



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.11.2002
COM(2002) 662 final

2002/0274 (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

(presented by the Commission)

EXPLANATORY MEMORANDUM

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 been amended three times: in 1996, 1998 and 2001. It now needs to be adapted in the light of recent technical and scientific developments. The intention of this proposal is to ensure functioning of the internal market, a high level of protection of human health and the protection of consumers' interests.

The Directive is proposed to be amended as follows:

1. Authorisation of a new food additive – hydrogenated poly-1-decene

Hydrogenated poly-1-decene

Hydrogenated poly-1-decene is a mixture of aliphatic hydrocarbons synthesised from pure 1-decene. It is a colourless, odourless and tasteless inert product. It is proposed for use as a glazing agent in confectionery and dried fruit. Glazing agents are substances which, when applied to the external surface of foodstuffs, provide a protective coating or impart a shiny appearance. Finland authorised temporarily hydrogenated poly-1-decene under Article 5 of Directive 89/107/EEC.

The Scientific Committee on Food (SCF) has assessed the information on the safety of hydrogenated poly-1-decene and expressed its opinion in July 2001. The Committee established an acceptable daily intake (ADI)¹ of 0-6 mg/kg body weight for hydrogenated poly-1-decene.

Since the prohibition of the use of white mineral oil in the European Union, the European food manufacturers have found alternative products. Many have turned to the use of vegetable oil-based products, but these suffer from the disadvantages of rancidity and stickiness.

Hydrogenated poly-1-decene overcomes these problems because the product is technically superior to the vegetable oil products. Hydrogenated poly-1-decene is not subject to rancidity; consequently it confers extended shelf life with improved taste and odour in all food applications by comparison with vegetable oils. For instance, in a confectionery application, sweets were found to be of good appearance and free of odour after one and a half years compared with only two months shelf life using vegetable oils.

2. Withdrawal of the authorisation for the use of some food additives
 - a) E 170(ii) calcium hydrogen carbonate is no longer used as a food additive therefore its withdrawal is proposed.

¹ Acceptable daily intake (ADI) = The amount of a food additive, expressed as mg/kg body weight, that can be ingested daily over a lifetime without incurring any appreciable health risk. The ADI is based on an evaluation of available toxicological data and established by identifying the No-Observed-Adverse-Effect-Level (NOAEL) in the most sensitive experiment among a battery of studies in test animals performed with the test compound and extrapolating to man by dividing the NOAEL with a safety factor of usually 100.

- b) E 230 biphenyl, E 231 orthophenyl phenol and E 232 sodium orthophenyl phenol were temporarily authorised under Directive 95/2/EC for treatment of citrus fruits. As these substances are to be considered as plant protection products, they fall under Directives 91/414/EEC² and 90/642/EEC³. For the sake of consistency, their withdrawal from Directive 95/2/EC is now proposed.
- c) Council Directive 67/427/EEC of 27 June 1967⁴ lays down the control measures on preservatives in and on citrus fruits. Since these preservatives would no longer be authorised for use in citrus fruits by Directive 95/2/EC, it is desirable to repeal this Directive.
- d) Phosphates (E 338 to E 452) have been permitted in cider and perry. The Commission has been informed that these substances are not used as food additives in cider and perry, therefore their withdrawal is proposed.

3. Authorisation for extending the use of authorised food additives

Food additives with ADI “not specified”⁵

- a) E 472c citric acid esters of mono- and diglycerides of fatty acids are proposed as an emulsifier in cocoa and chocolate products.

Two viscosity parameters are used in chocolate processing to ensure optimal processing and eating quality. Yield value is the minimum amount of force required to produce a flow. Plastic viscosity describes the flow characteristics once the flow has been initiated. Both yield value and plastic viscosity can be influenced by adding more fat. Since fat, and especially cocoa butter, is the most costly part of chocolate, it is desirable to influence these rheological properties by means of emulsifiers.

Emulsifiers with an effect on rheological properties of chocolate include E 322 lecithin, E 442 ammonium phosphatides, E 476 polyglycerol polyricinoleate and E 472c citric acid esters of which all but E 472c are currently allowed for chocolate within the EU.

Due to consumer concerns on the use of genetically modified organisms, citric acid esters have been developed as emulsifiers for chocolate. They are based on non-GM raw material such as sunflower oil. Citric acid esters can potentially affect either yield value or plastic viscosity or a combination of both. When affecting both yield value and plastic viscosity, they can be used as the sole alternative to the combined use of lecithin/ammonium phosphatide and polyglycerol polyricinoleate thereby reducing the number of emulsifiers in certain products.

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market OJ L 230, 19.8.1991, p.1.

³ Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables OJ L 350, 14.12.1990, p.71

⁴ OJ L 148, 11.7.1967, p.1.

