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European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners

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EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

Having regard to the Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (4), and in particular Article 3 (2) thereof,

Whereas differences between national laws relating to preservatives, antioxidants and other additives and their conditions of use hinder the free movement of foodstuffs; whereas this may create conditions of unfair competition;

Whereas the prime consideration for any rules on these food additives and their conditions of use should be the need to protect the consumer;

Whereas it is generally recognized that unprocessed foodstuffs and certain other foodstuffs should be free from food additives;

Whereas, having regard to the most recent scientific and toxicological information on these substances, some of them are to be permitted only for certain foodstuffs and under certain conditions of use;

Whereas it is necessary to lay down strict rules for the use of food additives in infant formulae, follow-on formulae and weaning foods, as referred to in 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 (5), and in particular Article 4 (1) (e) thereof;

Whereas this Directive is not intended to affect rules relating to sweeteners and colours;

Whereas, pending specific provisions pursuant to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (6), and pursuant to 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 (7), certain substances belonging to this category are provisionally covered by this Directive;

Whereas the Commission is to adapt Community provisions to accord with the rules laid down in this Directive;

Whereas the Scientific Committee for Food has been consulted for those substances which are not yet the subject of a Community provision;

Whereas it is necessary to include in this Directive specific provisions concerning additives referred to in other Community provisions;

Whereas it is desirable that when a decision is taken on whether a particular foodstuff belongs to a certain category of foods, the consultation of the Standing Committee for Foodstuffs procedure is followed;

Whereas modifications of existing purity criteria for food additives other than colours and sweeteners and new specifications for those where no purity criteria exist will be adopted in accordance with the procedure laid down in Article 11 of Directive 89/107/EEC;

Whereas the Scientific Committee for Food has not yet given an opinion on flour treatment agents; whereas those agents will be the subject of a separate Directive;

Whereas this Directive replaces Directives 64/54/EEC (8), 70/357/EEC (9), 74/329/EEC (10) and 83/463/EEC (11); whereas those Directives are hereby repealed,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive forming a part of the comprehensive Directive, within the meaning of Article 3 of Directive 89/107/EEC, and applies to additives other than colours, sweeteners and flour treatment agents.

2. Only additives which satisfy the requirements laid down by the Scientific Committee for Food may be used in foodstuffs.

3. For the purpose of this Directive:

(a) 'preservatives' are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms;

(b) 'antioxidants' are substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;

(c) 'carriers', including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

(d) 'acids' are substances which increase the acidity of a foodstuff and/or impart a sour taste to it;

(e) 'acidity regulators' are substances which alter or control the acidity or alkalinity of a foodstuff;

(f) 'anti-caking agents' are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

(g) 'anti-foaming agents' are substances which prevent or reduce foaming;

(h) 'bulking agents' are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;

(i) 'emulsifiers' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

(j) 'emulsifying salts' are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

(k) 'firming agents' are substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel;

(l) 'flavour enhancers' are substances which enhance the existing taste and/or odour of a foodstuff;

(m) 'foaming agents' are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

(n) 'gelling agents' are substances which give a foodstuff texture through formation of a gel;

(o) 'glazing agents' (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating;

(p) 'humectants' are substances which prevent foodstuffs from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium;

(q) 'modified starches' are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

(r) 'packaging gases' are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

(s) 'propellants' are gases other than air which expel a foodstuff from a container;

(t) 'raising agents' are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;

(u) 'sequestrants' are substances which form chemical complexes with metallic ions;

(v) 'stabilizers' are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilizers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff and include also substances which stabilize, retain or intensify an existing colour of a foodstuff;

(w) 'thickeners' are substances which increase the viscosity of a foodstuff.

4. Flour treatment agents other than emulsifiers are substances which are added to flour or dough to improve its baking quality.

5. For the purposes of this Directive the following are not considered as food additives:

(a) substances used for treatment of drinking water as provided for in Directive 80/778/EEC (12);

(b) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralization with sodium or potassium salts ('liquid pectin');

(c) chewing gum bases;

(d) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolytic enzymes;

(e) ammonium chloride;

(f) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

(g) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function;

(h) caseinates and casein;

(i) inulin.

Article 2

1. Only substances listed in Annexes I, III, IV and V may be used in foodstuffs for the purposes mentioned in Article 1 (3).

2. Food additives listed in Annex I are permitted in foodstuffs, for the purposes mentioned in Article 1 (3), with the exception of those foodstuffs listed in Annex II, following the 'quantum satis' principle.

