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COVER NOTE

from:	European Commission
date of receipt:	31 March 2010
to:	General Secretariat of the Council
Subject:	Draft Commission Directive amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners and repealing Decision 2004/374/EC

Delegations will find attached Commission document D008398/02.

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EUROPEAN COMMISSION

Brussels,
C(2010) final
D008398/02

Draft

COMMISSION DIRECTIVE

of

amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners and repealing Decision 2004/374/EC

(Text with EEA relevance)

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amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners and repealing Decision 2004/374/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[1], and in particular Article 31 thereof,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[2], and in particular Article 53 thereof,

After consulting the Scientific Committee on Food and the European Food Safety Authority,

Whereas:

(1) European Parliament and Council Directive 95/2/EC[3] on food additives other than colours and sweeteners lays down a list of food additives that may be used in the European Union and the conditions for their use.

(2) There have been technical developments in the field of food additives since the adoption of Directive 95/2/EC. This Directive should be adapted to take into account those developments.

(3) In accordance with Article 31 of Regulation (EC) No 1333/2008 until the establishment of the Union lists of food additives as provided for in Article 30 of that Regulation is completed, the Annexes to Directive 95/2/EC shall be amended, where necessary, by measures adopted by the Commission.

(4) The following stabilisers agar (E 406), carrageenan (E 407), locust bean gum (E 410), guar gum (E 412), xanthan gum (E 415), pectins (E 440), cellulose (E 460), carboxy methyl cellulose (E 466), oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated

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1 OJ L 354, 31.12.2008, p. 16.
2 OJ L 31, 1.2.2002, p. 1.
3 OJ L 61, 18.3.1995, p. 1.

distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxyl propyl starch (E 1440), hydroxy propyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and emulsifier mono- and diglycerides of fatty acids (E 471) are currently authorised under Directive 95/2/EC for a variety of uses. These food additives have been allocated an acceptable daily intake (ADI) 'not specified' by the Scientific Committee on Food (hereinafter SCF) and therefore do not present any hazard to the health of consumers. There is a technological need to extend their uses to unflavoured live fermented cream products and substitute products with a fat content of less than 20 % to ensure the stability and integrity of the emulsion. This use would benefit the consumer by providing the choice of reduced fat fermented cream products with similar properties as to the ordinary product. It is therefore appropriate to authorise this additional use.

(5) In 1990, the SCF evaluated sodium and potassium salts of lactate (E 325 and E 326), potassium acetate (E 261), sodium acetate (E 262i) and sodium hydrogen acetate (E 262ii) and came to the conclusion that they are all naturally present as constituents in food and estimates of their intake are likely to be insignificant compared to the intake from natural sources. Therefore they were all allocated a 'group ADI not specified'. Consequently, these food additives are generally permitted for use in all foodstuffs, other than those referred to in Article 2(3) of Directive 95/2/EC. There is a proposal to extend the use of these food additives into pre-packed preparations of fresh minced meat to control the growth of microbial pathogens, e.g. Listeria, *E. coli* O157. Based on this technological justification, and taking into account that this use raises no safety concern, it is appropriate to permit the additional use of these food additives in pre-packed preparations of fresh minced meat.

(6) Sorbates (E 200, E 202, E 203) and benzoates (E 210, E 211, E 212, E 213) are currently permitted as food additives under Directive 95/2/EC. An additional use as preservative of these food additives is proposed in seaweed-based fish product analogues (caviar analogues made of seaweed) as topping on various foods in order to prevent the growth of moulds and yeasts and the formation of mycotoxins. These salts are allocated an ADI of 0-25 mg/kg bw and 0-5 mg/kg/ bw respectively. On the basis of a worst case scenario where the maximum concentrations were used, the intake estimates are very low compared to the ADI. The exposure of the consumer as a result of this use does not give rise to safety concern. It is therefore appropriate to permit the additional use of sorbates and benzoates in seaweed based fish analogue products, bearing in mind the technological justification and the fact that this new product represents a niche market.

