18 months.
 - 2.5 Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation.
 - 3 Immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking. The products may undergo further treatments e.g. smoking.
 - 3.1 Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/maturation.
 - 3.2 Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours.
 - 3.3 Product has a minimum 4-week maturation period and a water/protein ratio of less than 1,7.
 - 3.4 Maturation period of at least 30 days.
 - 3.5 Dried product cooked to 70 °C followed by 8 to 12 day drying and smoking process. Fermented product subject to 14 to 30 day three-stage fermentation process followed by smoking.
 - 3.6 Raw fermented dried sausage without added nitrites. Product is fermented at temperatures in the range of 18 to 22 °C or lower (10 to 12 °C) and then has a minimum ageing/ripening period of 3 weeks. Product has a water/protein ratio of less than 1,7;

(d) Part D is amended as follows:

- (i) the Note is replaced by: 'The * in the table refers to the proportionality rule: when combinations of gallates, TBHQ, BHA and BHT are used, the individual levels must be reduced proportionally';
- (ii) row E 310 to E 321 and row E 310 to E 320 are replaced by the following:

'E 310	Propyl gallate	Fats and oils for the professional manufacture of heat-treated food-stuffs	200 * (gallates, TBHQ and BHA, individually or in combination)
E 311	Octyl gallate	Frying oil and frying fat, excluding olive pomace oil	100 * (BHT)
E 312	Dodecyl gallate		
E 319	Tertiary-butyl hydroquinone (TBHQ)	Lard; fish oil; beef, poultry and sheep fat	both expressed on fat
E 320	Butylated hydroxyanisole (BHA)	Cake mixes Cereal-based snack foods Milk powder for vending machines	200 (gallates, TBHQ and BHA, individually or in combination)
E 321	Butylated hydroxytoluene (BHT)	Dehydrated soups and broths Sauces Dehydrated meat Processed nuts Pre-cooked cereals	expressed on fat
		Seasonings and condiments	200 (gallates and BHA, individually or in combination) expressed on fat
		Dehydrated potatoes	25 (gallates, TBHQ and BHA, individually or in combination)
		Chewing gum Food supplements as defined in Directive 2002/46/EC	400 (gallates, TBHQ, BHT and BHA, individually or in combination)
		Essential oils	1 000 (gallates, TBHQ and BHA, individually or in combination)
		Flavourings other than essential oils	100 * (gallates, individually or in combination) 200 * (TBHQ and BHA, individually or in combination)';

(iii) the following row is added:

'E 586	4-Hexylresorcinol	Fresh, frozen and deep-frozen crustaceans	2 mg/kg as residues in crustacean meat;
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(4) Annex IV is amended as follows:

(a) the row for E 385 is replaced by the following:

E 385	Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA)	Emulsified sauces	75 mg/kg
		Canned and bottled pulses, legumes, mushrooms and artichokes	250 mg/kg
		Canned and bottled crustaceans and molluscs	75 mg/kg
		Canned and bottled fish	75 mg/kg
		Spreadable fats as defined in Annexes B and C to Regulation (EC) No 2991/94 (*), having a fat content of 41 % or less	100 mg/kg
		Frozen and deep-frozen crustaceans	75 mg/kg
		Libamáj, egészben és tömbben	250 mg/kg

(*) OJ L 316, 9.12.1994, p. 2.;

(b) the following row is inserted after the row for E 967:

E 968	Erythritol	Foodstuffs in general (except drinks and those foodstuffs referred to in Article 2(3))	quantum satis
		Frozen and deep-frozen unprocessed fish, crustaceans, molluscs and cephalopods	quantum satis
		Liqueurs	quantum satis
			For purposes other than sweetening;

(c) the following row is added:

E 426	Soybean hemicellulose	Dairy-based drinks intended for retail sale	5 g/l
		Food supplements as defined in Directive 2002/46/EC	1,5 g/l
		Emulsified sauces	30 g/l
		Pre-packaged fine bakery wares intended for retail sale	10 g/kg
		Pre-packaged ready to eat oriental noodles intended for retail sale	10 g/kg
		Pre-packaged ready to eat rice intended for retail sale	10 g/kg

		<i>Pre-packaged processed potato and rice products (including frozen, deep-frozen, chilled and dried processed products) intended for retail sale</i>	10 g/kg
		<i>Dehydrated, concentrated, frozen and deep-frozen egg products</i>	10 g/kg
		<i>Jelly confectionery, except jelly mini-cups</i>	10 g/kg;

- (d) in row E 468 the words 'Solid dietary supplements' are replaced by the words 'Food supplements as defined in Directive 2002/46/EC supplied in solid form';
- (e) in row E 338 to E 452 the words 'Dietary supplements' are replaced by the words 'Food supplements as defined in Directive 2002/46/EC';
- (f) in row E 405, row E 416, row E 432 to E 436, row E 473 and E 474, row E 475, row E 491 to E 495, row E 551 to E 559, and row E 901 to E 904, the words 'Dietary food supplements' are replaced by the words 'Food supplements as defined in Directive 2002/46/EC';
- (g) in row E 1201 and E 1202 the words 'Dietary food supplements in tablet and coated tablet form' are replaced by the words 'Food supplements as defined in Directive 2002/46/EC in tablet and coated tablet form';
- (h) in row E 405, row E 432 to E 436, row E 473 and E 474, row E 475, row E 477, row E 481 and E 482, row E 491 to E 495 the words 'Dietetic food intended for special medical purposes' are replaced by the words 'Dietary foods for special medical purposes as defined in Directive 1999/21/EC';
- (i) Row E 1505 to E 1520 is replaced by the following:

E 1505	Triethyl citrate	Flavourings	<i>3 g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer; individually or in combination. In the case of beverages, with the exception of cream liqueurs, the maximum level of E 1520 shall be 1 g/l;</i>
E 1517	Glyceryl diacetate (diacetin)		
E 1518	Glyceryl triacetate (triacetin)		
E 1520	Propan-1,2-diol (propylene glycol)		

- (j) the following rows are added:

E 1204	Pullulan	<i>Food supplements as defined in Directive 2002/46/EC in capsule and tablet form</i>	quantum satis
		<i>Breath freshening micro-sweets in the form of films</i>	quantum satis
E 1452	Starch Aluminium Octenyl Succinate	<i>Encapsulated vitamin preparations in food supplements as defined in Directive 2002/46/EC</i>	35 g/kg in food supplement';

(5) Annex V is amended as follows:

(a) the following row is inserted after the row for E 967:

E 968	Erythritol;	
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(b) the following row is inserted after the row for E 466:

E 462	Ethyl cellulose;	
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(c) in the third column of the row for E 551 and E 552 the following sentence is added:

'For E 551: in E 171 titanium dioxide and E 172 iron oxides and hydroxides (max. 90 % relative to the pigment).';

(6) Annex VI is amended as follows:

(a) in the first, second and third paragraph of the introductory note 'weaning foods' are replaced by 'processed cereal-based foods and baby foods';

(b) in Part 3, in the title, in row E 170 to E 526, row E 500, E 501 and E 503, row E 338, row E 410 to E 440, row E 1404 to E 1450 and row E 1451 'weaning foods' are replaced by 'processed cereal-based foods and baby foods';

(c) in Part 4, the following is inserted after row E 472:

E 473	Sucrose esters of fatty acids	120 mg/l	Products containing hydrolysed proteins, peptides and amino acids'
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ANNEX II

The Annex to Directive 94/35/EC is amended as follows:

- (1) in the first column of the row for E 420 to E 967, 'E 968' is added;
 - (2) in the second column of the row for E 420 to E 967, 'Erythritol' is added.
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