3. Except where specifically provided for, paragraph 2 does not apply to:

(a) - unprocessed foodstuffs,

- honey as defined in Directive 74/409/EEC (13)

- non-emulsified oils and fats of animal or vegetable origin,

- butter,

- pasteurized and sterilized (including UHT sterilization) milk and cream (including skimmed, plain and semi-skimmed),

- unflavoured, live fermented milk products,

- natural mineral water as defined in Directive 80/777/EEC (14) and spring water,

- coffee (excluding flavoured instant coffee) and coffee extracts,

- unflavoured leaf tea,

- sugars as defined in Directive 73/437/EEC (15),

- dry pasta,

- natural unflavoured buttermilk (excluding sterilized buttermilk).

Within the meaning of this Directive, the term 'unprocessed' means not having undergone any treatment resulting in a substantial change in the original state of the foodstuffs; however, the foodstuffs may have been, for example, divided, parted, severed, boned, minced, skinned, pared, peeled, ground, cut, cleaned, trimmed, deep-frozen or frozen, chilled, milled or husked, packed or unpacked;

(b) foods for infants and young children as referred to in Directive 89/398/EEC, including foods for infants and young children not in good health; these foodstuffs are subject to the provisions of Annex VI;

(c) the foodstuffs listed in Annex II, which may contain only those additives referred to in that Annex and those additives referred to in Annexes III and IV under the conditions specified therein.

4. Additives listed in Annexes III and IV may only be used in the foodstuffs referred to in those Annexes and under the conditions specified therein.

5. Only those additives listed in Annex V may be used as carriers or carrier solvents for food additives and must be used under the conditions specified therein.

6. The provisions of this Directive shall also apply to the corresponding foodstuffs intended for particular nutritional uses in accordance with Directive 89/398/EEC.

7. Maximum levels indicated in the Annexes refer to foodstuffs as marketed, unless otherwise stated.

8. In the Annexes to this Directive, 'quantum satis' means that no maximum level is specified. However, additives shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.

Article 3

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

- 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, or
- 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.

2. Paragraph 1 does not apply to infant formulae, follow-on formulae and weaning foods, as referred to in Directive 89/398/EEC, except where specially provided for.

Article 4

This Directive shall apply without prejudice to specific Directives permitting additives listed in the Annexes to be used as sweeteners or colours.

Article 5

Where necessary, it may be decided by the procedure laid down in Article 6 of this Directive:

- whether a particular foodstuff not categorized at the moment this Directive was adopted belongs to a category of foodstuffs referred to in Article 2 or in one of the Annexes, or
- whether a food additive listed in the Annexes and authorized at 'quantum satis' is used in accordance with the criteria referred to in Article 2, or
- whether a substance is a food additive within the meaning of Article 1.

Article 6

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee for Foodstuffs, set up under Decision 69/414/EEC (16), hereinafter referred to as 'the Committee'.

2. The Chairman shall refer the matter to the Committee either on his own initiative or at the request of the representative of a Member State.

3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 7

Member States shall, within three years of the entry into force of this Directive, establish systems to monitor the consumption and use of food additives and report their findings to the Commission.

The Commission shall report to the European Parliament and the Council within five years of the entry into force of this Directive on the changes which have taken place in the food additives market, the levels of use and consumption.

In accordance with the general criteria in point 4 of Annex II to Directive 89/107/EEC, within five years of the entry into force of this Directive, the Commission shall review the conditions of use referred to in this Directive, and propose amendments where necessary.

Article 8

1. Directives 64/54/EEC, 70/357/EEC, 74/329/EEC and 83/463/EEC are hereby repealed.
2. References to these repealed Directives and to the purity criteria for certain food additives referred to in them shall henceforth be construed as references to this Directive.

Article 9

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 25 September 1996 in order to:

- allow, by 25 September 1996 at the latest, trade in and use of products conforming to this Directive,
- prohibit by 25 March 1997 at the latest, trade in and use of products not conforming to this Directive; products put on the market or labelled before that date which do not comply with this Directive may, however, be marketed until stocks are exhausted.

They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 20 February 1995.

For the European Parliament

The President

K. HÄNSCH

For the Council

The President

J. PUECH

(1) OJ No C 206, 13. 8. 1992, p. 12, and OJ No C 189, 13. 7. 1993, p. 11.

(2) OJ No C 108, 19. 4. 1993, p. 26.

(3) Opinion of the European Parliament of 26 May 1993 (OJ No C 176, 28. 6. 1993, p. 117), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993), common position of the Council of 10 March 1994 (OJ No C 172, 24. 6. 1994, p. 4) and decision of the European Parliament of 16 November 1994 (OJ No C 341, 5. 12. 1994)

(4) OJ No L 40, 11. 2. 1989, p. 27.

