COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.10.2004
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2004/0237 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. AMENDMENT TO DIRECTIVE 95/2/EC

Directive 95/2/EC on food additives other than colours and sweeteners sets out a list of authorised food additives, the foodstuffs in which they may be used and their conditions of use. The Directive was adopted in February 1995 and has since been amended five times: in 1996, 1998, 2000 and twice in 2003.

It now needs again to be adapted in the light of recent technical and scientific developments. The intention of this proposal is to ensure the functioning of the internal market, a high level of protection of human health and the protection of consumers' interests.

It is proposed to amend the Directive as follows:

1. Revision of current authorisations

a) Nitrite and nitrate

Salts of nitrite and nitrate are permitted for use in meat products, cheese and certain fish products for preservation.

Due to the judgement of the Court of Justice in Case C-3/00, Denmark v. Commission, the Commission consulted the European Food Safety Authority (EFSA) for advice on the current authorisation of nitrite and nitrate in meat products.

On the basis of the opinion of EFSA, expressed in November 2003, the Commission is now proposing changes to current authorisations in order to keep the level of nitrosamines as low as possible by lowering the levels of nitrites and nitrates added to food whilst maintaining the microbiological safety of food products.

EFSA confirms that nitrite contributes to microbiological safety and also to the flavour, colour and anti-oxidative stability of meat products. Levels up to 100 mg/kg of added nitrite might suffice for preservation of many products, but some might require up to 150 mg/kg.

EFSA notes that nitrate provides no direct protection against the growth of *Clostridium botulinum* in most meat products. However, the use of nitrate as a reservoir of nitrite appears necessary, in particular, in traditionally-cured meat products.

EFSA recommends that the levels of nitrite and nitrate are set down 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*.

Furthermore, EFSA is of the opinion that monitoring of residual levels of nitrites/nitrates in the final product is of limited value. The main reason is that the rate of loss of nitrite in a product is dependent on a number of factors including the heat process used, the pH of the product, the storage temperature and the addition of ascorbic acid or other reducing agents. Consequently, the detection of low levels of nitrite will give no indication as to whether a product was recently manufactured

with an initial low level of nitrite or was a product that had been stored for several months at a low temperature with an initially modest level of nitrite, or whether it was a product which contained, in addition, ascorbate.

It is proposed to amend the current provisions 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 set as added amounts. However, for certain traditionally-manufactured meat products maximum residual levels should be set.

b) Weaning foods

Annex VI of Directive 95/2/EC lays down the provisions for the use of food additives in foods for infants and young children. In order to align the wording on foods for infants and young children with Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, it is proposed that every reference made to "weaning foods" shall be replaced by a reference to "processed cereal-based foods and baby foods". By this proposal, the Commission has fulfilled its commitment made during the adoption of Directive 2003/114/EC amending Directive 95/2/EC.

c) Food supplements and foods for special medical purposes

The designation of certain food categories in Directive 95/2/EC should be adapted to take into account Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements and Commission Directive 1999/21/EC on dietary foods for special medical purposes. Therefore, it is proposed that every reference made to "dietary food supplements" will be replaced by a reference to "food supplements as defined in Directive 2002/46/EC" and every reference to "dietetic foods intended for special medical purposes" will be replaced by a reference to "dietary foods for special medical purposes as defined in Directive 1999/21/EC".

d) p-Hydroxybenzoates

Directive 2003/114 amending Directive 95/2/EC on food additives other than colours and sweeteners obliges the Commission and the European Food Safety Authority to review the conditions for the use of E 214 – 219 p-hydroxybenzoates and their sodium salts before 1 July 2004.

EFSA has assessed the information on the safety of p-hydroxybenzoates and expressed its opinion on 13 July 2004. EFSA established a full-group acceptable daily intake (ADI) of 0-10 mg/kg bw 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 clear no-observed-adverse-effect-level (NOAEL).

It is proposed to withdraw E 216 propyl p-hydroxybenzoate and E 217 sodium propyl p-hydroxybenzoate from Directive 95/2/EC.

In addition, on the basis of the information received, it is proposed to withdraw the use of p-hydroxybenzoates in liquid dietary food supplements.

