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COMMISSION**

Draft Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on food additives authorised for use in foodstuffs intended for human consumption

(Text with EEA relevance)

(presented by the Commission)

EXPLANATORY MEMORANDUM

DRAFT PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on food additives authorised for use in foodstuffs intended for human consumption

1. INTRODUCTION

The Commission announced in the White Paper on Food Safety that it would up-date and complete existing Community legislation with regard to food additives (Action 11 in the White Paper).

Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption lays down the general principles for authorisation of food additives in the European Union.

This Directive is complemented with the European Parliament and the Council Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs and 95/2/EC on food additives other than colours and sweeteners. These three directives lay down the list of authorised food additives and their conditions of use to the exclusion of all others.

The Commission has been conferred implementing powers to lay down purity criteria for food additives authorised for use by the European Parliament and the Council and to verify the criteria are satisfied. This purity criteria are laid down in four Commission Directives (94/45/EC, 95/31/EC, 96/77/EC and 81/712/EEC¹).

In addition, the European Parliament and the Council have adopted a Decision No 292/97/EC on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs².

2. GENERAL OBJECTIVES

The objectives of this proposal are:

- To simplify food additive legislation by creating a single instrument for principles, procedures and authorisations;
- To confer the implementing powers on the Commission to update the Community list of authorised food additives;
- To consult the European Food Safety Authority (EFSA) for the safety evaluation of food additives;

¹ First Commission Directive 81/712/EEC of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity. OJ L 257, p. 10.9.1981. p 1.

² OJ L 48, 19.2.1997, p.13.

- To set up a re-evaluation programme for existing authorisations of food additives within 10 years;
- To require the authorisation of additives that consist of, contain or are produced from a GMO under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

3. SCOPE

The proposal applies to substances used as food additives as defined in the proposal that fall under functional classes described in Annex I of the proposal. For the purpose of this proposal 'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of or otherwise affecting the characteristics of such foods;

Substances used as processing aids as defined in the proposal do not fall under the scope of this proposal. For the purpose of this proposal 'processing aid' means any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

Food enzymes, whether fulfilling the definition of a food additive or a processing aid, do not fall under this proposal either. All food enzymes will be regulated under a separate proposal ([Draft proposal] for a European Parliament and Council Regulation (EC) No .../... on food enzymes).

4. PRINCIPLES OF THE AUTHORISATION PROCEDURE

a) General criteria

All food additives and their use in food will be evaluated for the following criteria: safety, technological need, benefit to the consumer and that the consumer is not being misled by the use.

b) EFSA evaluation

In line with the decision to separate risk management and risk assessment, all the applications for authorisation will be directed to EFSA which will carry out the safety evaluations. The authorisation will be considered by the Commission on the basis of the opinion from EFSA.

EFSA will set up guidelines on the information required for risk assessment. Meanwhile, the guidelines adopted by the Scientific Committee on Food remain

applicable (*Guidance on submission for food additive evaluations by the Scientific Committee on Food, expressed in 12 July 2001*).

EFSA has been consulted on the content of this Regulation on the matters that have effect on its work and agreed with it.

Scientific data and other information in the initial dossier submitted for the purpose of authorisation may not be used for the benefit of other applicants for a period of ten years, unless the applicant has agreed that such information may be used.

c) Authorisation

In addition to the safety of the substance, the other general criteria (technological need, consumer aspects) have to be examined before the authorisation is granted. This will be done by the Standing Committee on the Food Chain and Animal Health (SCFAH). The final authorisation will be granted by the Commission by entering the authorised food additive and its conditions of use in Annex II of this Regulation.

Authorisation will be granted for a ten year period and it is renewable on the basis of an application within 18 months before the expiry of the authorisation. As technology evolves, the need for a particular food additive may change in time. Therefore, it is desirable to regularly review authorisations in order to assess whether they are still relevant.

d) Genetic modification

A new food additive which consists, contains or is produced from a genetically modified organism, should be examined in respect of the genetic modification according to Regulation (EC) No 1829/2003 on genetically modified food and feed, prior to its authorisation under this Regulation.

A substance authorised for use as a food additive under this Regulation, which consists, contains or is produced from a genetically modified organism that were not subject to the initial safety evaluation, should be authorised in respect of the genetic modification, according to Regulation (EC) No 1829/2003 on genetically modified food and feed.

e) National authorisations

Temporary measures for a national authorisation of a new food additive will be abolished. The Member States have used their right for granting a national authorisation for a new food additive several times. However, the current experience has shown that transition within the time period laid down in Directive 89/107/EEC from national authorisation to Community authorisation is not always guaranteed. This creates confusion and unfair constraints to the food industry wishing to employ the new food additive. The national authorisation could be justified when the Community authorisations were to be adopted under co-decision procedure. However, they would not be justified under comitology procedure.

f) Existing authorisations

(i) Programme on **safety** assessment of authorised food additives

The Authority shall carry out a risk assessment on all currently authorised food additives (179 additive and additive groups). In consultation with the Authority, the Commission should set up an evaluation programme in order to define the need and the order of priorities for the risk assessment. Time limits for the evaluation should be laid down in the programme. To complete the evaluations may take up to ten years. The Authority will provide guidance to the food industry on the content of the application dossier.