⁵ ADI “not specified” = A term used when, 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.

- b) It is proposed that E 296 malic acid may be used in peeled potatoes to prevent browning. Peeled potatoes easily turn brown. To prevent browning, peeled potatoes are washed with anti-browning agents or are stored in water after peeling. Sulphites are the most frequently used agents to prevent browning. However, it is desirable to find alternatives to the use of sulphites especially as sulphites often negatively influence the texture of potatoes. An aqueous solution containing 0.25% malic acid and 0.5% ascorbic acid is efficient in preventing browning. E 300 ascorbic acid is already authorised for use in peeled potatoes. Therefore, also E 296 malic acid is proposed to be authorised in peeled potatoes.
- c) The use of E 440 pectin and E 509 calcium chloride in fruit compotes other than apple is proposed. Pectin is necessary to increase the thickness of fruit compotes that are naturally poor in pectin. Without pectin, the product is too liquid and therefore, not presentable to the consumer. As apples naturally contain a lot of pectin, the proposal does not include apple compote. For pectin to be functional the use of calcium chloride is necessary.
- d) E 460ii powdered cellulose is proposed for use in grated mozzarella as an anti-caking agent. Grated mozzarella is often added on top of pizza in restaurants, catering and households. When grated, particles of mozzarella tend to adhere together thus hindering the free flow of the cheese. The use of an anti-caking agent reduces this tendency and therefore enables better dosage and homogenous distribution of cheese, which is important to the quality of the product.
- e) The use of E 331 sodium citrates in UHT goat milk is proposed. The consumption of goat milk is increasing in addition to or as a substitute to cow's milk. Because of the instability of the raw material, production of goat milk treated with ultra high temperature needs different technological adaptations as compared to production of cow's milk. Currently disodium phosphate is permitted for stabilisation of UHT treated milk. Less sedimentation occurs in the milk where E 331 sodium citrates are added as compared to the use of phosphates. This is due to improved pH stability of the milk and to the lower scale of denaturation of milk proteins. Without a stabiliser goat milk coagulates before the temperatures for UHT treatment is reached, which would exclude the use of UHT treatment.
- f) Peeled whole chestnuts are preserved in liquid containing water, salt and organic acids. Chestnuts are delicate and break down easily due to shocks caused by transportation. Therefore, it is proposed to add thickening agents E 410 locust bean gum, E 412 guar gum and E 415 xanthan gum to the liquid surrounding chestnuts.
- g) Some lipophilic nutrients, such as vitamins A, D, E and K, need to be encapsulated for incorporation into food. There is a demand for the use of nutrients in infant foods, therefore it is proposed to allow the carry over of E 1450 starch sodium octenyl succinate in infant and follow-on formula and weaning foods from vitamin preparations or polyunsaturated fatty acid preparations.

E 1450 is permitted for foodstuffs in general. It is also permitted for use in weaning foods for infants and young children in good health at levels of up to 5% and in foods for infants and young children for special medical purposes (FSMP) at levels of up to 2%.

- h) It is also proposed that E 407a processed eucheama seaweed may be standardised with sugar. As processed eucheama seaweed is extracted from seaweed, which is biological material, it is subject to many types of variations e.g. due to the period of harvesting, the place of growth or the climatic conditions during growth. To produce equal quality of this additive all year round, sugar is added for standardisation.
- i) In order to insure complete consistency with the existing Community regulations on wine, it is proposed to include a mention of the authorised use of lysozyme (E 1150) in wine as laid down in Council Regulation 1493/1999, with the conditions of use specified in Commission Regulation 1622/2000. Lysozyme is used for the control of the growth of lactic bacteria in wine.

Food additives with a numerical ADI

- j) E 200 Sorbic acid is proposed for use as a preservative in dairy and fat based spreads with added foodstuffs. These types of spreads are more susceptible to microbial spoilage than normal fat spreads owing to their higher water content. These products are normally pasteurised. Practical experience has, however, shown that pasteurisation only is not sufficient for the preservation of these products. This applies, in particular, if they are packed in containers leaving some space above the product and if they are kept for some time after opening.

Temperature changes can result in condensation of humidity on the surface of the products which, even in closed containers, favours microbiological growth. After opening, contamination with microorganisms cannot be excluded. This can result in premature spoilage if the products are to be kept for some time. Storage in a refrigerator is not sufficient to prevent such microbial growth.

- k) E 555 potassium aluminium silicate is proposed as a carrier for food colours E 171 titanium dioxide and E 172 iron oxides and hydroxides. To create the desired lustre effect, the colouring pigments E 171 and/or E 172 are attached to a thin layer of potassium aluminium silicate platelets. E 555 acts purely as a carrier for the deposition of the metallic oxide and provides an interface at which light can be reflected or refracted. Depending upon the metal oxide used and the thickness of that oxide, the results are different colours and new pearl lustre effects for food application. With this innovation, the number of organic dyes used can be reduced.