(7) The use of sorbates (E 200, E 202, E 203) and benzoates (E 210, E 211, E 212, E 213) is requested for beers in keg to which more than 0,5 % fermentable sugars and/or fruit juices or concentrates have been added and which are directly served on draft. These beers in keg may stay connected to the beer tap for a longer time. As the connection of the keg to the tap cannot be performed under sterile conditions, microbiological contamination of the keg is possible. This is a problem for beers which still contain fermentable sugars because this may lead to the growth of hazardous microorganisms. Therefore antimicrobial agents are required in draft beers and to which fermentable sugars and/or fruit juices or concentrates have been added. From an intake point of view, the consumption on draft of such fruit beers remains marginal and the intake estimates for sorbates and benzoates, on the grounds of a 'worst case approach',

should be below their respective ADIs. Therefore it is appropriate to permit the additional use of sorbates and benzoates in beer in kegs containing more than 0,5 % added fermentable sugar and/or fruit juices or concentrates.

(8) To prevent the development of moulds on citrus fruit, their post harvest treatment with pesticides such as imazalil and thiabendazole is authorised. Sorbates (E 200, E 202, E 203) could be used to replace these pesticides partly or completely for the treatment of citrus fruit. Sorbates can be applied on the surface of the unpeeled fresh citrus fruit via the authorised waxes: beeswax, candelilla wax, carnauba wax and shellac (E 901, E 902, E 903 and E 904 respectively). The exposure of the consumer to these additives due to this use is not a cause of safety concern. It is therefore appropriate to authorise its additional use.

(9) Consumers may choose to supplement their intake of some nutrients with food supplements. For that purpose, vitamin A and combinations of vitamins A and D can be added to food supplements, as defined by Directive 2002/46/EC of the European Parliament and of the Council[4]. For reasons of safe handling, vitamin A and combinations of vitamins A and D have to be formulated into preparations that may require high humidity and high temperature, in the presence of starches and sugars. Such processing may favour the development of microorganisms. In order to prevent the growth of these microorganisms, the addition of sorbates (E 200, E 202, E 203) and benzoates (E 210, E 211, E 212 and E 213) should be authorised in vitamin A and in combinations of vitamins A and D when used in food supplements supplied in dried form.

(10) Sulphur dioxide and sulphites (E 220, E 221, E 222, E 223, E 224, E 226, E 227, E 228) are food additives authorised under Directive 95/2/EC which act primarily as antimicrobial agents and controlling chemical spoilage. Nowadays, transport of fresh fruit has become very important, in particular by sea freight. Such transport may be several weeks. The use of sulphur dioxide and sulphites will protect fresh blueberries against fungi growth. The additional use of sulphur dioxide and sulphites should be authorised in order to help preserve fresh blueberries against fungi growth, bearing in mind that this is likely to represent a niche market. Taking also into consideration the sound technological reasons for including these new authorisations, the need to facilitate worldwide trade and its negligible impact in term of sulphur and sulphite intake, it is therefore appropriate to authorise the additional use of sulphur dioxide in blueberries at the concentration level indicated in the Annex to this Directive.

(11) For the production of cinnamon sticks (*Cinnamomum ceylanicum* only), also known as ‘quills’, the fresh peels of the inner bark of the cinnamon tree is used. The peel is exposed to microbial contamination and insect attacks, particularly under tropical and humid climatic conditions, in the producing country. Sulphur dioxide fumigation is an appropriate treatment against such microbial contamination and insect attacks. In 1994, the SCF established an ADI of 0-0,7 mg/kg bw and considered that the use of sulphur dioxide and other sulphiting agents should be limited in order to limit the occurrence of severe asthmatic reactions. Although the use of sulphur dioxide and sulphites should be limited, this specific use represents a negligible contributor in relation to the intake of sulphur dioxide and sulphites. It is therefore appropriate to

[4] OJ L 183, 12.7.2002, p. 51.

authorise the additional use of sulphur dioxide and sulphites (E 220, E 221, E 222, E 223, E 224, E 226, E 227, E 228) only in this particular type of cinnamon.