(ii) Evaluation of **compliance with the general criteria** for authorisation of authorised food additives

Food additives currently authorised under Directives 94/35/EC, 94/36/EC and 95/2/EC shall be entered in Annex II of this proposal after a review carried out by the SCFCAH. The Standing Committee will evaluate the compliance of existing authorisations with the general criteria laid down in the Regulation taking into account the latest scientific opinion on the safety of the food additive. Until the Committee has completed the review of existing authorisations, the above-mentioned Directives shall remain applicable.

Directives 94/35/EC, 94/36/EC and 95/2/EC will continue to be amended in the light of scientific and technical progress until this Regulation comes into force. From that day onwards, the new authorisations will be added into Annex II of this Regulation.

5. LABELLING

Labelling of food additives sold to the manufacturer or directly to the consumer is regulated by Directive 89/107/EC. This proposal up-dates these rules especially to inform the manufacturer or the consumer where the additive consists, contains or is produced from genetically modified organisms. The wording is in compliance with the Regulation (EC) No 1829/2003 on genetically modified food and feed.

6. IMPLEMENTATION

Implementation of the measures proposed in the Regulation will be adopted by the Commission in accordance with the regulatory procedure laid down in Council Decision 1999/468/EC. This consists of authorising the use of food additives and laying down the conditions of use as well as laying down purity criteria and the verification of such criteria. As these are matters of high technicality that are adopted on the basis of commonly agreed principles, they should be trusted to the Commission for the sake of efficiency, simplification and transparency.

7. REPEALS

This proposal will repeal and replace the following Directives: Directive 89/107/EEC, Directive 94/35/EC, Directive 94/36/EC, Directive 95/2/EC and Decision No 292/07/EC. However, the Articles and Annexes of Directives 94/35/EC, 94/36/EC and 95/2/EC laying down the authorisation of use of food additives and their conditions of use should be maintained until the evaluation of current authorisations has been finalised and resulting authorisations included in Annex II of

this Regulation. The authorisations for E 1103 Invertase and E 1105 Lysozyme will be repealed from the date of application of the Regulation on food enzymes.

This proposal will also repeal Council Directives 65/66/EEC, 78/663/EEC and 78/664/EEC on purity criteria, which are already replaced by Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners.

Working document

Draft Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on food additives authorised for use in foodstuffs intended for human consumption

(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 Commission³,

Having regard to the opinion of the European Economic and Social Committee⁴,

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

Whereas:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (3) Food additives may only be used in foodstuffs if they have been approved for use by this Regulation and only in conditions set therein.
- (4) Food additives may be approved only if they fulfil criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological necessity for their use, their use must not mislead the consumer and their use must bring benefit to the consumer. Food additives must at all times comply with the approved criteria of purity.
- (5) Prior to the authorisation for use of a food additive the European Food Safety Authority, set up by Regulation (EC) No 178/2002, should be consulted on matters likely to affect public health.
- (6) A new food additive which consists, contains or is produced from a genetically modified organism, should be examined in the respect of the genetic modification according to the Regulation (EC) No 1829/2003 of the European Parliament and of the

³ OJ C [x], [x], p. [x]

⁴ OJ C [x], [x], p. [x]

- Council of 22 September 2003 on genetically modified food and feed⁵, prior to its authorisation under this Regulation.
- (7) A substance authorised for use as a food additive under this Regulation, which consists, contains or is produced from a genetically modified organism that were not subject to the initial safety evaluation, should be authorised in respect of the genetic modification, in accordance with the Regulation (EC) No 1829/2003 on genetically modified food and feed.
 - (8) The authorised food additives should be re-evaluated for their safety and compliance with the other criteria set in the Regulation, ten years after entry into force of the first authorisation.
 - (9) To re-evaluate the safety of food additives authorised before the entry in force of this Regulation, an evaluation programme should be set up by the Commission within one year after the adoption of this Regulation. The programme should define the need and the order of priorities according to which the authorised food additives are to be examined.
 - (10) The Standing Committee on Food Chain and Animal Health should re-evaluate all the existing authorisations for the criteria other than safety within two years after the adoption of this Regulation. As a result all retained authorisations are transferred to the Annex II of this Regulation and will be valid for 10 years.
 - (11) Provisions on labelling of food additives sold as such to the manufacturer or to the final consumer are contained in this Regulation; It is necessary to adjust the rules on labelling of these food additives to inform the user that the additive consists, contains or is produced from a genetically modified organism.
 - (12) Since the measures for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁶, they should be adopted by use of the regulatory procedure provided for in Article 5 of this Decision.
 - (13) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to food of Community origin or imported from a third country. They allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.
 - (14) This Regulation will repeal and replace the following Directives: Directive 89/107/EEC⁷, Directive 94/35/EC⁸, Directive 94/36/EC⁹ and Directive 95/2/EC¹⁰. However, the Articles and Annexes of Directives 94/35/EC, 94/36/EC and 95/2/EC

⁵ OJ L 268, 18.10.2003, p.1.

⁶ OJ L 184, 17.7.1999, p.23.

⁷ OJ L 40, 11.2.1989, p.28.

⁸ OJ L 237, 10.9.1994, p.3.

⁹ OJ L 237, 10.9.1994, p.13.

