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European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs

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EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/36/EC

of 30 June 1994

on colours 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 100a thereof,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (1), and in particular Article 3 (2) thereof,

Having regard to the proposal from the Commission (2),

Having regard to the opinion of the Economic and Social Committee (3),

Acting in accordance with the procedure referred to in Article 189b of the Treaty (4),

Whereas differences between national laws relating to the conditions of use of colours in food 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 and inform the consumer;

Whereas a food additive may only be used when there is evidence that it is technologically necessary and that its use is not harmful to health;

Whereas colours are used to restore original appearance of food whose colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;

Whereas colours are used to make food more visually appealing and help identify flavours normally associated with particular foods and to give colour to food otherwise colourless;

Whereas it is necessary to include certain colours intended for health marking of meat under the responsibility of the official veterinarian pursuant to the requirements of Directive 91/497/EEC (5), in particular Chapter XI of Annex I thereto;

Whereas only those colours authorized by this Directive should be used for the decoration of eggs or for the stamping of eggs as provided in Regulation (EEC) No 1274/91 (6);

Whereas colours are used to reinforce colours already present in food;

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

Whereas, having reagard to the most recent scientific and toxicological information on additives, some of these 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 additives in food for infants and young children;

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

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 Food procedure be followed;

Whereas this Directive replaces partially the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (7);

Whereas the modification of existing purity criteria on colouring matters and new specification for those where no purity criteria exist, will be proposed in accordance with the procedure of Article 11 of Directive 89/107/EEC;

Whereas, in order to protect consumers, the Community should promote research into the possible effects (including those of a cumulative and synergic nature) on human health of colours used in foodstuffs, with special reference to those whose harmlessness is in doubt,

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.
- 2. For the purposes of this Directive, 'colours' are substances which add or restore colour in a food, and include natural constituents of foodstuffs and natural sources which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food.

Preparations obtained from foodstuffs and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Directive.

- 3. However, the following substances shall not be considered colours for the purposes of this Directive:
- foodstuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound foodstuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect, such as paprika, turmeric and saffron,
- colours used for the colouring of the inedible external parts of foodstuffs, such as cheese coatings and sausage casings.

Article 2

- 1. Only the substances listed in Annex I may be used as colours in foodstuffs.
- 2. Colours may be used only in the foodstuffs listed in Annexes III, IV and V and under the conditions specified therein; colours may be used in those same foodstuffs when they are intended for particular uses in accordance with Directive 89/398/EEC (1).
- 3. Colours may not be used in the foodstuffs listed in Annex II except where specifically provided for in Annex III, IV or V.
- 4. Colours permitted for certain uses only are listed in Annex IV.
- 5. Colours permitted in general in foodstuffs and the conditions of use therefor are listed in Annex V.
- 6. The maximum levels indicated in the Annexes:

- relate to ready-to-eat foodstuffs prepared according to the instructions for use,
- refer to the quantities of colouring principle contained in the colouring preparation.
- 7. In the Annexes to this Directive 'quantum satis' means that no maximum level is specified. However, colouring matters shall be used according to 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.
- 8. For the purpose of health marking as provided in Directive 91/497/EEC and other marking required on meat products, only E 155 Brown HT, E 133 Brilliant Blue FCF or E 129 Allura Red AC or an appropriate mixture of E 133 Brilliant Blue FCF and E 129 Allura Red AC may be used.
- 9. Only those colours mentioned in Annex I may be used for the decorative colouring of eggshells or for the stamping of eggshells as provided in Regulation (EEC) No 1274/91.
- 10. Only those colours listed in Annex I, except E 123, E 127, E 128, E 154, E 160b, E 161g, E 173 and E 180, may be sold directly to consumers.
- 11. Within the meaning of this Directive 'unprocessed' means not having undergone any treatment resulting in a substantial change in the original state of the foodstuffs. However, they may have been for example divided, parted, servered, boned, minced, skinned, pared, peeled, ground, cut, cleaned, trimmed, deep-frozen, frozen, chilled, milled or husked, packed or unpacked.

Article 3

Without prejudice to other Community provisions, the presence of a colour in a foodstuff is permissible:

- in a compound foodstuff other than one mentioned in Annex II to the extent that the colour 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 such an extent that the compound foodstuff conforms to the provisions of this Directive.