(12) The European Food Safety Authority (hereinafter EFSA) assessed the information on the safety of use of nisin in an additional food category of liquid eggs, and on the safety of nisin produced using a modified production process. The EFSA confirmed in its opinion on 26 January 2006[5] the previously established ADI of 0-0,13 mg/kg for the nisin produced using a new manufacturing and extraction process based on fermentation of a sugar medium as a replacement for the traditionally milk-based medium. In this opinion, the EFSA also confirmed that the development of antibiotic resistance should not be expected from the use of nisin in food. According to the EFSA, there are no reports of nisin resistant bacterial mutants showing cross-resistance to therapeutic antibiotic. It considered that this is probably due to the differences between therapeutic antibiotics and nisin in terms of the antimicrobial mode of action. The EFSA furthermore confirmed in its opinion issued on 20 October 2006[6] that the additional use of nisin in pasteurised liquid eggs under the intended conditions of use (maximum limit at 6,25 mg/l) is not a safety concern and is justified from a technological point of view to extend the shelf life of the product and also to prevent the growth of food poisoning spore-forming species, like *Bacillus cereus*, which may survive from pasteurisation treatment. It is therefore appropriate to authorise this additional use of nisin in pasteurised liquid egg.

(13) Dimethyl dicarbonate (DMDC, E 242) is a food additive permitted under Directive 95/2/EC which acts as a preservative in non-alcoholic flavoured drinks, alcohol-free wine and liquid-tea concentrate. The authorisation of this additive was decided on the basis of a positive opinion issued by the SCF in 1990 and confirmed in 1996. The SCF was unable to set an ADI, as DMDC rapidly decomposes into carbon dioxide and methanol. In 2001, the SCF was requested to investigate the safety of use of DMDC in wine. At that time the SCF considered that the formation of methanol and other reaction products, such as methylcarbamate resulting from the use of DMDC for the treatment of alcoholic beverages and wine is similar to that formed in non-alcoholic beverages, and even a heavy consumption of wine would not pose any hazard from methanol and methylcarbamate. The use of DMDC has been requested in order to prevent spoilage as a result of fermentation in unopened non-sterile filled bottles of cider, perry and fruit wines, alcohol-reduced wine, wine-based drinks and all other products covered by Council Regulation (EEC) No 1601/91[7]. These additional uses are not considered as being of safety concern for the consumer. Moreover, the use of DMDC could contribute to the reduction of the sulphur dioxide exposure. It is therefore appropriate to authorise the additional uses of DMDC in cider, perry and fruit wines, alcohol-reduced wine, wine-based drinks and other products covered by Regulation (EEC) No 1601/91.

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5 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of nisin (E 234) as a food additive, *The EFSA Journal* (2006) 314, p. 1.

6 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on the safety in use of nisin as a food additive in an additional category of liquid eggs and on the safety of nisin produced using a modified production process as a food additive, *The EFSA Journal* (2006) 314b, p. 1.

7 OJ L 149, 14.6.1991, p. 1.

(14) The EFSA assessed the information on the safety of use of extracts of rosemary when used as an antioxidant in foodstuffs. Extracts of rosemary are derived from *Rosmarinus officinalis* L. and contain several compounds which exert antioxidative functions (mainly phenolic acids, flavonoids, diterpenoids and triterpenes). Although the toxicological data on extracts of rosemary were insufficient for the EFSA to establish a numerical ADI, the EFSA considered in its opinion on 7 March 2008[8] that the margin of safety was high enough to conclude that dietary exposure resulting from the proposed uses and use levels were of no safety concern. Extracts of rosemary can therefore be authorised where there is a technological justification for their use. The proposed uses of extracts of rosemary as antioxidant should be authorised and E 392 should be assigned as E number for extracts of rosemary.

(15) Whey is a by-product of cheese manufacturing. Some whey protein containing drinks have been developed in order to provide a diet sufficiently rich in proteins. To keep the proteins in suspension during the heat treatment of such drinks, the phosphates must be at levels that are higher than for normal non-alcoholic flavoured drinks. Phosphates should be authorised in whey protein containing sport drinks.

(16) Beeswax (E 901) is currently authorised as a glazing agent for use in small products of fine bakery wares coated with chocolate. This authorisation does not cover ice cream wafers that are not coated with chocolate. In addition to the fact that beeswax can be considered as an alternative to chocolate in pre-packed ice cream wafers, the coating of the wafers with beeswax would prevent the migration of water to the wafer and ensure its crunchiness and the extension of the shelf life of the product and is therefore considered technologically justified. Therefore beeswax should be authorised as a glazing agent to replace fully or partly the in-layer chocolate in pre-packed wafers containing ice-cream.