¹⁰ OJ L 61, 18.3.1995, p.3.

laying down the authorisation of use of food additives and their conditions of use should be maintained until the review of current authorisations by the Standing Committee on the Food Chain and Animal Health has been finalised and resulting authorisations have been included in Annex II of this Regulation. This proposal will also repeal Council Directives 65/66/EEC¹¹, 78/663/EEC¹² and 78/664/EEC¹³ on purity criteria, which are already replaced by Commission Directive 96/77/EC.

HAVE ADOPTED THIS REGULATION:

¹¹ OJ L 22, 9.2.1965, p.373.
¹² OJ L 223, 14.8.1978, p.7.
¹³ OJ L 223, 14.8.1978, p.30.

CHAPTER I

General provisions

Article 1 *Subject matter*

This Regulation updates and supersedes previous Directives concerning food additives authorised for use in foodstuffs intended for human consumption with a view to continuing to ensure the effective functioning of the internal market and a high level of protection of human health and the interests of consumers via more comprehensive and streamlined procedures.

To this end the Regulation lays down

- general criteria and safety requirements for the use of food additives in and on foods;
- Community procedures for the evaluation and authorisation of food additives;
- the list of food additives permitted for use in foodstuffs and their conditions of use;
- provisions for the labelling of food additives sold to the food manufacturer or sold as such to the final consumer.

Article 2 *Scope*

1. This Regulation shall apply to food additives as defined in Article 3(1).
2. This Regulation shall not apply to:
 - (a) processing aids;
 - (b) substances used for the protection of plants and plant products in conformity with Community rules relating to plant health;
 - (c) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC¹⁴ with the exception of substances and materials referred to in Article 6(1) of the said Directive;
 - (d) substances falling within the scope of [the proposal for a] Regulation [...] of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods¹⁵;

¹⁴ OJ L 184, 15.7.1988, p.61.

¹⁵ COM (2003) 671 final COD (2003/0262)

- (e) substances falling within the scope of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements¹⁶;
- (f) food enzymes, falling within the scope of [the proposal for a] Regulation [...] on food enzymes;
- (g) foodstuffs with sweetening properties;
- (h) foodstuffs, whether dried or in concentrated form, including 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;
- (i) colours used for the colouring of the inedible external parts of foodstuffs, such as some cheese coatings and sausage casings;
- (j) substances used for treatment of drinking water as provided for in Directive 80/778/EEC¹⁷;
- (k) 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');
- (l) chewing gum bases;
- (m) 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;
- (n) ammonium chloride;
- (o) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;
- (p) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function;
- (q) caseinates and casein;
- (r) inulin;

3. Where necessary, it may be determined in accordance with the procedure laid down in Article 32 whether a substance falls within the scope of this Regulation.

¹⁶ OJ L 183, 12.7.2002, p. 51

¹⁷ OJ L 229, 30.8.1980, p.11

Article 3
Definitions

For the purposes of this Regulation, the definitions laid down in Regulation (EC) 178/2002 shall apply.

For the purposes of this Regulation the following definitions shall also apply:

- (1) 'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of or otherwise affecting the characteristics of such foods;
- (2) 'processing aid' means any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product;
- (3) 'genetically modified organism ("GMO")' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC¹⁸, with the exclusion of organisms obtained through the techniques of genetic modification listed in Annex I B of Directive 2001/18/EC;
- (4) 'functional class' means description of the technical function a food additive exerts in the foodstuff;
- (5) 'unprocessed foodstuff' means a foodstuff 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;
- (6) 'with no added sugar'; without any added mono- or disaccharides or any other foodstuff used for its sweetening properties;
- (7) 'energy-reduced'; with an energy value reduced by at least 30% compared with the original foodstuff or a similar product.
- (8) In the Annexes to this Regulation, '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.

¹⁸ OJ L 106, 17.4.2001, p. 1.

Article 4
General requirements

1. No person shall place on the market a food additive for food use or food containing a food additive falling within the scope of this Regulation unless:
 - (a) it is covered by an authorisation granted in accordance with this Regulation;
 - (b) the conditions for use set out in this Regulation for the authorisation of the substance are met;
 - (c) the conditions on labelling set out in this Regulation and/or in Directive 2000/13/EEC are met.
2. In case of food additives consisting of, containing or produced from a genetically modified organism (GMO), no person shall place the product on the market other than the authorisation holder named in the authorisation Regulation or a person acting under his written authority.
3. Provisions that may have effect upon public health shall be adopted after consultation with the European Food Safety Authority, hereinafter referred to as 'the Authority'.
4. Food additives permitted for use in foodstuffs and their conditions of use are laid down in Annex II.
5. All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Any producer of the food additive shall inform the Commission and the Authority immediately of any new scientific or technical information which might affect the assessment of the safety of the authorised food additive. If necessary, the Authority shall then review the assessment.

Article 5
Functional classes of food additives

1. The inclusion of a food additive in one of the functional classes in Annex I shall be on the basis of the principal function normally associated with the food additive in question. However, the allocation of the additive to a particular functional class does not exclude the possibility of the additive being authorised for several functions.
2. Where necessary, as a result of scientific progress or technological development, additional food additive functional classes may be established in Annex I of this Regulation in accordance with the procedure referred to in Article 32.

Article 6
Risk assessment

1. A risk assessment of the food additive shall be carried out by the Authority.

2. To assess the possible harmful effects of a food additive or derivatives thereof, the food additive must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use, the phenomenon of human intolerance to substances foreign to the body and the anticipated human exposure to the proposed additive from food.
3. The details on the required information for the risk assessment shall follow the guidelines set by the Authority.