(e) Gelling agents in jelly mini-cups

In April 2004, the Commission 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 (Decision 2004/374/EC)[1]. Jelly mini-cups are described as jelly confectionery of a firm consistency, contained in semi-rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cup or mini-capsule to project the confectionery into the mouth and containing food additives derived from seaweed and or certain gums.

EFSA has assessed the risk of choking from the presence in jelly mini-cups of gel-forming additives and expressed its opinion on 12 July 2004. It concludes that "any gel-forming additive whether derived from seaweed or from non-seaweed origin or any other type that gave rise to confectionery product of a similar size, with similar physical and/or physicochemical properties and that could be ingested in the same way as the jelly mini-cups, would give rise to a risk for choking."

It is proposed to withdraw the use of the following gel-forming food additives in jelly mini-cups: E 400 alginic acid, E 401 sodium alginate, E 402 potassium alginate, E 403 ammonium alginate, E 404 calcium alginate, E 406 agar, E 407 carrageenan, E 407a processed euchema seaweed, E 410 locust bean gum, E 412 guar gum, E 413 tragacanth, E 414 acacia gum, E 415 xanthan gum, E 417 tara gum and E 418 gellan gum.

2. Authorisation of new food additives

a) Erythritol

Erythritol is a four-carbon sugar alcohol (polyol) that has sweetness approximately 60-80% that of sucrose. It occurs naturally in minor amounts in some fruits, mushrooms, fermented foods and cheese.

The Scientific Committee on Food (SCF) has assessed the information on the safety of erythritol and expressed its opinion on 5 March 2003. The Committee concluded that in accordance with the Committee's earlier opinion on other polyols it is considered inappropriate to establish a numerical ADI for erythritol and 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 technical 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 proposed to permit the use of erythritol in the same food applications as the other currently-permitted polyols.

[1] OJ L 118, 23.4.2004, p. 70.

In addition, it is proposed to amend Directive 94/35/EC on sweeteners for use in foodstuffs, as erythritol can also be used for sweetening purposes like the other currently-permitted polyols. The fact that polyols have a dual use was already recognised by the SCF in its evaluation of sweeteners in 1984.

b) 4-Hexylresorcinol

Black spots (melanosis) form on the shell of raw, refrigerated and frozen crustaceans within a few hours after harvesting by the action of polyphenol oxidase on naturally-occurring colourless phenols, resulting in coloured quinones. These subsequently polymerise to insoluble dark melanins. Refrigeration alone does not prevent this process, but only slows it down as the enzyme remains active during refrigeration, ice storage and post-freeze thawing. Sulphites are used to inhibit melanosis.

The Scientific Committee on Food has assessed the information on the safety of 4-hexylresorcinol and expressed its opinion in March 2003. The Committee concluded that 4-hexylresorcinol is toxicologically acceptable for prevention of melanosis in crustaceans, provided residues in crustacean meat do not exceed 2 mg/kg.

It is proposed that 4-hexylresorcinol can be used as an alternative to sulphites for preventing browning of crustaceans. France authorised 4-hexylresorcinol temporarily for this use under Article 5 of Directive 89/107/EEC.

c) Soybean hemicellulose

Soybean hemicellulose is refined water-soluble polysaccharide extracted from soy fibre. Soy fibre is a mixture of cellulosic and non-cellulosic structural components of the internal cell wall of soybeans. The raw material from which the soluble hemicellulose is extracted is a high-fibre-containing by-product of the soy oil and soy protein production process. Soybean hemicellulose intended for sale in the EU will be made from traditional soya, as this is the product which was evaluated by the SCF.

The Scientific Committee on Food has assessed the information on the safety of soybean hemicellulose and expressed its opinion in April 2003. The Committee concluded that the use of soybean hemicellulose is acceptable in the foods requested and at the inclusion levels requested. The Committee recommends that, in view of possible allergenic potential, consumers should be informed that the product is derived from soybean. However, as all the products derived from soybean are to be labelled as laid down in Directive 2003/89/EC amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs, the Committee's recommendations are already a legal obligation.