(17) The EFSA assessed the information on the safety of use of beeswax considering its additional use as a carrier of flavourings in non-alcoholic flavoured drinks. Although the available data on beeswax itself were insufficient to establish an ADI, the EFSA came to the conclusion that, due to the low toxicological profile of beeswax, the existing food uses and the proposed new use of beeswax do not raise safety concern. It is therefore appropriate to authorise this additional use of beeswax as a carrier of flavourings in non-alcoholic flavoured drinks.

(18) Triethyl citrate (E 1505) is currently authorised within the EU under Directive 95/2/EC as a carrier in flavourings, and in dried egg white. Its ADI was established by the SCF in 1990 at 0-20 mg/kg. An extension of use of triethyl citrate has been proposed as glazing agent of food supplement tablets. Triethyl citrate would increase the film resistance of the coating, protecting the tablet from external environment and also increase the duration of release of the product. According to the worst case scenario, this additional source of triethyl citrate intake is negligible (0,25 % of the ADI) compared to the full ADI. Therefore it is appropriate to authorise the additional use of triethyl citrate at EU level as a glazing agent for food supplement tablets.

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[8] Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of rosemary extracts as a food additive, *The EFSA Journal* (2008) 721, p. 1.

(19) The EFSA assessed the information on the safety of polyvinyl alcohol (PVA) as a film-coating agent for food supplements and expressed its opinion on 5 December 2005[9]. The EFSA found the use of PVA in the coating of food supplements that are in the form of capsules and tablets to be of no safety concern. The EFSA considered that the potential human exposure to PVA under the intended conditions of use is expected to be low. PVA is reported to be minimally absorbed following oral administration. The maximum limit of use has been fixed at 18 g/kg based on the worst case scenario and on the basis of which the EFSA has undertaken its risk assessment. Due to the good adhesion qualities and film strength of polyvinyl alcohol, this new food additive is expected to play a technological role as film coating agent for food supplements, in particular in applications where moisture barrier and moisture protection properties are required. It is therefore appropriate to authorise this use at EU level. This new food additive should be assigned the E number E 1203.

(20) The EFSA assessed the information on the safety of use of six grades of polyethylene glycols (PEG 400, PEG 3000, PEG 3350, PEG 4000, PEG 6000, PEG 8000) as film coating agents for use in food supplement products and expressed its opinion on 28 November 2006[10]. The EFSA found the use of these grades of polyethylene glycol as a glazing agent in film-coating formulations for food supplement tablets and capsules under the intended conditions of use of no safety concern. The EFSA has also taken into consideration in its risk assessment the additional source of exposure to these PEGs originating from the use of pharmaceutical products and considered that only a limited additional intake may result from the already approved use of PEG 6000 as carrier for sweeteners, as well as from the use of PEG in food contact materials. It is therefore appropriate to authorise this new use at EU level. In addition, due to the limited intake from PEG 6000 as carrier of sweeteners and its similar toxicological profile with respect to the other PEG grades (the six PEGs have been allocated a group tolerable daily intake (TDI), it is also appropriate to authorise the use of the PEGs evaluated by the EFSA as an alternatives to PEG 6000 as carrier of sweeteners. All these PEGs should be assigned E 1521 as E number.

(21) The EFSA assessed the information on the safety of use of cassia gum as a new food additive acting as gelling agent and thickener and expressed its opinion on 26 September 2006[11]. The EFSA found the use of cassia gum as indicated under the conditions specified raised no safety concern. Although the EFSA considered the available toxicological data on cassia gum as insufficient to derive an ADI, they did not consider that the existing data gave cause for concern. In particular the EFSA highlighted the specific low absorption of cassia gum and the fact that, if hydrolysed at all, cassia gum would be degraded to compounds that will enter the normal metabolic pathways. There is a technological justification for the use of cassia gum through its synergistic gelling effects when added to other regular food gums. It is therefore

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9 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyvinyl alcohol as a coating agent for food supplement, *The EFSA Journal* (2005) 294, p. 1.

