

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93)153 final - SYN 368

Brussels, 19 April 1993

Amended proposal for a

COUNCIL DIRECTIVE

on Colours for use in foodstuffs.

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

Explanatory memorandum

In response to the opinion of the European Parliament⁽¹⁾ delivered on 16 December 1992 on the proposal for a Council Directive on colours for use in foodstuffs⁽²⁾ and in accordance with the third paragraph of Article 149 of the Treaty establishing the European Economic Community, the Commission has decided to amend the above mentioned proposal.

The Commission accepted amendments concerning:

- * A recital of the promotion of toxicological research on colour substances and the introduction in the legal text of the "quantum satis" principle because this increases the clearness.
- * Provisions for the colours used in stamping meat and colouring of meat and eggs because it is required by other Directives.
- * Establishment of a monitoring system of consumption of colours for the revision of the Directive. This would be a tool which will be used for updating the Directive.
- * Prohibition of colours in processed vegetables. Fruit preserves are already covered by the Commission's proposal. There is no necessity for the colouring of preserved vegetables.
- * Restriction of use of colours in certain meat products, cheese and breakfast cereals, because only a few colours are effectively used.
- * Prohibition of use of colours in wholemeal bread, but not in brown and malt bread because these are traditional products in some Member States.
- * Additions of two colours in meat products, because of their use in some traditional British meat products.
- * Restriction on the use of amaranth and brown FK because of their very low Acceptable Daily Intake (ADI) levels.

The Commission did not accept the amendments concerning :

- * Applicability of the directive on food intended for export to non-Member States, because the EEC can not make legislation for non-Member States.
- * Instructions for the publication in the Official Journal of certain items in one language only and establishment of an information campaign for the consumer are outside the scope of the proposal on colours.

(1) OJ No C , . .1993, p.

(2) OJ No C 12, 18.1.1992, p. 7.

- * Labelling dispositions should be dealt with in Directive 79/112/EEC.
- * Dispositions for controls by Member States of the respect of the Directive falls within the scope of the Directive on the official control of foodstuffs.
- * Prohibition of use of 2 colours of the positive list and restrictions for use of Tartrazin and Ponceau 4R for which there is positive evaluation of the Scientific Committee for Food.
- * Prohibition of use of colours in aromatised milk products, cheese products, processed vegetables and prohibition of use of colours in jams and jellies, because several Member States have a traditional use of certain colours in these products.
- * The permission of use of colours for sick babies is lacking the opinion of the Scientific Committee for Food.
- * For the restriction of the caramel type colours in beer, all caramel colours are approved by the SCF and there may be a technological necessity.
- * Concerning the replacement of the "quantum satis" levels by fixed levels and the changes in the maximum levels of use of colours in foodstuffs, there is no necessity for fixing maximum limits for colours for which there is no health concern.
- * Concerning the changes in the definition of cooked sausage and canned mushy and processed legumes, the proposed definition does not cover all foodstuffs which may be coloured.

Amended proposal for a
COUNCIL DIRECTIVE

on colours for use in foodstuffs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament(2),

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

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(4), and in particular Article 3(2) thereof,

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 the consumer and to prevent him from being misled;

Whereas a food additive may only be used when there is evidence that the use of this additive has an advantage for the consumer;

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 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 regard 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 Commission should adapt certain Community provisions to accord with the rules laid down in this Directive;

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, as last amended by the Act of Accession of Spain and Portugal(5);

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;

(1)

(2)

(3)

(4) OJ No L 40, 11.2.1989, p. 27.

(5) OJ No 115, 11.11.1962, p. 2645/62.

HAS 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. Colours are substances which add or restore colour in a food, and include natural components of foodstuffs and natural sources, which are normally not consumed as foodstuffs as such and not normally used as characteristic ingredients of food.
3. The following substances shall not be considered colours for the purposes of this Directive:
 - foodstuffs, flavourings and their components, 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 egg shells and for stamping meat and 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.
3. Colours may not be used in the foodstuffs listed in Annex II except where specifically provided for in Annex III, Annex IV or Annex 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. Maximum levels indicated in the Annexes refer to foodstuffs as marketed, unless otherwise stated.

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 and other marking required on meatproducts as provided in Council Directive 91/497/EEC⁽¹⁾, only E 155 Brown HT, 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 eggshell and for the stamping of eggshell as provided for in Regulation (EEC) No 1274/91⁽²⁾

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 6, whether a particular foodstuff belongs to a category of foods mentioned in Article 2(2), (3), (4) and (5), and whether substances are colours in the meaning of Article 1.