Article 7

Risk assessment of genetic modification

1. A substance, subject to authorisation for use as a food additive, which consists, contains or is produced from genetically modified organisms, shall be examined in respect of the genetic modification according to Regulation (EC) No 1829/2003 on genetically modified food and feed, prior to the assessment set out in Article 11 of this Regulation and prior to its authorisation for use.
2. A substance authorised for use as a food additive by this Regulation, which consists, contains or is produced from genetically modified organisms that were not subject to the initial safety evaluation, shall be authorised in respect of the genetic modification, in accordance with Regulation (EC) No 1829/2003 on genetically modified food and feed. The additive in question may be put on the market only after the granting of authorisation by Commission Decision, as laid down by Article 7 of the said Regulation.

Article 8

Purity criteria of food additives

1. Food additives must at all times comply with the approved purity criteria. The purity criteria are laid down at the time the food additive is approved for use for the first time.
2. The Commission adopts the purity criteria, on the recommendation of the Authority, under the procedure laid down in Article 32.
3. Where necessary, the methods of analysis needed to verify that the purity criteria referred to in paragraph 1 are satisfied may be laid down under the procedure laid down in Article 32. However, in the absence of Community rules and methods, Member States shall take all necessary steps to satisfy themselves that controls and inspections are carried out:

- in accordance with standards recognised by international bodies

in the absence of such standards, in accordance with scientifically recognised national rules which comply with the general principles of the Treaty.

CHAPTER II

Placing on the market of a food additive

Article 9 *Authorisation*

1. Any person seeking:
 - an authorisation for a new food additive shall submit an application in accordance with Article 11;
 - a modification of conditions of use of an authorised food additive shall submit an application in accordance with Article 14;
 - a change in purity criteria of an authorised food additive shall submit an application in accordance with Article 15;
 - a renewal of the existing authorisation shall submit an application in accordance with Article 16.
2. An authorisation shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation, or in accordance with Articles 53 and 54 of Regulations (EC) 178/2002.

Article 10 *Conditions for authorisation*

1. No food additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that, when used in accordance with conditions to be set in the Annex II of this Regulation, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3:
2. Food additives can only be used provided that:
 - they do not present hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,
 - a reasonable technological need can be demonstrated and the purpose cannot be achieved by other means which are economically and technologically practicable,
 - their use does not mislead the consumer
 - their use benefits the consumer.

3. The use of a food additive may be considered only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer. To this end, it must serve one or more of the following purposes:
 - (a) to preserve the nutritional quality of the food: an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;
 - (b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
 - (c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;
 - (d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.
4. Without prejudice to paragraph 3, the use of sweeteners must serve one or more of the following purposes:
 - (a) to replace sugar for the production of energy-reduced food, non-cariogenic food or food without added sugars;
 - (b) for the extension of shelf life through the replacement of sugar;
 - (c) for the production of dieteric products.
5. Without prejudice to paragraph 3, the use of colours must serve one or more of the following purposes:
 - (a) to restore original appearance of food whose colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;
 - (b) to make food more visually appealing;
 - (c) to help identify flavours normally associated with particular foods;
 - (d) to give colours to food otherwise colourless.

Article 11

Application for authorisation of a new food additive

1. To obtain the authorisation referred to in Article 9, an application shall be submitted in accordance with the following points:

- (a) the application shall be sent to the competent authority of a Member State accompanied by the following:
 - (i) the name and address of the applicant;
 - (ii) a technical dossier containing the information in accordance with the guidance referred to in paragraph 2;
 - (iii) a summary of the technical dossier;
 - (iv) a proposal for purity criteria;
 - (v) for food additives consisting of, containing or produced from GMOs and covered by Regulation (EC) No 1829/2003 on genetically modified food and feed, a copy of the details of the application for authorisation under this Regulation.
 - (b) The competent authority referred to in (a) shall:
 - (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (ii) inform without delay the Authority, and
 - (iii) make the application and any supplementary information supplied by the applicant available to the Authority.
 - (c) The Authority shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.
2. The Authority shall publish detailed guidance concerning the preparation and the submission of the application¹⁹

Article 12
Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application as to whether the food additive and its intended uses comply with Article 10 (2) first indent.

The Authority may extend the said period by a maximum period of a further six months. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the

¹⁹ Pending such publication, applicants may consult the “Guidance on Submissions for Food Additive Evaluations by the Scientific Committee on Food” (opinion expressed on 11 July 2001, or its latest update).

Authority. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time, as that information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.

3. In order to prepare its opinion, the Authority shall:
 - (a) verify that the information and documents submitted by the applicant are in accordance with Articles 11 or 15, in which case the application shall be regarded as valid;
 - (c) inform the applicant, the Commission and the Member States if an application is not valid.
4. In the event of an opinion in favour of the application, the opinion shall include the following elements where applicable:
 - (a) the designation of the food additive including allocation within functional classes provided for in Article 5,
 - (b) a specification of the food additive, including purity criteria and methods of analysis;
 - (c) depending on the outcome of the evaluation, if necessary, recommendations for any conditions or restrictions of use in relation to acceptable daily intake of the food additive;
5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.
6. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 30.