10 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyethylene glycol (PEG) as a film coating agent for use in food supplement products, *The EFSA Journal* (2006) 414, p. 1.

11 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to an application on the use of cassia gum as a food additive, *The EFSA Journal* (2006) 389, p. 1.

appropriate to authorise these uses at EU level and to assign E 427 as E number for cassia gum.

(22) The EFSA evaluated the safety of neotame as a flavour enhancer and expressed its opinion on 27 September 2007[12]. The EFSA concluded that neotame is of no safety concern with respect to the proposed uses as a flavour enhancer and established an ADI of 0-2 mg/kg bw/day. Therefore it is necessary to authorise the use of neotame as a flavour enhancer.

(23) The EFSA assessed the information on the safety of use of L-cysteine (E 920) in certain foodstuffs intended for infants and young children. The EFSA concluded in its opinion on 26 September 2006[13] that its proposed use in processed cereal-based foods and foods (specifically baby biscuits) for infants and young children is of no safety concern. Biscuits for infants and young children are required to have a suitable composition, including a controlled content of sugar and fat. However, biscuits with a low fat content have increased brittleness with an associated risk of choking and suffocation due to the biscuit breaking in the child's mouth. The function of the L-cysteine is to act as a dough improver to control the texture of the final product. It is therefore appropriate to authorise the use of L-cysteine in biscuits for infants and young children at EU level.

(24) Commission Decision 2004/374/EC[14] suspended the placing on the market and import of jelly mini-cups containing gel-forming food additives derived from seaweed and certain gums (E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417, E 418) due to the risk of choking posed by these products. Directive 95/2/EC was amended accordingly by Directive 2006/52/EC of the European Parliament and of the Council[15]. Commission Decision 2004/374/EC should therefore be repealed as its provisions have been included in Directive 95/2/EC.

(25) The EFSA assessed the safety of use of an enzyme preparation based on thrombin with fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food and concluded in its opinion on 26 April 2005[16] that this use of the enzyme preparation when produced as outlined in the opinion is of no safety concern. The enzyme preparation consists of thrombin (EC 3.4.21.5) and fibrinogen, both of which are obtained from blood plasma. The thrombin-fibrinogen preparation is applied to meat where the thrombin transforms fibrinogen to fibrin which interacts with collagen enabling the binding of meat pieces in order to produce portion-controlled and standardised products with a uniform shape, thickness and quality. The preparation is also used to upgrade raw materials by binding together small pieces of meat into new

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12 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission on neotame as a sweetener and flavour enhancer, *The EFSA Journal* (2007) 581, p. 1.

13 Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of L-cysteine in foods intended for infants and young children, *The EFSA Journal* (2006) 390, p. 1.

14 OJ L 118, 23.4.2004, p. 70.

15 OJ L 204, 26.7.2006, p. 10.

16 Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to the use of an enzyme preparation based on thrombin:fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food, *The EFSA Journal* (2005) 214, p. 1.

size products. However, in some cases, the use of this enzyme preparation could mislead the consumer as to the state of the final food. It is therefore appropriate to restrict the use of thrombin with fibrinogen in combined meat preparations and meat products which are pre-packed and intended for the final consumer only, in order to ensure that the consumer is informed by means of the labelling about the true nature of the combined food. The food enzyme 'bovine and/or porcine thrombin' should be authorised as a food additive to be used together with fibrinogen which will be added as an ingredient to the meat preparation or meat product. 'Bovine and/or porcine thrombin' and its conditions of use should be carried over to the list of food enzymes when this is established in accordance with Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes[17].

(26) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II to VI to Directive 95/2/EC are amended in accordance with the Annex to this Directive.

Article 2

Commission Decision 2004/374/EC is repealed.