Article 5

Any provision necessary to adapt existing Community provisions to the rules laid down in this Directive shall be adopted within 6 months of notification, in accordance with the procedure laid down in Article 6.

(1) OJ No L 268, 24.9.1991, p. 69.

(2) OJ No L 121, 16.5.1991, p. 11.

Article 6

Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Standing Committee for Foodstuffs, hereinafter referred to as "the Committee", either on his own initiative or at the request of the representative of a Member State.

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, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Article 7

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 the 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 5 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 8

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

References to the repealed provisions shall be construed as references to the corresponding provisions of 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 1 November 1992 in order to:

- allow trade in and use of products conforming to this Directive not later than 1 November 1993,
- prohibit trade in and use of products not conforming to this Directive not later than 1 November 1994.

They shall at once inform the Commission thereof.

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

Article 10

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

LIST OF PERMITTED FOOD COLOURS

Note : Aluminium lakes prepared from colours mentioned in this annex are authorised.

EEC N°	COMMON NAME	COLOUR INDEX NUMBER (1) OR DESCRIPTION
E 100	Curcumin	75300
E 101	i) Riboflavin ii) Riboflavin-5'-phosphate	
E 102	Tartrazine	19140
E 104	Quinoline Yellow	47005
E 110	Sunset Yellow FCF, Orange Yellow S	15985
E 120	Cochineal, Carminic acid Carmines	75470
E 122	Azorubine, Carmoisine	14720
E 123	Amaranth	16185
E 124	Ponceau 4R, Cochineal Red A	16255
E 127	Erythrosine	45430
E 128	Red 2G	18050
E 129	Allura Red AC	16035
E 131	Patent Blue V	42051
E 132	Indigotine, Indigo Carmine	73015
E 133	Brilliant Blue FCF	42090

(1) Colour index numbers are taken from the 3rd edition 1982, volumes 1-7, 1315. Also amendments 37-40 (125), 41-44 (127-50), 45-48 (130), 49-52 (132-50), 53-56 (135).

EEC N°	COMMON NAME	COLOUR INDEX NUMBER (1) OR DESCRIPTION
E 140	Chlorophylls and Chlorophyllins i) chlorophylls ii) chlorophyllins	75810 75815
E 141	Copper complexes of chlorophylls and chlorophyllins i) copper complexes of chlorophylls ii) copper complexes of chlorophyllins	75815
E 142	Green S	44090
E 150a	Plain caramel (2)	
E 150b	Caustic sulphite caramel	
E 150c	Ammonia caramel	
E 150d	Sulphite ammonia caramel	
E 151	Brilliant Black BN, Black PN	28440
E 153	Vegetable Carbon	
E 154	Brown FK	
E 155	Brown HT	20285

(1) Colour index numbers are taken from the 3rd edition 1982, volumes 1-7, 1315. Also amendments 37-40 (125), 41-44 (127-50), 45-48 (130), 49-52 (132-50), 53-56 (135).

(2) The term caramel relates to products of a more or less intense brown colour which are intended for colouring. It does not correspond to the sugary aromatic product obtained from heating sugar and which is used for flavouring food (e.g. confectionery, pastry, alcoholic drinks).

EEC N°	COMMON NAME	COLOUR INDEX NUMBER (1) OR DESCRIPTION
E 160a	Carotenes : i) Mixed carotenes ii) Beta-carotene	75130 40800
E 160b	Annatto, bixin, norbixin	75120
E 160c	Paprika extract, capsanthin, capsorubin	
E 160d	Lycopene	
E 160e	Beta-apo-8'-carotenal (C 30)	40820
E 160f	Ethyl ester of Beta-apo-8'- carotenic acid (C 30)	40825
E 161b	Lutein	
E 161g	Canthaxanthin	
E 162	Beetroot Red, betanin	
E 163	Anthocyanins	Prepared by physical means from fruits and vegetables
E 170	Calcium carbonate	77220
E 171	Titanium dioxide	77891
E 172	Iron oxides and hydroxides	77491, 77492 77499
E 173	Aluminium	
E 174	Silver	
E 175	Gold	
E 180	Litholrubine BK	

(1) Colour Index numbers are taken from the 3rd edition 1982, volumes 1-7, 1315. Also amendments 37-40 (125), 41-44 (127-50), 45-48 (130), 49-52 (132-50), 53-56 (135).