It is proposed to use soybean hemicellulose as an emulsifier in sauces, food supplements and flavourings, as a thickener in bakery ware and in jelly confectionery, as a stabiliser in frozen foods and dairy-based drinks and as an anti-caking agent in rice and noodles.

Soybean hemicellulose has the following effects in food.

It stabilizes protein particles under acidic conditions. This property together with low viscosity is used in the production of acidic dairy beverages, such as yoghurt drinks, to obtain good flavour release, smooth feel in the mouth and a light, refreshing taste.

It has strong emulsifying and emulsion-stabilizing properties. This enables production of different-flavoured acidic beverages in highly diluted conditions.

It is soluble in both cold and hot water without gel formation and has good water-binding capacity. Therefore, when used in applications such as baked foods, which are kept deep-frozen and then heated by microwave, soybean hemicellulose minimizes damage caused by the treatment and maintains the softness and tastefulness of the product, as opposed to it becoming glutinous and stiff. In non-fried instant noodles, soybean hemicellulose improves the texture of the dough and shortens the cooking time of the noodles.

It has strong anti-caking properties. By coating the surface of the rice or noodle particle, soybean hemicellulose controls the stickiness of the particles preventing them from becoming too glutinous and keeping their glossy appearance, which improves their mixing characteristics with other added ingredients.

d) Ethyl cellulose

Ethyl cellulose is the ethyl ether of cellulose. It is prepared from wood pulp or cotton by treatment with alkali and ethylation of the alkali-treated cellulose with ethyl chloride. Ethyl cellulose is already widely used as a pharmaceutical excipient in solid-dosage forms, where it acts as a binder and/or filler substance in tablets.

The European Food Safety Authority has assessed the information on the safety of ethyl cellulose and expressed its opinion in February 2004. The Authority decided to include ethyl cellulose in the group ADI "not specified"[2] for modified celluloses established by the Scientific Committee on Food.

The main application of ethyl cellulose is in food supplements and encapsulated flavourings. It is proposed that the use of ethyl cellulose would be permitted in a similar way to other celluloses (foodstuffs in general except in those listed in Article 2(3)) and as a carrier for food additives).

3. Authorisation for extending the use of authorised food additives

a) Sodium hydrogen carbonate in sour milk cheese

Sour milk cheese is ripened cheese manufactured from sour milk quark. Sour milk quark is made from pasteurised low-fat milk. During the manufacture of sour milk cheese, the raw material sour milk quark is first ground in order to obtain a uniform mixture. E 500ii sodium hydrogen carbonate is added to the mixture in order to

[2] ADI "not specified" means that on the basis of the available toxicological, biochemical and clinical data, the total intake of the substance, arising from its natural occurrence and/or its present use or uses in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health. For this reason, the establishment of a numerical limit for the ADI is not considered necessary for the substance.

buffer the lactic acid to a pH value of around 5, thereby creating the necessary growth conditions for the ripening cultures. It is proposed to allow the use of sodium hydrogen carbonate in sour milk cheese.

b) Sorbates and benzoates in crustaceans

Currently, it is authorised to use a mixture of sorbates (E 200 - 203) and benzoates (E 210 - 213) in cooked shrimps for preservation. In addition, the use of sorbates is allowed in cooked crayfish tails and cooked pre-packed marinated molluscs. However, the latter also requires the addition of benzoates for preservation. Therefore, it is proposed to allow the use of a mixture of sorbates and benzoates in all cooked crustacean and molluscs, not only in cooked shrimps.

According to the information contained in the Danish Report on EU Food Additives Monitoring (February 2003), the average intake per day of products, such as cooked crustaceans and molluscs, is 0.05 g (overestimation). On the basis of the use level of 1 g benzoates per kilogram, such an intake would result in 0.05 mg benzoates per day, a negligible contribution to the total consumption of benzoates.

c) Silicon dioxide as a carrier

E 551 silicon dioxide is permitted as a carrier for food colours at the maximum level of 5%. It is proposed to permit the use of silicon dioxide as a carrier for food colours E 171 titanium dioxide and E 172 iron oxides and hydroxides at the level of maximum 90% relative to the pigment. This would allow the creation of innovative colour effects such as colour travel (colour changing by angle of light) and colour flop (two colours visible at the same time). With this innovation, the number of organic dyes used can be reduced.

d) Additives in traditional Hungarian products

Directive 95/2/EC limits the use of additives listed in Annex I in traditional French bread "*Pain courant francais*". The same limited use is proposed for similar traditional Hungarian bread "*Búzakenyér, fehér és félbarna kenyerek.*"

It is also proposed that in Hungarian liver patés (libamáj, libamáj egészben, libamáj tömbben) similar to *foie gras*, ascorbic acid (E 300), sodium ascorbate (E 301) and calcium disodium EDTA (E 385) may be used.