(5) OJ No L 186, 30. 6. 1989, p. 27.

(6) OJ No L 230, 19. 8. 1991, p. 1. Directive as last amended by Commission Regulation (EEC) No 3600/92 (OJ No L 366, 15. 12. 1992, p. 10).

- (7) OJ No L 350, 14. 12. 1990, p. 71.
- (8) OJ No 12, 27. 1. 1964, p. 161/64.
- (9) OJ No L 157, 18. 7. 1970, p. 31.
- (10) OJ No L 189, 12. 7. 1974, p. 1.
- (11) OJ No L 255, 15. 9. 1983, p. 1.
- (12) OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).
- (13) OJ No L 221, 12. 8. 1974, p. 10.
- (14) OJ No L 229, 30. 8. 1980, p. 1.
- (15) OJ No L 356, 27. 12. 1973, p. 71.
- (16) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX I

FOOD ADDITIVES GENERALLY PERMITTED FOR USE IN FOODSTUFFS NOT REFERRED TO IN ARTICLE 2 (3)

Note

1. Substances on this list may be added to all foodstuffs with the exception of those referred to in Article 2 (3) following the quantum satis principle.

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

3. Explanation of symbols used:

*The substances E 290, E 938, E 939, E 941, E 942 and E 948 may also be used in the foodstuffs referred to in Article 2 (3).

>REFERENCE TO A GRAPHIC> The substances E 410, E 412, E 415 and E 417 may not be used to produce dehydrated foodstuffs intended to rehydrate on ingestion.

>TABLE>

ANNEX II

FOODSTUFFS IN WHICH A LIMITED NUMBER OF ADDITIVES OF ANNEX I MAY BE USED

>TABLE>

ANNEX III

CONDITIONALLY PERMITTED PRESERVATIVES AND ANTIOXIDANTS

PART A Sorbates, benzoates and p-hydroxybenzoates

>TABLE>

>TABLE>

PART B Sulphur dioxide and sulphites

>TABLE>

>TABLE>

PART C Other preservatives

>TABLE>

>TABLE>

>TABLE>

PART D Other antioxidants

Note

The * in the table refers to the proportionality rule: when combinations of gallates, BHA and BHT are used, the individual levels must be reduced proportionally.

>TABLE>

ANNEX IV

OTHER PERMITTED ADDITIVES

The maximum levels of use indicated refer to foodstuffs ready for consumption prepared following manufacturers' instructions.

>TABLE>

ANNEX V

PERMITTED CARRIERS AND CARRIER SOLVENTS

Note

Not included in this list are:

1. Substances generally considered as foodstuffs;
2. Substances referred to in Article 1 (5);
3. Substances having primarily an acid or acidity regulator function, such as citric acid and ammonium hydroxide.

>TABLE>

ANNEX VI

FOOD ADDITIVES PERMITTED IN FOODS FOR INFANTS AND YOUNG CHILDREN

Note

Formulae and weaning foods for infants and young children may contain E 414 acacia gum (gum arabic) and E 551 silicon dioxide resulting from the addition of nutrient preparations containing not more than 10 g/kg of each of these substances, as well as E 421 mannitol when used as a carrier for vitamin B 12 (not less than 1 part vitamin B 12 to 1 000 parts mannitol).

The maximum levels of use indicated refer to foodstuffs ready for consumption prepared following manufacturers' instructions.

PART 1 FOOD ADDITIVES PERMITTED IN INFANT FORMULAE FOR INFANTS IN GOOD HEALTH

Notes

1. For the manufacture of acidified milks, non-pathogenic L(+)-lactic acid producing cultures may be used.
2. If more than one of the substances E 322 and E 471 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substance in that foodstuff.

>TABLE>

PART 2 FOOD ADDITIVES PERMITTED IN FOLLOW-ON FORMULAE FOR INFANTS IN GOOD HEALTH

Note

1. For the manufacture of acidified milks, non-pathogenic L(+)-lactic acid producing cultures may be used.
2. If more than one of the substances E 322 and E 471 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substance in that foodstuff.
3. If more than one of the substances E 407, E 410 and E 412 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.

>TABLE>

PART 3 FOOD ADDITIVES PERMITTED IN WEANING FOODS FOR INFANTS AND YOUNG CHILDREN IN GOOD HEALTH

>TABLE>

PART 4 FOOD ADDITIVES PERMITTED IN FOODS FOR INFANTS AND YOUNG CHILDREN FOR SPECIAL MEDICAL PURPOSES

The tables in Parts 1 to 3 of Annex VI are applicable.