ANNEX II

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

Unprocessed foodstuffs (*)

Mineral water as mentioned in directive 80/777/EEC(1)

Milk, semi-skimmed and skimmed milk, pasteurized or sterilized (including UHT sterilisation) (**)

Fermented milk(**)

Preserved milks as mentioned in the directive 76/118/EEC(**) (2)

Butter-milk(**)

Cream and cream powder(**)

Virgin oils and olive oil

Egg yolk, egg white, whole egg and egg powder

Flour and starch

Bread

Pasta

Sugars as defined in directive 73/437/EEC(3)

Tomato paste and tomato preserves

Fruit juice and fruit nectar as mentioned in directive 75/726/EEC(4)

Fruit preserves

Vegetable preserves and processed vegetables

Extra Jam, extra jelly, and chestnut puree as mentioned in the directive 79/693/EEC(5)

Fish, meat, poultry, game, meat preparations and prepared meat.

Cocoa and chocolate products as mentioned in directive 73/241/EEC(6)

Coffee, including instant coffee

Tea, tea extracts and infusions, including instant tea mixes

Spices

Wine as defined by the regulation 87/822/EEC(7)

Foods for infants and young children as mentioned in directive 89/398/EEC(8)

Honey

(*) Within the meaning of this directive, unprocessed foodstuffs are foodstuffs that have not undergone any treatment resulting in a substantial change in the original state of the foodstuffs. However, they may have been, for example, divided, parted, severed, boned, skinned, pared, peeled, ground, cut, cleaned, trimmed, frozen or chilled.

(**) unflavoured

(1) OJ L229,30.8.80, p.1

(2) OJ L24,30.1.76, p.49

(3) OJ L356,27.12.73 p.71

(4) OJ L311,1.12.75, p.40

(5) OJ L205,13.8.79, p.5

(6) OJ L63,5.3.74, p.34

(7) OJ L84,27.3.87, p.1

(8) OJ L186,30.6.89, p.27

ANNEX III

FOODSTUFFS TO WHICH ONLY CERTAIN PERMITTED COLOURS MAY BE ADDED

FOODSTUFFS	PERMITTED COLOUR	MAXIMUM LEVEL
<u>brown or malt bread</u>	E 150a Plain caramel E 150b Caustic sulphite caramel E 150c Ammonia caramel E 150d Sulphite ammonia caramel	quantum satis
Beer	E 150a Plain caramel E 150b Caustic sulphite caramel E 150c Ammonia caramel E 150d Sulphite ammonia caramel	quantum satis
Butter (including reduced fat butter and concentrated butter)	E 160a Carotenes E 160b Annatto, Bixin, Norbixin	quantum satis
Margarine, minarine, other fat emulsions, and fats essentially free from water	E 100 Curcumin E 160a Carotenes E 160b Annatto, Bixin Norbixin	quantum satis

FOODSTUFFS	PERMITTED COLOUR	MAXIMUM LEVEL
<u>Blue-green veined and marbled cheese</u>	E 131 Patent blue V E 140 Chlorophylls and chlorophyllins E 141 Copper complexes of chlorophylls and chlorophyllins	q u a n t u m
<u>Morbier cheese</u>	E 153 Vegetable carbon	
<u>Orange, yellow and broken white cheese</u>	E 160a Carotenes E 160b Annatto, Bixin, Norbixin E 171 Titanium dioxide	s a t i s
Refined vegetables oils except olive oil (for colour restoration only)	E 100 Curcumin E 160a Carotenes E 160b Annatto, Bixin Norbixin	quantum satis
Chorizo	E 120 Cochineal, Carminic acid, Carmines E 124 Ponceau 4R, Cochineal Red A	200 mg/kg 250 mg/kg
Sobrasada	E 110 Sunset yellow FCF E 124 Ponceau 4R Cochineal Red A	135 mg/kg 200 mg/kg