4. Revision of current authorisations

- a) The SCF reviewed the safety of E 903 carnauba wax as a glazing agent in light of new information. In its opinion, expressed on 11 July 2001 and revised on 17 April 2002, the Committee confirmed that the use of carnauba wax is acceptable. As a follow-up to this opinion, it is proposed to revise the current authorisations by setting numerical maximum use level for carnauba wax in foods where its use is already authorised.
- b) It is proposed that partially baked and prepacked bakery wares intended for retail sale, preserved with E 200 sorbic acid, could be sold also to the mass catering and restaurant trades. Pre-baked bakery products are more susceptible to moulding than finished bakery foods due to their higher water content and insufficient formation and hardening of the crust. Mistakes made in storage thus quickly lead to premature

moulding and spoiling of products. The problem is especially faced by small enterprises as well as by the retail trade and private households.

It is also proposed that bread with a reduced energy content could be preserved with sorbic acid. This type of bread is considerably more prone to moulding than normal bread due to its higher water content.

- c) It is proposed to amend the designation “semi-preserved and preserved meat products” to “cured meat products and canned meat products” concerning the use of E 315 erythorbic acid and E 316 sodium erythorbate. The amendment clarifies the type of meat products where the use of antioxidants is necessary.
- d) It is proposed to replace the designation “fine bakery wares (*scones and sponge ware only*)” by “fine bakery wares” concerning the use of E 541 sodium aluminium phosphate. E 541 is used as a leavening agent. Currently the use is restricted to scones and sponge wares that are mainly produced in the United Kingdom. The amendment would allow the bakers in other Member States to have the advantage of using this leavening agent.
- e) Annex VI, part 4 of Directive 95/2/EC lays down the provisions for use of food additives in FSMPs for infants and young children. It is proposed to amend the title to make a reference to Commission Directive 1999/21/EC on dietary foods for special medical purposes.
- f) E 472c citric acid esters of mono- and diglycerides of fatty acids are currently permitted in infant formulae and follow-on formulae and in FSMPs for infants, but only if the product contains protein hydrolysates, peptides or amino acids. It is proposed that E 472c could be used as an emulsifier also in other types of foods for infants for special medical purposes (which contain whole protein or do not contain any protein).

It is particularly important for FSMP to remain stable over prolonged periods. FSMP for infants and young children are frequently fed through very narrow-bore nasogastric tubes. Poor emulsion stability can lead to separation of fat and sedimentation of insoluble particles, which may block feeding tubes. This can adversely affect the ability to maintain adequate feeding regimes. Many products for infants and young children are available in powdered form to be reconstituted to liquid before use and are required to retain an intact emulsion when reconstituted for up to 24 hours from preparation. Maintenance of stability allows consistent nutrient provision throughout feeding. For products taken orally, palatability is particularly important, especially for infants and young children over six months of age. Poor palatability can affect dietary compliance in young children and therefore compromise their dietary management.

5. Clarification of the scope of the functional class “stabilisers”

Stabilisers are substances which make it possible to maintain the physico-chemical state of a foodstuff. Stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff and substances which stabilise, retain or intensify an existing colour of a foodstuff.

It is proposed to clarify the definition of “stabiliser” to cover also substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food.

The use of these types of substances fulfils the definition of the use of a food additive. Therefore, it is desirable to regulate such uses under Directive 95/2/EC. This will ensure that only substances subject to safety evaluation and authorisation at Community level are used and that the consumer is informed of this use through labelling.

6. Food additives in flavourings

Food additives are necessary for storage and use of flavourings in a similar way as they are necessary for the production and preservation of many processed foodstuffs. For example preservatives are needed to preserve flavourings, emulsifiers are necessary for equal dispersion of an oily flavouring in a water-based drink and anti-caking agents ensure that a powdered flavouring is free flowing and can be evenly dispersed in foods.

Regulations on the use of additives in flavourings vary between the Member States, both in respect to the number of authorised additives as well as to the conditions of use. This hinders the free movement of flavourings and foodstuffs containing these flavourings and creates conditions of unequal and unfair competition as well as potential differences in consumer protection.

Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production lays down that a list of additives necessary for the storage and use of flavourings and their conditions of use shall be adopted in order to protect public health and ensure fair trade. This proposal clarifies the rules for additives in flavourings in the scope of Directive 95/2/EC.

The carry over of most additives into final food via the addition of flavourings is low since in general flavoured foods contain less than one percent of the flavouring. Therefore, the amount of an additive carried over is not sufficient to exert a technological function in the food. For these additives, maximum use levels are set in the flavourings. Such levels are easy to control by the food control authorities as well as by the food producing companies. In a few cases, however, it might be difficult to clearly judge whether a transferred additive has a technological function in the food or not (polysorbates, beta-cyclodextrin, carrier solvents). In these cases, the maximum use level for the additive is set in the flavoured food.