Article 3

1. Member States shall adopt and publish, by 31 March 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with Article 1 of this Directive. They shall forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from 1 April 2011 at the latest.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

[17] OJ L 354, 31.12.2008, p. 7.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
José Manuel BARROSO
The President

ANNEX

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

1. Annex II is amended as follows:

(a) the entry concerning 'Pre-packed preparations of fresh minced meat' is replaced by the following:

Pre-packed preparations of fresh minced meat	'E 261	Potassium acetate	*quantum satis*
	E 262i	Sodium acetate	
	E 262ii	Sodium hydrogen acetate	
	E 300	Ascorbic acid	
	E 301	Sodium ascorbate	
	E 302	Calcium ascorbate	
	E 325	Sodium lactate	
	E 326	Potassium lactate	
	E 330	Citric acid	
	E 331	Sodium citrates	
	E 332	Potassium citrates	
	E 333	Calcium citrates	

(b) at the end of the Annex, the following entry is added:

'Unflavoured live fermented cream products and substitute products with a fat content of less than 20 %	E 406	Agar	*quantum satis*'
	E 407	Carrageenan	
	E 410	Locust bean gum	
	E 412	Guar gum	
	E 415	Xanthan gum	
	E 440	Pectins	
	E 460	Cellulose	
	E 466	Carboxy methyl cellulose	
	E 471	Mono- and diglycerides of fatty acids	
	E 1404	Oxidised starch	
	E 1410	Monostarch phosphate	
	E 1412	Distarch phosphate	
	E 1413	Phosphated distarch phosphate	
	E 1414	Acetylated distarch phosphate	
	E 1420	Acetylated starch	
	E 1422	Acetylated distarch adipate	
	E 1440	Hydroxyl propyl starch	
	E 1442	Hydroxy propyl distarch phosphate	
	E 1450	Starch sodium octenyl succinate	
	E 1451	Acetylated oxidised starch	

2. Annex III is amended as follows:

(a) at the end of Part A, the following entries are added:

'Seaweed-based fish analogue products	1 000	500				
Beer in kegs containing more than 0,5 % added fermentable sugar and/or fruit juices or concentrates	200	200		400		
Unpeeled fresh citrus fruit (surface treatment only)	20					
Food supplements as defined in Directive 2002/46/EC supplied in dried form containing preparations of vitamin A and of combinations of vitamin A and D				1 000 in the product ready for consumption'		

(b) at the end of Part B, the following entries are added:

'Blueberries (*Vaccinium corymbosum* only)	10
Cinnamon (*Cinnamomum ceylanicum* only)	150'

(c) Part C is amended as follows:

(i) the entry concerning the additive E 234 is replaced by the following:

'E 234	Nisin ([1])	Semolina and tapioca puddings and similar products	3 mg/kg
		Ripened cheese and processed cheese	12,5 mg/kg
		Clotted cream	10 mg/kg
		Mascarpone	10 mg/kg
		Pasteurised liquid egg (white, yolk or whole egg)	6,25 mg/l

([1]) This substance may be present in certain cheeses as a result of fermentation process.'

(ii) the entry concerning the additive E 242 is replaced by the following:

'E 242	Dimethyl dicarbonate	Non-alcoholic flavoured drinks Alcohol-free wine Liquid-tea concentrate	250 mg/l ingoing amount, residues not detectable
		Cider, perry, fruit wines Alcohol-reduced wine Wine-based drinks and products covered by Regulation (EEC) No 1601/91	250 mg/l ingoing amount, residues not detectable'

(d) in Part D the following entry is inserted after the entry concerning additive E 316:

‘E 392	Extracts of rosemary	Vegetable oils (excluding virgin oils and olive oils) and fat where content of polyunsaturated fatty acids is higher than 15 % w/w of the total fatty acid, for the use in non heat treated food products	30 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Fish oils and algal oil	50 mg /kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Lard, beef, poultry, sheep and porcine fat Fats and oils for the professional manufacture of heat-treated foodstuffs Frying oil and frying fat, excluding olive oil and olive pomace oil Snack foods (snack based on cereals, potatoes or starch)	
		Sauces	100 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis

		Fine bakery wares	200 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Food supplements as defined in Directive 2002/46/EC	400 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dehydrated potatoes Egg products Chewing gum	200 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Milk powder for vending machines Seasoning and condiments Processed nuts	200 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Dehydrated soups and broths	50 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dehydrated meat	150 mg/kg (expressed as the sum of carnosol and carnosic acid)