FOODSTUFFS	PERMITTED COLOUR	MAXIMUM LEVEL
"Pasturmas" (edible external coating)	E 100 Curcumin E 101 i) Riboflavin ii) Riboflavin -5'- phosphate E 120 Cochineal, Carminic acid, Carmines	quantum satis
Sausages (including eg salami, cervelat, hot dog), patés, meat pies and luncheon meat, burger meat containing minimum content meat/fat of 82% and a minimum of 6% of cereals	E 100 Curcumin E 110 Sunset yellow E 120 Cochineal, carminic acid, carmines E 124 Ponceau 4R E 129 Allura Red E 150a Plain caramel E 150b Caustic sulphite caramel E 150c Ammonia caramel E 150d Sulphite ammonia caramel E 160a Carotenes E 160b Annatto Bixin, Norbixin E 160c Paprika extract, Capsanthin, Capsorubin E 162 Beetroot red, betanin E 171 <u>Titanium</u> <u>dioxide</u> E 172 <u>Iron oxide</u>	20 mg/kg 50 mg/kg 100 mg/kg 40 mg/kg 150 mg/kg quantum satis quantum satis quantum satis quantum satis 20 mg/kg 20 mg/kg 10 mg/kg quantum satis quantum satis quantum satis

FOODSTUFFS	PERMITTED COLOUR	MAXIMUM LEVEL
<u>Extruded, puffed and/or fruit flavoured breakfast cereals</u>	<u>E 150c Ammonia Caramel</u> <u>E 160a Carotenes</u> <u>E 160b Annatto, bixine, nor-bixine</u> <u>E 160c Paprika extract, capsanthine, capsorubine</u>	<u>quantum satis</u> <u>quantum satis</u> <u>200 mg/kg</u> <u>quantum</u> <u>satis</u>
<u>Fruit flavoured breakfast cereals</u>	<u>E 120 Cochineal carminic acid, carmines</u> <u>E 162 Beetroot red betanine</u> <u>E 163 Anthocyanins</u>	<u>singly or in combination</u> <u>200 mg/kg</u>

ANNEX IV

COLOURS PERMITTED FOR CERTAIN USES ONLY

COLOUR	FOODSTUFFS	MAXIMUM LEVEL
E 123 Amaranth	<u>Alcoholic drinks, aperitif wines and spirit drinks</u>	<u>30 mg/kg</u>
E 127 Erythrosine	<u>fish roe</u> Cocktail cherries and candied cherries Cherries in syrup and cherries in cocktails	<u>30 mg/kg</u> 200 mg/kg 150 mg/kg
E 128 Red 2G	Sausages and burgers with a starch content of more than 6 % Decorations and coatings Vegetable protein flour	20 mg/kg 50 mg/kg 150 mg/kg
E 154 Brown FK	Smoked and cured fish	20 mg/kg
E 161g Canthaxanthin	Cooked sausages	30 mg/kg
E 173 Aluminium	External coating of sugar confectionery for the decoration of cakes and pastries	quantum satis
E 174 Silver	External coating of confectionery (chocolate excluded) Liqueurs	quantum satis
E 175 Gold	External coating of confectionery (chocolate excluded) Liqueurs	quantum satis
E 180 Litholrubine BK	Edible Cheese surface	quantum satis

ANNEX V

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

1. The following colours may be used in all foodstuffs other than those listed in Annex II, 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

2. The following colours may be used singly or in combination in the following foods up to the maximum level specified in the table.

- 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 160b Annatto, Bixin, Norbixin
- 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

FOODSTUFFS	MAXIMUM LEVEL
Non-alcoholic flavoured drinks (*)	100 mg/l
Jams, jellies, marmelades and other similar fruit preparations	200 mg/kg
Candied fruits	200 mg/kg
Preserves of red fruits	200 mg/kg
Confectionery	300 mg/kg
Decorations and coatings (*)	500 mg/kg
Fine bakery wares (e.g. viennoiserie, biscuits, cakes and wafers) (*)	200 mg/kg
Edible ices (*)	150 mg/kg
Processed cheese	200 mg/kg
Desserts (*)	150 mg/kg
Vegetables and fruits in vinegar, brine or oil	150 mg/kg
Sauces, Seasonings and condiments (*)	500 mg/kg
Mustard	300 mg/kg
Fish and crustacean pastes, fish roe, salmon substitute, surimi, smoked or preserved fish	500 mg/kg
Ready-to-eat savouries	200 mg/kg
Edible cheese rind and edible collagen casings	quantum satis
Fruit wines, aromatized wines and spirits (*)	200 mg/l
Cider or perry	100 mg/l
Formulae for particular nutritional uses (*)	50 mg/kg
Dietary supplements	quantum satis
Soups and broths(*)	300mg/kg
Canned mushy and processed legumes	200 mg/kg
Vegetable protein flour	100 mg/kg

(*) Maximum levels refer to ready-for-consumption foodstuffs prepared according to the manufacturer's instructions.

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DOCUMENTS

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