It is proposed to allow the use of sorbates and benzoates for preservation of Hungarian quick-frozen chestnut puree "*Gyorsfagyasztott gesztenyepüré"*.

2. AMENDMENT TO DIRECTIVE 94/35/EC

Directive 94/35/EC on sweeteners for use in foodstuffs sets out a list of authorised sweeteners, the foodstuffs in which they may be used and their conditions of use. The Directive was adopted in June 1994 and has been amended twice: in 1996 and 2003.

It now needs to be adapted in the light of recent technical and scientific developments. The intention of this proposal is to ensure the functioning of the internal market, a high level of protection of human health and the protection of consumers' interests.

It is proposed to amend the Directive as follows:

Authorisation of a new food additive erythritol

Due to its sweetness, erythritol may be used for sweetening purposes as a replacement for sugar. It is proposed that erythritol may be used in table top sweeteners and in energy reduced foods and foods with no added sugars.

In table top sweeteners, erythritol is used at levels where it contributes significantly to the sweetness, typically in combinations with intense sweeteners, whereby it also serves as a carrier. The sensorial profile-modifying properties of erythritol are of great importance resulting in sweetness synergy, improved feel in the mouth and masking of unwanted off-flavours. In addition, erythritol's crystalline structure and density are similar to that of sucrose.

Permitted polyols share technological properties that have justified authorisations under Directive 94/35/EC, such as sweetness, reduced caloric value and non-cariogenicity. Erythritol shares all these technical properties. In addition, it is non-caloric (0 to 0,2 kcal/g, other polyols 2,4 kcal/g) and it has the highest digestive tolerance of all polyols. Due to the latter, it is proposed to exempt erythritol from the labelling rule regarding labelling of laxative effect in table-top sweeteners containing polyols.

SUBSIDIARITY IMPACT STATEMENT

1. What are the objectives of the proposed measure with regard to the Community's obligations?

Directive 89/107/EEC provides for the adoption of specific Directives to harmonise the use of different categories of additives in foodstuffs. Directive 95/2/EC on food additives other than colours and sweeteners was adopted on 20 February 1995. Directive 94/35/EC on sweeteners for use in foodstuffs was adopted on 30 June 1994. They now need to be adapted in the light of recent technical and scientific developments.

2. Does competence for the proposed measure lie solely with the Community or is it shared with the Member States?

Competence for the proposed measure lies solely with the Community.

3. To what extent is this a problem on a Community scale?

The use of food additives in foodstuffs is fully harmonised in the European Community.

Harmonisation of the use of food additives at Community level was a priority for completion of the internal market. The framework Directive 89/107/EEC on food additives was adopted on 21 December 1988 and the three specific Directives (colours, sweeteners, miscellaneous) in 1994 and 1995. Since then, the rules relating to the use of additives have been the same in the fifteen Member States. This structure ensures a high level of consumer protection, offers the consumer greater freedom of choice between different foodstuffs and guarantees the free movement of foodstuffs.

Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs are based on the principle of the positive list. A list of authorised food additives is set out in the Annexes to the Directives with a list of the foodstuffs in which they may be used and the conditions of use. All food additives not included in the list are prohibited except for the new additives that are temporarily authorised by Member States for a limited period of two years.

4. What is the most effective solution taking into account the means available to the Community and the Member States?

The use of food additives should be regulated uniformly in the European Community to ensure a high level of food safety and free trade in foodstuffs within the Community.

5. What practical additional benefit will the proposed measure provide and what would be the cost of failure to take action?

Previously, the Scientific Committee on Food and, since July 2003, the European Food Safety Authority have evaluated the substances to be used as food additives. If the Commission proposes the use of these substances as food additives, and the European Parliament and the Council adopt the proposal, they can be authorised at Community level. If the Commission does not propose the use of these substances, they cannot be used in the Community.

6. What form of action is open to the Community?

A new Directive adopted by the European Parliament and the Council under the procedure laid down in Article 95 is needed to amend Directive 95/2/EC and Directive 94/35/EC.

7. Is it absolutely necessary to adopt uniform rules or would a Directive establishing general principles and leaving implementation to the Member States be sufficient?

The Commission proposal is based on the principle of complete harmonisation at Community level, as prescribed by the framework Directive on food additives.

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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[3],

Having regard to the opinion of the European Economic and Social Committee[4],

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty[5],

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 authorised for use in foodstuffs intended for human consumption[6].

(2) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners[7] 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 of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs[8] lays down a list of sweeteners that may be used in the Community and the conditions for their use.

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3 OJ C […] of […], p. […].
4 OJ C […] of […], p. […].
5 OJ C […] of […], p. […].
6 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).
7 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).
8 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).

(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 these developments.

(5) On the basis of an opinion of 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 lowering 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 set as added amounts. However, for certain traditionally-manufactured meat products maximum residual levels should be set.

(6) Directive 2003/114 amending Directive 95/2/EC on food additives other than colours and sweeteners obliges the Commission and the European Food Safety Authority to review the conditions for the use of E 214 – 219 p-hydroxybenzoates and their sodium salts before 1 July 2004. EFSA has assessed the information on the safety of p-hydroxybenzoates and expressed its opinion on 13 July 2004. EFSA established a full-group acceptable daily intake (ADI) of 0-10 mg/kg bw 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 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.

(7) In April 2004, the Commission 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 risk of choking on these products (Decision 2004/374/EC)[9]. In the light of 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 (SCF) has assessed the information on the safety of erythritol and expressed its opinion on 5 March 2003. The Committee concluded 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 technical 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-

[9] OJ L 118, 23.4.2004, p. 70.

permitted polyols. It is also necessary to exempt erythritol from the labelling rule regarding labelling of laxative effect in table-top sweeteners containing polyols.

(9) The Scientific Committee on Food has 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 certain foods requested and at certain inclusion levels. It is therefore appropriate to permit such use for certain purposes.

(10) The European Food Safety Authority has assessed the information on the safety of ethyl cellulose and expressed its opinion on 17 February 2004. The Authority 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 similar way as other celluloses.

(11) During the manufacture of sour milk cheese, E 500ii sodium hydrogen carbonate is added to the pasteurised milk in order to buffer 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.

(12) Currently, it is authorised to use a mixture of sorbates (E 200 - 203) and benzoates (E 210 - 213) in cooked shrimps for preservation. It is appropriate to extend that authorisation to its use in all cooked crustaceans and molluscs.

(13) 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.

(14) Directive 95/2/EC limits the use of additives listed in Annex I to that Directive in traditional French bread "*Pain courant francais*". The same limitattion 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. It is necessary to allow the use of sorbates and benzoates for preservation of Hungarian quick-frozen chestnut puree.

(15) 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.

(16) 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[10], 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[11]

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

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

and Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[12].

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

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is amended as follows:

(1) In paragraph 2 of Article 3 the words 'weaning foods' are replaced by the words 'processed cereal-based foods and baby foods'.

(2) The Annexes are amended in accordance with Annex I to this Directive.

Article 2

Directive 94/35/EC is amended as follows:

(1) In Article 5(2) the word "polyols" are replaced by the words " polyols except E 968 erythritol".

(2) The Annex is amended in accordance with Annex II to this Directive.

Article 3

1. Member States shall bring into force 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 *[18 months after entry into force]* at the latest,

(b) prohibit trade in and use of products which do not comply with this Directive by *[24 months after entry into force]* at the latest.

However, products placed on the market or labelled before that date referred to in point (b) which do not comply with this Directive may be marketed until stocks are exhausted.

2. When Member States adopt those measures, 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.

[12] OJ L 91, 7.4.1999, p. 29. Directive as amended by the Act of Accession of 2003.