		Meat and fish products, excluding dehydrated meat and dried sausage	150 mg/kg (expressed as the sum of carnosol and carnosic acid) Expressed on fat basis
		Dried sausage	100 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Flavourings	1000 mg/kg (expressed as the sum of carnosol and carnosic acid)
		Dried milk for the manufacturing of ice cream	30 mg/kg (expressed as the sum of carnosol and carnosic acid)”

3. Annex IV is amended as follows:

(a) in the entry concerning additives E 338, E 339, E 340, E 341, E 343, E 450, E 451 and E 452, the following row is inserted after the row concerning ‘vegetable protein drinks’:

		‘Whey protein containing sport drinks	4 g/kg’

(b) the following entry is inserted before the entry concerning additives E 432, E 433, E 434, E 435 and E 436:

'E 427	Cassia gum	Edible ices	2 500 mg/kg
		Fermented milk products with the exception of unflavoured live fermented milk products	
		Dairy-based dessert and similar products	
		Filling, topping and coating for fine bakery wares and dessert	
		Processed cheese	
		Sauces and salads dressing	
		Dehydrated soups and broths	
		Heat-treated meat products	1 500 mg/kg'

(c) in the entry for E 901, E 902, and E 904, in the third column, under the use 'As glazing agent only for', the following entry is added:

		'— Pre-packed wafers containing ice cream (only for E 901)	*quantum satis*'

(d) in the entry for E 901, E 902, and E 904, in the third column, below the use as 'Peaches and pineapples (surface treatment only)', the following entry is added:

		'Flavourings in non-alcoholic flavoured drinks (only for E 901)	0,2 g/kg in the flavoured drinks'

(e) the following entry is inserted after the entry concerning the additive E 959:

‘E 961	Neotame	Water-based flavoured drinks, energy-reduced or with no added sugar	2 mg/l as flavour enhancer
		Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	2 mg/l as flavour enhancer
		“Snacks”: certain flavours of ready-to-eat, pre-packed, dry, savoury starch products and coated nuts	2 mg/kg as flavour enhancer
		Starch-based confectionery, energy-reduced or with no added sugar	3 mg/kg as flavour enhancer
		Breath-freshening micro-sweets, with no added sugar	3 mg/kg as flavour enhancer
		Strongly flavoured throat pastilles with no added sugar	3 mg/kg as flavour enhancer
		Chewing gum with no added sugar	3 mg/kg as flavour enhancer
		Energy-reduced jams, jellies and marmalades	2 mg/kg as flavour enhancer
		Sauces	2 mg/kg as flavour enhancer
		Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	2 mg/kg as flavour enhancer

		Food supplements as defined in Directive 2002/46/EC supplied in a solid form	2 mg/kg as flavour enhancer
		Food supplements as defined in Directive 2002/46/EC based on vitamins and/or mineral elements and supplied in a syrup-type or non-chewable form	2 mg/kg as flavour enhancer’

(f) the following entry is inserted after the entry concerning additive E 1202:

‘E 1203	Polyvinyl alcohol	Food supplements as defined in Directive 2002/46/EC in capsule and tablet form	18 g/kg’

(g) after the entry concerning the additive E 1202, the entry concerning only the food additive E 1505 is replaced by the following:

‘E 1505	Triethyl citrate	Food supplements as defined in Directive 2002/46/EC in capsule and tablet form	3,5 g/kg
		Dried egg white	*quantum satis*’

(h) the following entries are inserted after the entry concerning the additive E 1452:

‘E 1521	Polyethylene glycol	Food supplements as defined in Directive 2002/46/EC in capsule and tablet form	10 g/kg
—	Bovine and/or porcine thrombin	Pre-packed meat preparations and pre-packed meat products intended for the final consumer only	1 mg/kg expressed as thrombin To be used together with fibrinogen The food shall bear the information “combined meat parts” in the proximity of its sales name’

4. Annex V is amended as follows

the entry concerning the additive ‘Polyethyleneglycol 6000’ is replaced by the following:

‘E 1521	Polyethylene glycol	Sweeteners’

5. Annex VI is amended as follows,

the following entry is added after the entry concerning additive E 526:

‘E 920	L-cysteine	Biscuits for infants and young children	1 g/kg’