Article 13

Community authorisation

1. The Commission shall prepare, where appropriate, a draft of a measure to be taken in respect of the application taking into account the requirements of Article 10, the opinion of the Authority, relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft measure is not in accordance with the opinion of the Authority, the Commission shall provide an explanation of the reasons for the differences.
2. The measure referred to in paragraph 1 shall be
 - A draft Regulation amending Annex II, by including the substance on the list of authorised food additives or modifying conditions of use set in Annex II;
 - A draft Directive laying down purity criteria mentioned in Article 9 amending Directive 95/31/EC, 95/45/EC or 96/77/EC, as appropriate;
 - A draft Decision, addressed to the applicant, refusing authorisation.

3. The measure shall be adopted in accordance with the procedure laid down in Article 32. The Commission shall inform the applicant of its adoption without delay.
4. The measure referred to in paragraph 2, first indent, must:
 - (a) specify the foodstuffs to which the food additive may be added and the conditions under which it may be added;
 - (b) be limited to the lowest level of use necessary to achieve the desired effect;
 - (c) take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the possible daily intake of the food additive by consumers in those groups;
 - (d) take into account benefit to the consumer;
 - (e) take into account whether the consumer could be misled by the use of a food additive.
5. The authorised food additive and its conditions of use shall be entered in the Annex II of this Regulation. Each entry in the Annex shall mention the date of authorisation.
6. Without prejudice to Article 17, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 16.
7. The granting of an authorisation shall not diminish the general civil and criminal liability of any food business operator in respect to the authorised food additive or food containing the authorised food additive.

Article 14

Application for modification of conditions of use of an authorised food additive

1. To obtain the authorisation to use an authorised food additive in a food or food category in which it has not been permitted or a modification of the conditions of use, an application shall be submitted in accordance with the following points:
 - (a) The application shall be sent to the competent authority of a Member State accompanied by the following:
 - (i) the name and address of the applicant;
 - (ii) a technical dossier containing the information in accordance with the guidance referred to in paragraph 2;(iii) a summary of the technical dossier.
 - (b) The competent authority referred to in (a) shall:

- (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (ii) inform without delay the other Member States and the Commission; and
 - (iii) make the application and any supplementary information supplied by the applicant available to the other Member States and the Commission.
2. The Commission shall publish detailed guidance concerning the preparation and submission of the application.
3. If necessary, the Commission, on its own initiative or at the request of a Member State, may consult the Authority for advice. For its opinion, the Authority shall follow Article 12 where appropriate.
4. The Commission shall without delay prepare a draft of the measure to be taken in accordance with Article 13.

Article 15
Application for a change in purity criteria

1. To obtain the authorisation referred to in Article 9, an application shall be submitted in accordance with the following points:
 - (a) The application shall be sent to the competent authority of a Member State accompanied by the following:
 - (i) the name and address of the applicant;
 - (ii) a technical dossier containing the information in accordance with the guidance referred to in paragraph 2;
 - (iii) a summary of the technical dossier.
 - (b) The competent authority referred to in (a) shall:
 - (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (ii) inform without delay the Authority; and
 - (iii) make the application and any supplementary information supplied by the applicant available to the Authority.
 - (c) The Authority shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.

2. The Authority shall publish detailed guidance concerning the preparation and the submission of the application²⁰.
3. For its opinion, the Authority shall follow Article 12 where appropriate.
4. The Commission shall without delay prepare a draft of the measure to be taken in accordance with Article 13.

Article 16
Application for renewal of authorisation

1. Without prejudice to Article 17, authorisations under this Regulation shall be renewable for ten-year periods, on the written application to the Commission by the original applicant or any food business operator at the latest 18 months before the expiry date of the authorisation.
2.
 - (a). The application shall be sent to the competent authority of a Member State accompanied by the following:
 - (i) the name and address of the applicant;
 - (ii) a reference to the original authorisation;
 - (iii) the justification for continued use of the said food additive;
 - (iv) any new information which has become available with regard to the evaluation of the safety in use of the food additive;
 - (v) where appropriate, a proposal for amending or complementing the conditions of the original authorisation.
 - (b) The competent authority referred to in (a) shall:
 - (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (ii) inform without delay the other Member States and the Commission;
and
 - (iii) make the application and any supplementary information supplied by the applicant available to the other Member States and the Commission.

²⁰ Pending such publication, applicants shall consult the “Guidance on Submissions for Food Additive Evaluations by the Scientific Committee on Food” (opinion expressed on 11 July 2001, or its latest update).

2. The Commission shall publish detailed guidance concerning the preparation and submission of the application.
3. If necessary, the Commission, on its own initiative or upon a request of a Member State may consult the Authority for advice. For its opinion, the Authority shall follow Article 12 where appropriate.
4. The Commission shall without delay prepare a draft of the measure to be taken in accordance with Article 13.
6. Where, for reasons beyond the control of the applicant, no measure is adopted on the renewal of an authorisation until one month before its expiry date, the period of authorisation shall automatically be extended by 6 months. The Commission shall inform the applicant and the Member States about the delay.