The proposal is to authorise only those additives which are strictly necessary for the storage and use of flavourings. In comparison to the present situation in the Member States, the number of additives authorised in flavourings will be strongly reduced. Also, the proposed maximum levels are in many cases lower than the levels authorised by the Member States. In addition, only such uses of additives are proposed which comply with the general criteria laid down in Annex II of the framework Directive on food additives (Directive 89/107/EEC), in particular with the criterion that they present no hazard to the health of consumers.

Technological justifications

Sorbic acid and its salts (E 200, E 202 and E 203) are preservatives having an activity against yeast and moulds but being also effective against bacteria. They are used in flavours containing natural raw materials such as concentrated juices in order to preserve them.

Benzoic acid and its salts (E 210 to E 213) are preservatives. E 210 is active against microbial agents at pH ranges 2.5-4 and is particularly active against yeast and moulds at pH values 5-6. It has low solubility in water. E 211 is much more soluble in water than E 210. E 212 and E 213 are used in flavourings with water/ethanol as a solvent, because they are more soluble than E 211 when the ethanol content is relatively high.

Gallates (E 310 to E 312) are used as antioxidants and are synergistic with both butyl hydroxyanisole (E 320 BHA) and tocopherols (E 306 to E 309). They are very efficient in lipophilic materials.

E 320 BHA has an almost equivalent overall antioxidant activity as gamma-tocopherol but is more stable particularly under conditions of high oxidative stress. It is more polar and hence more applicable for the stabilisation of low molecular weight aldehydes and other flavouring substances of higher polarity. It is the most effective antioxidant for use in citrus oils and flavourings containing a high amount of aldehyde. It also helps prevent rapid oxidation of vegetable oil carrier solvents in oil-soluble liquid flavourings, especially where high levels of short chain aliphatic acids are used, as they tend to promote oxidation of the oil.

E 338 to E 340 phosphoric acid and its salts are acidity regulators and indispensable to improve the yield of extraction of the flavouring from the starting material, wherever solubility of substances in aqueous solution is affected by pH. They are needed as acidulants, pH-adjusting agents and as stabilisers for dispersions and suspensions. E 338 and E 339 are used together to obtain a neutral buffer in water-based flavours. E 340 is used in flavours for low sodium foodstuffs.

E 341 calcium phosphate, E 451 triphosphates and E 452 polyphosphates are valuable anti-caking agents by adjusting the water activity of powder flavourings and hence avoid clumping. Additionally triphosphates have shown positive effects on the moisture regulation of dry flavourings. In this function, the use as a drying agent is of special interest. For paste-like flavourings, triphosphates are necessary as a thickening agent. Polyphosphates are able to form complexes with ions such as Ca^{2+} , Mg^{2+} and $\text{Fe}^{2+}/\text{Fe}^{3+}$. This effect helps to prevent and reduce autoxidation processes. Therefore polyphosphates are important additives for the maintenance of quality and sensorial profile.

E 450 diphosphates are used as sequestrants/chelating agents in the production of spray dried powder flavourings. They reduce metal ion catalysis which can result in discoloration and oxidation of fats and terpenes and they enhance the anti-oxidative effects of tocopherols, gallates and BHA.

E 416 karaya gum is a high-molecular weight hydrocolloid stabiliser used in the formation of emulsions and suspensions. It is very stable at low pH and is resistant to thermal treatments and other culinary processes, e.g. freezing.

E 432 to E 436 polysorbates are emulsifiers essential for the solubilisation of oleoresins and similar flavouring raw materials. They ensure a uniform dispersal of flavouring substances into the food product and function well in oil-in-water-systems.

E 551 silicon dioxide acts as a drying agent when liquid flavourings are added to powder supports. It serves to absorb these oils so that they will not coat or stick to other particles. It improves the flowability of flavourings in the powder form by separating particles that might otherwise stick together. This is important particularly if the food manufacturer will be mechanically dosing the flavouring into finished foods.

E 900 dimethyl polysiloxane is used to reduce or prevent the formation of foam.

E 459 beta-cyclodextrin is used for complexation of flavour compounds, hence it reduces their volatility and helps reducing the loss of flavour during processing and/or preparation.

E 1505 triethyl citrate, E 1517 diacetin, E 1518 triacetin, E 1519 benzyl alcohol and E 1520 propylene glycol are needed as carrier solvents. Carrier solvents are added to dilute the concentrated flavouring to enable it to be used in a factory environment since it is easier to dose accurately a dilute product. It is also more safe from environmental and health point of view to handle a diluted product rather than a highly concentrated substance with a strong odour. In addition, a carrier solvent is required to ensure even distribution of the flavours. Different carrier solvents are necessary due to variation in solubility of flavourings.