Article 4

It may be decided by the procedure laid down in Article 5, whether a particular foodstuff belongs to a category of foods mentioned in the Annexes, and whether substances are colours in the meaning of Article 1.

Article 5

- 1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Standing Committee on Foodstuffs, set up pursuant to Decision 69/414/EEC (1), 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 down in that Article. The chairman shall not vote.
- 4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the Committee's opinion.

(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 6

Member States shall, within three years of the adoption of this Directive, establish systems to monitor the consumption and use of colours and report their findings to the Commission.

The Commission shall report to the European Parliament within five years of the adoption of the Directive on changes which have taken place in the colours market, the levels of use and consumption.

In accordance with the general criteria of point 4 of Annex II to Directive 89/107/EEC, within five years from the adoption of this Directive, the Commission shall review the conditions of use mentioned in this Directive, and propose modifications where necessary.

Article 7

Articles 1 to 7, Article 8 (1), second indent and (2), and Articles 9 to 15 of the Directive of 23 October 1962 on colouring matters in foodstuffs are hereby repealed.

References to the repealed provisions shall be construed as references to the corresponding provisions of this Directive.

Article 8

The Commission shall, to coincide with the date of entry into force of this Directive, launch a campaign, in conjunction with the European Parliament, national ministries, the food and retail industries and consumer bodies, to inform consumers about the evaluation and authorization procedures for permitted colours, and the meaning of the 'E' number system.

Article 9

- 1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1995 in order to:
- allow, not later than 31 December 1995, trade in and use of products conforming to this Directive,
- prohibit, not later than 30 June 1996, 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 at once inform the Commission thereof.

2. When Member States adopt the measures referred to in paragraph 1, 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 Member States.

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 30 June 1994.

For the European Parliament

The President

E. KLEPSCH

For the Council

The President

A. BALTAS

- (1) OJ No L 40, 11. 2. 1989, p. 27. Directive as amended by Directive 94/34/EC (see page 1 of this Official Journal).
- (2) OJ No C 12, 8. 1. 1992, p. 7.
- (3) OJ No C 313, 30. 11. 1992, p. 1.
- (4) Opinion of the European Parliament of 10 March 1993 (OJ No C 115, 26. 4. 1993, p. 105), confirmed on 2 December 1993 (OJ No C 342, 20. 12. 1993), Council common position of 9 March 1994 (not yet published in the Official Journal) and Decision of the European Parliament of 9 March 1994 (OJ No C 91, 28. 3. 1994, p. 79).
- (5) OJ No 268, 24. 9. 1991, p. 69. Directive as amended by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1).
- (6) Commission Regulation (EEC) No 1274/91 of 15 May 1991 introducing detailed rules for implementing Regulation (EEC) No 1907/90 on certain marketing standards for eggs (OJ No L 121, 16. 5. 1991, p. 11). Regulation as last amended by Regulation (EC) No 1259/94 (OJ No L 137, 1. 6. 1994, p. 54).
- (7) OJ No 115, 11. 11. 1962, p. 2645/62. Directive as last amended by Directive 85/7/EEC (OJ No L 2, 3. 1. 1985, p. 22).
- (1) OJ No L 186, 30. 6. 1989, p. 27.
- (1) OJ No L 291, 19. 11. 1969, p. 9.

ANNEX I

>TABLE>

ANNEX II

FOODSTUFFS WHICH MAY NOT CONTAIN ADDED COLOURS, EXCEPT WHERE SPECIFICALLY PROVIDED FOR IN ANNEX III, IV OR V

(The designations used in Annex II do not prejudice the 'carry over' principle in cases where products contain ingredients with legitimate colouring in their own right.)