Article 17

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or the Commission, the Standing Committee on the Food Chain and Animal Health shall deliver an opinion on whether an authorisation is still in accordance with this Regulation, in accordance with Article 13, where applicable.
2. If necessary, the Standing Committee may consult the Authority for advice. For its opinion, the Authority shall follow Article 12 where appropriate.
3. A draft measure modifying an authorisation shall specify any necessary changes in the conditions of use.
4. The final measure, i.e. the modification, suspension or revocation of the authorisation shall be adopted in accordance with the procedure referred to in Article 32.
5. The Commission shall without delay inform the interested parties of the measure taken.

Article 18

Evaluation programme on risk assessment of authorised food additives

1. Food additives authorised for use in foodstuffs in Directive 94/35/EC, 94/36/EC and 95/2/EC before entry into force of this Regulation shall be subject to a risk assessment carried out by the Authority.

The Commission shall adopt an evaluation programme for these additives in accordance with the procedure laid down in Article 32 within six months of the entry into force of this Regulation.

That programme shall define in particular:

- the need and order of priorities according to which food additives authorised for use in foodstuffs in Directive 94/35/EC, 94/36/EC and 95/2/EC are to be examined,

- the time limits for safety evaluation.
- 2. The persons responsible for placing the food additive on the market shall forward the data necessary for the evaluation to the Authority, if necessary at the latter's request.
- 3. The Authority shall publish detailed guidance concerning the preparation and the submission of the application²¹.
- 4. For its opinion, the Authority shall follow Article 12 where appropriate.
- 5. The Commission shall without delay examine the opinion of the Authority and, if necessary, prepare a draft of the measure to be taken in accordance with Article 13.

Article 19
Status of existing authorisations

- 1. Food additives authorised for use in foodstuffs under Directives 94/35/EC, 94/36/EC and 95/2/EC and their conditions of use shall be entered in Annex II of this Regulation after a review on their compliance with Article 6 in accordance with the procedure laid down in Article 32. Each entry in the Annex shall mention the date of authorisation.

²¹ Pending such publication, applicants shall consult the "Guidance on Submissions for Food Additive Evaluations by the Scientific Committee on Food" (opinion expressed on 11 July 2001, or its latest update).

CHAPTER III

Labelling

Article 20

Labelling of food additives not intended for sale to the final consumer

1. Food additives not intended for sale to the final consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:
 - (a)
 - for food additives sold singly or mixed with each other, for each additive, the name laid down by this Regulation applying to the product and its E-number, or in the absence of such provisions, by a description of the products that is sufficiently precise to enable it to be distinguished from products with which it could be confused, in descending order of the proportion by weight in the total;
 - when other substances or materials or food ingredients to facilitate storage, sale, standardisation, dilution or dissolution of a food additive or food additives are incorporated in the additives, the name of the additive in accordance with the first indent and an indication of each component in descending order of the proportion by weight in the total;
 - (b)
 - either the statement 'for use in food',
 - or the statement 'restricted use in food',
 - or a more specific reference to its intended food use;
 - (c) if necessary, the special conditions of storage and use;
 - (d) directions for use, if the omission thereof would preclude appropriate use of the additive;
 - (e) a mark identifying the batch or lot;
 - (f) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;
 - (g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any Community provisions, or in their absence national provisions, applying to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the

combined percentage may be given as a single figure. Quantitative limitation is expressed either numerically or by the *quantum satis* principle;

- (h) the net quantity;
 - (i) an indication of the presence of an additive or other substances as listed in paragraph (a) second indent, that consist, contain or are produced from a genetically modified organism in accordance with Articles 12 to 14 of the Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.
2. By way of derogation from paragraph 1, the information required in point (a), second indent, points (d) to (g), may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication “intended for the manufacture of foodstuffs and not for retail sale” appears on a conspicuous part of the packaging or container of the product in question.

Article 21

Labelling of food additives intended for sale to the final consumer

1. Without prejudice to Directive 2000/13/EC, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs²², additives should not be marketed, where they are destined to the ultimate consumer, unless they contain the following information, which must be conspicuous, clearly legible and indelible:
- (a) the name under which the product is sold. This name shall be constituted by the name laid down by this Regulation applying to the product and its E-number, or in the absence of such provisions, by a description of the products that is sufficiently precise to enable it to be distinguished from products with which it could be confused;
 - (b) the information required by Article 20 (1) (a) to (f) and (h) to (i);
2. The sales description of a table-top sweetener must include the term ‘...-based table-top sweetener’, using the name(s) of the sweetening substance(s) used in its composition.
3. The labelling of a table-top sweetener containing polyols and/or aspartame and or aspartame-acesulfame salt must bear the following warnings:
- polyols: ‘excessive consumption may induce laxative effects’,
 - aspartame/aspartame-acesulfame salt: ‘contains a source of phenylalanine’.

²²

OJ L 109, 6.5.2000, p.29.

Article 22
Other provisions

1. Articles 20 and 21 shall not affect more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures, or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or the transport of such substances.
2. Member States shall refrain from laying down requirements more detailed than those contained in Articles 20 and 21 concerning the manner in which the particulars provided for therein are to be shown.
3. The particulars provided for in Articles 20 and 21 shall appear in a language easily understandable to purchasers unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

Article 23
Health marking

For the purpose of health marking as provided in Directive 91/497/EEC and other marking required on meat products, only the following food colours may be used: E 155 Brown HT, E 133 Brilliant Blue FCF, E 129 Allura Red AC or an appropriate mixture of E 133 Brilliant Blue FCF and E 129 Allura Red.