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. It now needs 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 is based on the principle of the positive list. A list of authorised food additives is set out in the Annex to the Directive 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?

The Scientific Committee on Food has evaluated the substances to be used as food additives. If the Commission proposes the use of these substances as food additives, 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.

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.

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission⁶,

Having regard to the opinion of the Economic and Social Committee⁷,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁸,

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 consumption⁹.
- (2) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners¹⁰ lays down a list of food additives that may be used in the Community and the conditions for their use.
- (3) There have been technical developments in the field of food additives since the adoption of Directive 95/2/EC. That Directive should be adapted to take account of those developments.
- (4) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production¹¹ provides for the adoption of a list of additives necessary for the storage and use of flavourings, and the adoption of any special conditions for the use of such additives that may be necessary for the protection of public health and to ensure fair trade.

⁶ OJ C , , p. .

⁷ OJ C , , p. .

⁸ [...]

⁹ OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC (OJ L 237, 10.9.1994, p. 1).

¹⁰ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2001/5/EC (OJ L 55, 24.2.2001, p. 59).

¹¹ OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 47, 15.2.1991, p. 25).

- (5) It is desirable to incorporate into Directive 95/2/EC those measures on additives necessary for the storage and use of flavourings, in order to contribute to transparency and consistency of Community legislation, and to facilitate compliance with Community legislation on food additives by food manufacturers, especially by small and medium size enterprises. In addition, according 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 safety¹², flavourings fall within the definition of 'food'.
- (6) While the use of additives which are necessary to ensure the safety and quality of flavourings and to facilitate their storage and use should be authorised, the levels of additives present in such flavourings should be the minimum required to achieve the intended purpose. In addition, consumers should not be misled on the use of additives.
- (7) The presence of an additive in a foodstuff, due to the use of a flavouring, is generally low and the additive does not have a technological function in the foodstuff. However, if under certain circumstances the additive does have a technological function in the compound foodstuff, it should be considered as an additive of the compound foodstuff and not as an additive of the flavouring, and the relevant rules relating to the additive in the particular foodstuff should apply, including the labelling rules laid down in 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 foodstuffs¹³.
- (8) Food manufacturers should be informed about the concentrations of all additives in flavourings in order to enable them to comply with Community legislation. This is in accordance with Directive 88/388/EEC, which requires quantitative labelling of each component subject to a quantitative limitation in a foodstuff.
- (9) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring market unity and a high level of consumer protection to lay down rules on the use of additives in flavourings. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (10) In accordance with a request from a Member State and the opinion of the Scientific Committee on Food, established under Commission Decision 97/579/EC¹⁴, hydrogenated poly-1-decene, which was authorised at national level under Directive 89/107/EEC, should be approved at Community level.
- (11) Biphenyl (E 230), orthophenyl phenol (E 231) and sodium orthophenyl phenol (E 232) are listed as preservatives in and on citrus fruits in Directive 95/2/EC. However, they fall under the definition of plant protection products in Council Directive 91/414/EEC

¹² OJ L 31, 1.2.2002, p. 1.

¹³ OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p.19).

¹⁴ OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).

of 15 July 1991 concerning the placing of plant protection products on the market¹⁵. Therefore, they should no longer come within the scope of Directive 95/2/EC.

- (12) Directive 95/2/EC should therefore be amended accordingly.
- (13) Council Directive 67/427/EEC¹⁶ lays down the control measures on preservatives in and on citrus fruits. Since those preservatives are no longer authorised for use in citrus fruits by Directive 95/2/EC, it is necessary to repeal that Directive.
- (14) The Scientific Committee on Food has been consulted on the adoption of provisions liable to have an effect on public health, pursuant to Article 6 of Directive 89/107/EEC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/2/EC is amended as follows:

- (1) In Article 1(3), point (v) is replaced by the following:

“(v) ‘stabilisers’ are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food.”
- (2) Article 3(1) is replaced by the following:

“1. The presence of a food additive in a foodstuff is permissible:

 - (a) in a compound foodstuff other than one mentioned in Article 2 (3) to the extent that the food additive is permitted in one of the ingredients of the compound foodstuff;
 - (b) in a foodstuff where a flavouring has been added to the extent that the food additive is permitted in the flavouring in compliance with this Directive and has been carried over to the foodstuff via the flavouring, provided the food additive has no technological function in the final foodstuff; or
 - (c) if the foodstuff is destined to be used solely in the preparation of a compound foodstuff and to an extent such that the compound foodstuff conforms to the provisions of this Directive.”
- (3) The Annexes are amended as set out in the Annex to this Directive.

¹⁵ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2002/64/EC (L 189, 18.7.2002, p. 27).

¹⁶ OJ L 148, 11.7.1967, p. 1.

Article 2

Directive 67/427/EEC is repealed.

Article 3

Member States shall adopt and publish, before [...], the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions in such a way that:

- (a) trade in and use of products which comply with this Directive are permitted from [18 months after entry into force];
- (b) trade in and use of products which do not comply with this Directive are prohibited from [24 months after entry into force].

However, products put on the market or labelled before the date specified in point (b) and which do not comply with this Directive may be marketed until stocks of such products are exhausted.

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.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

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

(1) In Annex I:

(a) Note 2 is replaced by the following:

‘2. The substances listed under numbers E 407, E 407a and E 440 may be standardised with sugars, on condition that this is stated in addition to the number and designation.’

(b) in the list of additives, the following is deleted: ‘(ii) Calcium hydrogen carbonate’

(c) in the list of additives, for E 466 the name “Cellulose gum” is added and for E 469 the name “Enzymatically hydrolysed cellulose gum” is added.

(2) In Annex II:

(a) the following is added to the list of additives and the maximum levels concerning ‘Cocoa and chocolate products as defined in Directive 73/241/EEC’:

| | | |
|--|---|----------------------|
| | ‘E 472c Citric acid esters of mono- and diglycerides of fatty acids | <i>Quantum satis</i> |
|--|---|----------------------|

(b) the following is inserted in the list of additives and the maximum level for ‘Frozen and deep-frozen unprocessed fruit and vegetables; prepacked, refrigerated unprocessed fruit and vegetables ready for consumption and prepacked, unprocessed and peeled potatoes’:

| | | |
|--|--------------------|--|
| | ‘ E 296 Malic acid | <i>Quantum satis</i> (only for peeled potatoes)’ |
|--|--------------------|--|

(c) the following is added to the list of additives and the maximum level for ‘Fruit compote’:

| | | |
|--|--|---|
| | ‘ E 440 Pectin E 509 Calcium chloride | <i>quantum satis</i> (only for fruit compote other than apple)’ |
|--|--|---|

(d) the following is inserted in the list of additives and the maximum level for ‘*Mozzarella* and whey cheese’:

| | | |
|--|------------------------------|--|
| | ‘ E 460ii Powdered cellulose | <i>quantum satis</i> (only for grated <i>Mozzarella</i>)’ |
|--|------------------------------|--|

(e) the following rows are added at the end of the Annex:

| | | |
|---------------------|-----------------------|----------------------|
| ‘UHT goat milk | E 331 Sodium citrates | 4 g/l |
| Chestnuts in liquid | E 410 Locust bean gum | <i>Quantum satis</i> |
| | E 412 Guar gum | |
| | E 415 Xanthane gum | |

(3) In Part A of Annex III:

(a) the designation ‘Partially baked, pre-packed bakery wares intended for retail sale’ is replaced by the following: ‘Partially baked, pre-packed bakery wares and energy-reduced bread’

(b) at the end of this Part, the following rows are added:

| | | | | | | |
|--|-------|--|--|------|--|--|
| ‘Flavourings | | | | 1500 | | |
| Dairy or fat based spreads with added foodstuffs | 1500’ | | | | | |

(4) In Part C of Annex III:

(a) the following rows are deleted:

| | | | |
|--------|---------------------------|-----------------------------------|--|
| ‘E 230 | Biphenyl, diphenyl | Surface treatment of citrus fruit | 70 mg/kg |
| E 231 | Orthophenyl phenol | Surface treatment of citrus fruit | 12 mg/kg individually or in combination expressed as orthophenyl phenol’ |
| E 232 | Sodium orthophenyl phenol | | |

(b) the following foodstuff is added to E 1105:

| | | | |
|---------|----------|--|----------------------|
| ‘E 1105 | Lysozyme | Wine in accordance with Regulation (EC) No 1493/1999 ¹⁷ and its implementing Regulation (EC) No 1622/2000 ¹⁸ | <i>Pro memoria</i> ’ |
|---------|----------|--|----------------------|

(5) In Part D of Annex III:

(a) the following foodstuffs and maximum levels are added to E 310, E 311, E 312 and E 320:

| | | | |
|--------|--------------------------------|---------------------------------------|--|
| ‘E 310 | Propyl gallate | Essential oils | 1000 mg/kg (gallates and BHA, individually or in combination) |
| E 311 | Octyl gallate | | |
| E 312 | Dodecyl gallate | | |
| E 320 | Butylated hydroxyanisole (BHA) | Flavourings other than essential oils | 100 mg/kg (gallates, individually or in combination) or 200 mg/kg (BHA)’ |

¹⁷ OJ L 179, 14.4.1999, p.1.

¹⁸ OJ L 194, 31.7.2000, p.1.

(b) in the list of foodstuffs concerning E 315 and E 316, the designation ‘Semi-preserved and preserved meat products’ is replaced by the following: ‘Cured meat products and canned meat products’

(6) In Annex IV:

(a) the following foodstuff and maximum level concerning E 338 to E 452 are added:

| | | | |
|--|--|--------------|----------|
| | | ‘Flavourings | 50 g/kg’ |
|--|--|--------------|----------|

(b) the following foodstuff and maximum level concerning E 338 to E 452 are deleted:

| | | | |
|--|--|------------------|--------|
| | | ‘Cider and perry | 2 g/l’ |
|--|--|------------------|--------|

(c) the following foodstuff and maximum level are added to E 416:

| | | | |
|--------|------------|-------------|----------|
| ‘E 416 | Karaya gum | Flavourings | 50 g/kg’ |
|--------|------------|-------------|----------|

(d) the following foodstuffs and maximum levels concerning E 432 to E 436 are added:

| | | | |
|--|--|---|-----------|
| | | ‘Flavourings, except liquid smoke flavourings and flavourings based on spice oleoresins*’ | 10 g / kg |
| | | Liquid smoke flavourings and flavourings based on spice oleoresins | 75 g/kg’ |

* Spice oleoresins are defined as extracts of spices from which the extraction solvent has been evaporated leaving a mixture of the volatile oil and resinous material from the spice’

(e) in the list of foodstuffs concerning E 541, the designation ‘Fine bakery wares (*scones* and *sponge wares* only)’ is replaced by the following: ‘Fine bakery wares’

(f) the following foodstuff and maximum level concerning E 551 to E 559 are added:

| | | | |
|--|--|--------------|-------------------------|
| | | ‘Flavourings | 50 g / kg (only E 551)’ |
|--|--|--------------|-------------------------|

(g) the following foodstuff and maximum level are added to E 900:

| | | | |
|--------|-----------------------|-------------|-----------|
| ‘E 900 | Dimethyl polysiloxane | Flavourings | 10 mg/kg’ |
|--------|-----------------------|-------------|-----------|

(h) in the list for foodstuffs and maximum levels for E 903, the maximum levels are replaced by the following:

| | | | |
|--------|--------------|---|--|
| 'E 903 | Carnauba wax | <p>As glazing agents only:</p> <ul style="list-style-type: none"> - confectionery (including chocolate) . - small products of fine bakery wares coated with chocolate - snacks - nuts - coffee beans - dietary food supplements - fresh citrus fruits, melons, apples, pears, peaches and pineapples (surface treatment only) | <p>500 mg/kg</p> <p>1200 mg/kg (only for chewing gum)</p> <p>200 mg/kg</p> <p>200 mg/kg</p> <p>200 mg/kg</p> <p>200 mg/kg</p> <p>200 mg/kg</p> <p>200 mg/kg'</p> |
|--------|--------------|---|--|

(i) the following foodstuffs and maximum levels are added to E 459:

| | | | |
|--------|-------------------|---|---|
| 'E 459 | Beta-cyclodextrin | <p>Encapsulated flavourings in</p> <ul style="list-style-type: none"> - flavoured teas and flavoured powdered instant drinks - flavoured snacks | <p>0,5 g/kg</p> <p>1 g/kg</p> <p>in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer'</p> |
|--------|-------------------|---|---|

(j) the following row is added at the end of the Annex:

| | | | |
|--------------------------------------|---|---|---|
| 'E 907 | Hydrogenated poly-1-decene | As glazing agent for - sugar confectionery - dried fruits | 2 g/kg 2 g/kg |
| E 1505 E 1517 E 1518 E 1520 | Triethyl citrate Diacetin Glyceryl triacetate (triacetin) Propan-1,2-diol (propylene glycol) | Flavourings | 3 g/kg from all sources in foodstuffs as consumed or as reconstituted according to the instructions of the manufacturer; individually or in combination |
| E 1519 | Benzyl alcohol | Flavourings for - non-alcoholic flavoured drinks - liqueurs, aromatised wines, aromatised wine-based drinks and aromatised wine-products cocktails - confectionery and fine bakery wares | 50 mg/kg 100 mg/kg 250 mg/kg from all sources in foodstuffs as consumed or as reconstituted according to instruction of the manufacturer.' |

(7) In Annex V:

(a) the following row is added:

| | | |
|--------|------------------------------|---|
| 'E 555 | Potassium aluminium silicate | In E 171 titanium dioxide and E 172 iron oxides and hydroxides (max 90% relative to the pigment)' |
|--------|------------------------------|---|

(b) for E 468 the name "Cross-linked cellulose gum" is added.