- 1. Unprocessed foodstuffs
- 2. All bottled or packed waters
- 3. Milk, semi-skimmed and skimmed milk, pasteurized or sterilized (including UHT sterilization) (unflavoured)
- 4. Chocolate milk
- 5. Fermented milk (unflavoured)
- 6. Preserved milks as mentioned in Directive 76/118/EEC
- 7. Butter-milk (unflavoured)
- 8. Cream and cream powder (unflavoured)
- 9. Oils and fats of animal or vegetable origin

- 10. Eggs and egg products as defined in Article 2 (1) of Directive 89/437/EEC
- 11. Flour and other milled products and starches
- 12. Bread and similar products
- 13. Pasta and gnocchi
- 14. Sugar, including all mono- and disaccharides
- 15. Tomato paste and canned and bottled tomatoes
- 16. Tomato-based sauces
- 17. Fruit juice and fruit nectar as mentioned in Directive 75/726/EEC and vegetable juice
- 18. Fruit, vegetables (including potatoes) and mushrooms canned, bottled or dried; processed fruit, vegetables (including potatoes) and mushrooms
- 19. Extra jam, extra jelly, and chestnut purée as mentioned in Directive 79/693/EEC; crème de pruneaux
- 20. Fish, molluscs and crustaceans, meat, poultry and game as well as their preparations, but not including prepared meals containing these ingredients
- 21. Cocoa products and chocolate components in chocolate products as mentioned in Directive 73/241/EEC
- 22. Roasted coffee, tea, chicory; tea and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products
- 23. Salt, salt substitutes, spices and mixtures of spices
- 24. Wine and other products defined by Regulation (EEC) No 822/87
- 25. Korn, Kornbrand, fruit spirit drinks, fruit spirits, Ouzo, Grappa, Tsikoudia from Crete, Tsipouro from Macedonia, Tsipouro from Thessaly, Tsipouro from Tyrnavos, Eau de vie de marc Marque nationale luxembourgeoise, Eau de vie de seigle Marque nationale luxembourgeoise, London gin, as defined in Regulation (EEC) No 1576/89
- 26. Sambuca, Maraschino and Mistra as defined in Regulation (EEC) No 1180/91
- 27. Sangria, Clarea and Zurra as mentioned in Regulation (EEC) No 1601/91
- 28. Wine vinegar
- 29. Foods for infants and young children as mentioned in Directive 89/398/EEC including foods for infants and young children not in good health
- 30. Honey
- 31. Malt and malt products
- 32. Ripened and unripened cheese (unflavoured)
- 33. Butter from sheep and goats' milk

ANNEX III

>TABLE>

ANNEX IV

>TABLE>

ANNEX V

COLOURS PERMITTED IN FOODSTUFFS OTHER THAN THOSE MENTIONED IN ANNEXES II AND III

Part 1

The following colours may be used in foodstuffs mentioned in Annex V Part 2 and in all other foodstuffs other than those listed in Annexes II and III at quantum satis.

- E 101 (i) Riboflavin (ii) Riboflavin-5′-phosphate
- E 140 Chlorophylls and chlorophyllins
- E 141 Copper complexes of chlorophylls and chlorophyllins
- E 150a Plain caramel
- E 150b Caustic sulphite caramel
- E 150c Ammonia caramel
- E 150d Sulphite ammonia caramel
- E 153 Vegetable carbon
- E 160a Carotenes
- E 160c Paprika extract, capsanthin, capsorubin
- E 162 Beetroot Red, betanin
- E 163 Anthocyanins
- E 170 Calcium carbonate
- E 171 Titanium dioxide
- E 172 Iron oxides and hydroxides

Part 2

The following colours may be used singly or in combination in the following foods up to the maximum level specified in the table. However, for non-alcoholic flavoured drinks, edible ices, desserts, fine bakery wares and confectionery, colours may be used up to the limit indicated in the appropriate table but the quantities of each of the colours E 110, E 122, E 124 and E 155 may not exceed 50 mg/kg or mg/l.

- E 100 Curcumin
- E 102 Tartrazine
- E 104 Quinoline Yellow
- E 110 Sunset Yellow FCF Orange Yellow S
- E 120 Cochineal, Carminic acid, Carmines
- E 122 Azorubine, Carmoisine
- E 124 Ponceau 4R, Cochineal Red A
- E 129 Allura Red AC
- E 131 Patent Blue V
- E 132 Indigotine, Indigo carmine
- E 133 Brilliant Blue FCF
- E 142 Green S

- E 151 Brilliant Black BN, Black PN
- E 155 Brown HT
- E 160d Lycopene
- E 160e Beta-apo-8′-carotenal (C 30)
- E 160f Ethyl ester of Beta-apo-8′-carotenic acid (C 30)
- E 161b Lutein
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