Only those colours mentioned in Annex II may be used for the decorative colouring of eggshells or for the stamping of eggshells as provided in Regulation (EEC) No 1274/91.

CHAPTER IV

Placing on the market of a foodstuff containing a food additive (conditions of use)

Article 24

Principles for use of a food additive in foodstuffs

The following principles shall apply when food additives are used in accordance with this Regulation:

1. No food additives may be used in unprocessed foodstuffs, unless otherwise laid down in specific provisions.
2. Colours and sweeteners may not be used in food for infants and young children as referred to in Directive 89/398/EEC, including food for infants and young children who are not in good health, unless otherwise laid down in specific provisions.
3. The provisions of this Regulation shall also apply to the corresponding foodstuffs intended for particular nutritional uses in accordance with Directive 89/398/EEC.
4. Carry over principle:
 - (a) The presence of a food additive in a foodstuff is permissible:
 - (i) in a compound foodstuff other than one mentioned in Annex II to the extent that the food additive is permitted in one of the ingredients of the compound foodstuff, or
 - (ii) 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 Regulation and has been carried over to the foodstuff via the flavouring, provided the food additive has no technological function in the final food, or
 - (iii) 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 Regulation.
 - (b) Paragraph (a) 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.
 - (c) The level of additives in flavourings shall be limited to the minimum necessary to guarantee the safety and quality of flavourings and to facilitate their storage. Furthermore, the presence of additives in flavourings must not mislead consumers or present a hazard to their health. If the presence of an additive in a foodstuff, as a consequence of adding flavourings, has a technological function

in the foodstuff, it shall be considered as an additive of the foodstuff and not as an additive of the flavouring.

(d) Without prejudice to paragraph (a), the presence of an intense sweetener is permissible:

(i) in a compound foodstuffs with no added sugar or energy-reduced, in compound dietary foodstuffs intended for a low-calorie diet, and in compound foodstuffs with a long shelf-life, insofar as the intense sweetener is permitted in one of the ingredients of the compound foodstuff.

5. Maximum levels indicated in the Annexes refer to ready-to-eat foodstuffs prepared according to the instructions for use, unless otherwise stated.
6. Maximum levels for colours refer to the quantities of colouring principle contained in the colouring preparation.

Article 25

Where necessary, it may be decided by the procedure laid down in Article 32,

- whether a particular foodstuff belongs to a category of foodstuffs mentioned in Annex II, or
- whether a food additive listed in Annex II and authorised at “quantum satis” is used in accordance with the criteria referred to in Article 3(9).

Article 26 Compliance

1. After a food additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a foodstuff into which it has been incorporated shall ensure that any conditions or restrictions which have been imposed on the placing on the market and use of the additive are respected.
2. Where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs may be laid down under the procedure laid down in Article 32. However, in the absence of Community rules and methods, Member States shall take all necessary steps to satisfy themselves that controls and inspections are carried out:

– in accordance with standards recognized by international bodies

– in the absence of such standards, in accordance with scientifically recognized national rules which comply with the general principles of the Treaty.

Article 27
Monitoring of food additive intake

1. Member States shall establish systems to monitor the consumption and use of food additives and report their findings to the Authority.
2. The Authority shall propose a methodology to the Member States in order to gather information on dietary intake of food additives in the European Union.
3. The Authority shall publish every five years a report on the level of consumption of food additives and changes which have taken place between two reporting periods. This report shall be made publicly available.

Article 28
Traditional foodstuffs

1. This Regulation does not affect the application of provisions of Member States existing on 1 January 1992, which prohibit the use of certain additives in certain specific foodstuffs which are considered as traditional and are produced on their territory.
2. Without prejudice to provisions of Regulation (EEC) No 2081/92 on designation of origin²³ and (EEC) No 2082/92 certificates of specific character²⁴, the list of foodstuffs considered as traditional where the prohibition on the use of certain categories of additives in the production of foodstuffs may be maintained, is laid down in Annex III of this Regulation.

²³ OJ L 208, 24.7.1992, p.1

²⁴ OJ L 208, 24.7.1992, p.9.

CHAPTER V OTHER PROVISIONS

Article 29 Public access

1. Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.
2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents when handling applications for access to documents held by the Authority.
3. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 30 Confidentiality

1. The applicant may indicate which information submitted under the present Regulation should be treated as confidential because its disclosure may significantly harm his competitive position. Verifiable justification must be given in such cases.
2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.
3. Without prejudice to Article 39 (3) of Regulation (EC) No 178/2002, information relating to the following shall not be considered confidential:
 - (a) the name and the address of the applicant and the name of the food additive;
 - (b) in the case of an opinion in favour of authorising the evaluated food additive, a clear description and characterisation of the product and the conditions of its use in or on specific foods or food categories;
 - (c) information of direct relevance to the assessment of the safety of the food additive.
 - (d) the analytical method or methods.
4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and Member States with all information in its possession.

5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public in order to protect human health.
6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.

[Article 31

Data protection (subject to scrutiny, does not represent the views of the Commission)

1. The scientific data and other information in a dossier
 - for approval of a new food additive
 - for a new application of an authorised additive
 - for submission of safety studies following a request of the Authority

may not be used for the benefit of a subsequent applicant for a period of ten years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:

 - the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and,
 - the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and,
 - the additive, the new application or continuing use could not have been approved without the submission of the proprietary data by the prior applicant.
2. Until the end of the ten years period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether an authorisation could be or could have been granted without the submission of data designated as proprietary by the prior applicant.]