(8) In Annex VI:

(a) in the introductory note, the following subparagraph is inserted after the first subparagraph:

‘Formulae and weaning foods for infants and young children may contain E 1450 starch sodium octenyl succinate resulting from the addition of vitamin preparations or polyunsaturated fatty acid preparations. The carry over of E 1450 in the product ready for consumption is not to be more than 100 mg/kg from vitamin preparations and 1000 mg/kg from polyunsaturated fatty acid preparations.’

(b) in Part 4, the title is replaced by the following:

‘Food additives permitted in dietary foods for infants and young children for special medical purposes as defined in Commission Directive 1999/21/EC’**

** Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, (OJ L 91, 7.4.1999, p. 29).’

(c) in Part 4, the following is added to the table:

| | | | |
|--------|---|--|---------------------|
| E 472c | Citric acid esters of mono- and diglycerides of fatty acids | 7,5 g/l sold as powder 9 g/l sold as liquid | From birth onwards’ |
|--------|---|--|---------------------|

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

TITLE OF PROPOSAL

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

DOCUMENT REFERENCE NUMBER

SANCO/3348/2002

THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The area of food additives is fully harmonised in the EU. An amendment is proposed for the positive list of food additives other than colours and sweeteners as laid down in Directive 95/2/EC. This Directive was developed according to the provisions of Council Directive 89/107/EEC (the framework Directive on food additives), which request the Commission to make a proposal on all food additives and the food categories in which the approved food additives may be used together with the conditions of use.

European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners was adopted in February 1995. The previous amendment of the Directive was adopted in February 2001. Since then, development at technical and scientific level as well as in the manufacture of foodstuffs has progressed. Therefore, there is a need to amend Directive 95/2/EC.

The current situation in the Member States concerning the authorisation of additives in flavourings is diverse and hinders the free movement of flavourings and foodstuffs containing these flavourings and creates conditions of unequal and unfair competition.

Therefore, the present proposal aims to harmonise legislation in the Community on additives necessary for the storage and use of flavourings while ensuring a high level of protection of human health and protection of consumers' interest, as well as to ensure fair trade practices.

It is therefore necessary to introduce a proposal for an amendment to the European Parliament and Council Directive 95/2/EC modifying the positive list of food additives.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

- which sectors of business

All sectors of the food industry using additives and flavourings for the manufacture of foodstuffs are affected.

- which sizes of business (what is the concentration of small and medium-sized firms)

All size of businesses.

- are there particular geographical areas of the Community where these businesses are found

There is a homogeneous geographic distribution.

3. What will business have to do to comply with the proposal?

One new food additive is authorised and the authorisation of several already authorised food additives is extended to new foods and food categories. This is favourable to the food manufacturers who have requested these new uses on the basis of the innovation in the business.

The authorisation of certain food additives in certain foodstuffs will be withdrawn, the production will have to be adapted accordingly.

Especially the flavouring industries have to respect the regulations which allow only certain additives to be added to flavourings at specified maximum levels. The food producing companies have only to ensure that they use flavourings containing additives which comply with this Directive. Only for products to which high amounts of flavourings are added (more than 1%) the food producing companies have to ensure that the additive carried over via the flavouring does not have a technological function in the final food. In addition, if flavourings are used which contain the additives E 459, E 1505, E, 1517, E 1518 or E 1520 (Article 2 (g)) they have to respect the maximum level established in food.

4. What economic effects is the proposal likely to have?

- on employment
- on investment and the creation of new businesses
- on the competitiveness of businesses

By national legislation, the Member States have authorised different additives at different maximum levels in flavourings. This proposal harmonises the rules in the Community. Thus, by creating conditions of equal and fair competition positive effects can be expected for the flavouring and food businesses.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

The proposal does not provide special measures for SME. All enterprises are treated equally.

CONSULTATION

6. List the organisations, which have been consulted about the proposal and outline their main views.

Associated Commission services have been formally consulted.

The following organisations and associations were consulted: European Flavour and Fragrance Association (EFFA), Smoke Flavourings Manufacturers Association (SFMA), Confederation of the food and drink industries of the EU (CIAA), European Dairy Association (EDA), Association of the Industry of Juices and Nectars from Fruits and Vegetables (AIJN), Federation of European Food Additives and Food Enzymes Industries (ELC), European Chemical Industry Council (CEFIC), Association of the Chocolate, Biscuit and Confectionery Industries of the EU (CAOBISCO), Federation of the Intermediate Products Industries for the Bakery and Confectionery Trades in the EEA (FEDIMA), Association of the Food Industries for Particular Nutritional Uses of the EU (IDACE), Liaison Centre for the Meat Processing Industry in the EU (CLITRAVI) and the European Consumers' Organisation (BEUC).