Article 4

1. Member States shall adopt and publish, by […] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   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.

Article 5

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

Article 6

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

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 4 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 may not be used in jelly mini-cups (*)

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(*) For the purpose of this Directive, jelly mini-cups means 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"

(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	*quantum satis* *quantum satis* (only for sour milk cheese)'

(b) In the row for '*Pain courant français'* after the words '*Pain courant français*' the following words are added: '*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-hydroxybenzote" are deleted.

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

– The following rows are deleted:

‘Shrimps, cooked				2000		
Crayfish tails, cooked, and pre-packed marinated cooked molluscs	2000					
Liquid dietary food supplements						2000’

– The following rows are added:

‘Crustacean and molluscs, cooked		1000		2000		
Food supplements as defined in Directive 2002/46/EC (*) supplied in liquid form				2000		
Gyorsfagyasztott gesztenyepüré				1000’		

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

(iii) 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 C the rows for E 249 and E 250 and the rows for E 251 and E 252 are replaced by the following:

‘E No	Name	Foodstuff	Maximum level that may be added during the manufacturing
‘E 249	Potassium nitrite*	Meat products	150 mg/kg

E 250	Sodium nitrite*	Sterilised meat products (Fo > 3.00)**	100 mg/kg expressed as $NaNo_2$
		Wiltshire cured bacon and ham	175 mg/kg as a residue
		Dry cured bacon and ham	175 mg/kg as a residue
		Cured tongue, jellied veal, brisket	10 mg/kg as a residue expressed as $NaNo_2$
E 251 E 252	Sodium nitrate Potassium nitrate	Non-heat-treated meat products	150 mg/kg expressed as $NaNo_3$
		Wiltshire cured bacon and ham	250 mg/kg as a residue
		Dry cured bacon and ham	250 mg/kg as a residue
		Cured tongue, jellied veal, brisket	10 mg/kg as a residue expressed as $NaNo_3$
E 251 E 252	Sodium nitrate Potassium nitrate	Hard, semi-hard and semi-soft cheese	150 mg/kg in cheese milk
		Dairy-based cheese analogue	150 mg/kg in cheese milk
		Pickled herring and sprat	500 mg/kg expressed as $NaNo_3$'

* When labelled "for food use", nitrite may only be sold in a mixture with salt or a salt substitute.

** Fo-value 3 is equivalent to 3 min heating at 121ºC (reduction of the bacterial load of one billion spores in each 1000 cans to one spore in a thousand cans).'

(c) In Part D the following row is added:

'E 586	4-hexylresorcinol	Fresh, frozen and deep-frozen crustaceans	2 mg/kg as residues in crustacean meat'

(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 of 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 es 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	5 g/l
		Food supplements as defined in Directive 2002/46/EC	1,5 g/kg
		Emulsified sauces	30 g/l
		Bakery ware	10 g/kg
		Noodles	10 g/kg
		Rice	10 g/kg
		Processed potato and rice products (including frozen, deep-frozen, chilled and dried processed products)	10 g/kg
		Pre-fried frozen and deep-frozen potatoes	10 g/kg
		Dehydrated, concentrated, frozen and deep-frozen egg products	10 g/kg
		Jelly confectionery, except jelly mini-cups	10 g/kg
		Flavourings	1,5 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 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, row E 901 to E 904, and row E 1201 and E 1202 the words 'Dietary food supplements' are replaced by the words 'Food supplements as defined in Directive 2002/46/EC'.

(f) 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'.

(5) Annex V is amended as follows:

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

'E 968	Erythritol'	

(b) The following row is inserted after the row for E 466:

‘E 462	Ethyl cellulose’	

(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 the words ‘weaning foods’ are replaced by the words ‘processed cereal-based foods and baby foods’.

(b) In Part 3, in the title, in row E 170 to 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 the words ‘weaning foods’ are replaced by the words ‘processed cereal-based foods and baby foods’.

ANNEX II

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

(a) In the first column of the row for E 420 to E 967, the word ‘E 968’ is added.

(b) In the second column of the row for E 420 to E 967, the word “Erythritol” is added.