Article 32

Implementing powers of the Commission

1. The Commission shall be assisted by the Committee referred to in Article 58(1) of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.

Article 33
Competent authorities of Member States

Each Member State shall notify to the Commission and to the Authority the name and address, as well as contact point, of the national competent authority or authorities designated to be responsible in its territory for receiving the application for authorisation referred to in Articles 11, 14, 15 and 16. The Commission shall publish the name and address of the national competent authorities as well as the contact points notified in accordance with this Article.

Article 34
Repeals

1. The following Directives and Articles are repealed with effect from the date of application of this Regulation:

- Directive 89/107/EEC;
- Directive 94/35/EC, Articles 1 to 11;
- Directive 94/36/EC, Article 1, 2(1) to (9), 2(11), 3 to 9;
- Directive 95/2/EC, Article 1, 2(1), 2(6), 2(7), 3 to 11;
- Decision No 292/07/EC²⁵;
- Decision 2002/247/EC²⁶;
- Directive 65/66/EEC;
- Directive 78/663/EEC;
- Directive 78/664/EEC.

2. The following Directives, Articles and Annexes are repealed with effect one year from the date of application of this Regulation:

- Directive 94/35/EC, Annex;
- Directive 94/36/EC, Article 2(10), Annexes I, II, III, IV and V;
- Directive 95/2/EC, Article 2(2) to (5), Annexes I, II, III, IV, V and VI.

²⁵ OJ L 48, 19.2.1997, p.13.

²⁶ OJ L 84, 28.3.2002, p.69.

3. The authorisations for E 1103 Invertase and E 1105 Lysozyme laid down in Directive 95/2/EC are repealed with effect from the date of application of the [proposal for a] Regulation on food enzymes.
4. References to these repealed Directives shall be construed as references to this Regulation.

Article 35
Transitional measures

Foodstuffs and food additives that have been lawfully placed on the market before the date of application of this Regulation may be marketed until the stocks are exhausted.

Article 36
Entry into force

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

It shall apply from [one year after the date of publication of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Functional classes of food additives

- (1) "sweeteners" are substances (polyols and intense sweeteners) used to impart a sweet taste to foodstuffs, including table top sweeteners.
- (2) "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 Regulation.
- (3) "preservatives" are substances which prolong the shelf-life of foodstuffs including food additives by protecting them against deterioration caused by micro-organisms;
- (4) 'antioxidants' are substances which prolong the shelf-life of foodstuffs including food additives by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;
- (5) 'carriers', including carrier solvents, are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive [or a flavouring] without altering its technological function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;
- (6) 'acids' are substances which increase the acidity of a foodstuff and/or impart a sour taste to it;
- (7) 'acidity regulators'²⁷ are substances which alter or control the acidity or alkalinity of a foodstuff;
- (8) 'anti-caking agents' are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;
- (9) 'anti-foaming agents' are substances which prevent or reduce foaming;
- (10) 'bulking agents' are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;
- (11) '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;
- (12) '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;
- (13) '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;

²⁷ These can act as two-way acidity regulators.

- (14) 'flavour enhancers' are substances which enhance the existing taste and/or odour of a foodstuff;
- (15) 'foaming agents' are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;
- (16) 'gelling agents' are substances which give a foodstuff texture through formation of a gel;
- (17) '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;
- (18) '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;
- (19) '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;
- (20) 'packaging gases' are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;
- (21) 'propellants' are gases other than air which expel a foodstuff from a container;
- (22) 'raising agents' are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;
- (23) 'sequestrants'²⁸ are substances which form chemical complexes with metallic ions;
- (24) 'stabilisers'²⁹ 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.
- (25) 'thickeners' are substances which increase the viscosity of a foodstuff;
- (26) 'flour treatment agents' are substances, other than emulsifiers, which are added to flour or dough to improve its baking quality.

²⁸ Inclusion of this term in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.

²⁹ This category also comprises foam stabilizers.

ANNEX II

Authorisation list.

Working document

ANNEX III

Products for which the Member States concerned may maintain the prohibition of certain categories of additives

Member State	Foodstuffs	Categories of additives which may continue to be banned
Germany	Traditional German beer (“Bier nach deutschem Reinheitsgebot gebraut”)	All except propellant gases
Greece	“Feta”	All
France	Traditional French bread	All
France	Traditional French preserved truffles	All
France	Traditional French preserved snails	All
France	Traditional French goose and ducks preserves (“confit”)	All
Austria	Traditional Austrian “Bergkäse”	All except preservatives
Finland	Traditional Finnish “Mämmi”	All except preservatives
Sweden Finland	Traditional Swedish and Finnish fruit syrups	Colours
Denmark	Traditional Danish “Kødboller”	Preservatives and colours
Denmark	Traditional Danish “Leverpostej”	Preservatives (other than sorbic acid) and colours
Spain	Traditional Spanish “Lomo embuchado”	All except preservatives and antioxidants
Italy	Traditional Italian “Salame cacciatore”	All except preservatives, antioxidants, flavour enhancers and packaging gas
Italy	Traditional Italian “Mortadella”	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas
Italy	Traditional Italian “Cotechino e zampone”	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas