

REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
on food additives
(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 Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

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) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests, via comprehensive and streamlined procedures.

(4) This Regulation harmonises the use of food additives in foods in the Community. This includes the use of food additives in foods covered by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses ⁽³⁾ and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs. It also harmonises the use of food additives in food additives and food enzymes thus ensuring their safety and quality and facilitating their storage and use. This has not previously been regulated at Community level.

(5) Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose described in this Regulation, such as the preservation of food. All food additives should be covered by this Regulation, and therefore in the light of scientific progress and technological development the list of functional classes should be updated. However, substances should not be considered as food additives when they are used for the purpose of imparting flavour and/or taste or for nutritional purposes, such as salt replacers, vitamins and minerals. Moreover, substances considered as foods which may be used for a technological function, such as sodium chloride or saffron for colouring and food enzymes should also not fall within the scope of this Regulation. However, preparations obtained from foods and other natural source material that are intended to have a technological effect in the final food and which are obtained by selective extraction of constituents (e.g. pigments) relative to the nutritive or aromatic constituents, should be considered additives within the meaning of this Regulation. Finally, food enzymes are covered by Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes ⁽⁴⁾, which excludes the application of this Regulation.

(6) Substances not consumed as food itself but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

⁽¹⁾ OJ C 168, 20.7.2007, p. 34.

⁽²⁾ Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 142), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 10), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

⁽³⁾ OJ L 186, 30.6.1989, p. 27.

⁽⁴⁾ See page 7 of this Official Journal.

- (7) Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological need for their use, and their use must not mislead the consumer and must be of benefit to the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product, including its fruit and vegetable content. The approval of food additives should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors, the precautionary principle and the feasibility of controls. The use and maximum levels of a food additive should take into account the intake of the food additive from other sources and the exposure to the food additive by special groups of consumers (e.g. allergic consumers).
- (8) Food additives must comply with the approved specifications, which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity. The specifications previously developed for food additives included in Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽¹⁾, Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs ⁽²⁾ and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners ⁽³⁾ should be maintained until the corresponding additives are entered in the Annexes to this Regulation. At that time, the specifications related to such additives should be set out in a Regulation. Those specifications should relate directly to the additives included in the Community lists in the Annexes to this Regulation. However, considering the complex character and substance of such specifications, for the sake of clarity they should not be integrated as such in the Community lists but should be set out in one or more separate Regulations.
- (9) Some food additives are permitted for specific uses for certain authorised oenological practices and processes. The use of such food additives should comply with this Regulation and with the specific provisions laid down in the relevant Community legislation.
- (10) In order to ensure harmonisation, the risk assessment and approval of food additives should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽⁴⁾
- (11) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽⁵⁾, the European Food Safety Authority (hereinafter referred to as the Authority) is to be consulted on matters likely to affect public health.
- (12) A food additive which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽⁶⁾ should be authorised in accordance with that Regulation as well as under this Regulation.
- (13) A food additive already approved under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the specifications laid down, should be submitted for evaluation by the Authority. 'Significantly different' could mean, *inter alia*, a change of the production method from extraction from a plant to production by fermentation using a micro-organism or a genetic modification of the original micro-organism, a change in starting materials, or a change in particle size, including the use of nanotechnology.
- (14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Where necessary, the Commission together with the Member States should consider appropriate action.
- (15) Member States which maintained on 1 January 1992 prohibitions on the use of certain additives in certain specific foods which are considered traditional and are produced on their territory should be permitted to continue to apply those prohibitions. Moreover, as regard products such as 'Feta' or 'Salame cacciatore', this Regulation should be without prejudice to more restrictive rules linked to the use of certain denominations under Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽⁷⁾ and Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed ⁽⁸⁾.

⁽⁴⁾ See page 1 of this Official Journal.

⁽⁵⁾ OJ L 31, 1.2.2002, p. 1.

⁽⁶⁾ OJ L 268, 18.10.2003, p. 1.

⁽⁷⁾ OJ L 93, 31.3.2006, p. 12.

⁽⁸⁾ OJ L 93, 31.3.2006, p. 1.

⁽¹⁾ OJ L 178, 28.7.1995, p. 1.

⁽²⁾ OJ L 226, 22.9.1995, p. 1.

⁽³⁾ OJ L 339, 30.12.1996, p. 1.

- (16) Unless subject to further restrictions, an additive may be present in food, other than by direct addition, as a result of carry-over from an ingredient in which the additive was permitted, provided that the level of the additive in the final food is no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice.
- (17) Food additives remain subject to the general labelling obligations as provided for in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽¹⁾ and, as the case may be, in Regulation (EC) No 1829/2003 and in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms ⁽²⁾. In addition, specific provisions on the labelling of food additives sold as such to the manufacturer or to the final consumer should be contained in this Regulation.
- (18) Sweeteners authorised under this Regulation may be used in table-top sweeteners sold directly to consumers. Manufacturers of such products should make information available to the consumer by appropriate means to allow them to use the product in a safe manner. Such information could be made available in a number of ways including on product labels, Internet websites, consumer information lines or at the point of sale. In order to adopt a uniform approach to the implementation of this requirement, guidance drawn up at Community level may be necessary.
- (19) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽³⁾.
- (20) In particular the Commission should be empowered to amend the Annexes of this Regulation and to adopt appropriate transitional measures. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (21) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of certain amendments to Annexes II and III relating to substances already authorised under other Community law as well as any appropriate transitional measures related to these substances.
- (22) In order to develop and update Community law on food additives in a proportionate and effective way, it is necessary to collect data, share information and coordinate work between Member States. For that purpose, it may be useful to undertake studies to address specific issues with a view to facilitating the decision-making process. It is appropriate that the Community finance such studies as part of its budgetary procedure. The financing of such measures is covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽⁴⁾.
- (23) Member States are to carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.
- (24) Since the objective of this Regulation, namely to lay down Community rules on food additives, cannot be sufficiently achieved by the Member States and can therefore, in the interests of market unity and a high level of consumer protection, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (25) Following the adoption of this Regulation the Commission, assisted by the Standing Committee on the Food Chain and Animal Health, should review all the existing authorisations for criteria, other than safety, such as intake, technological need and the potential to mislead the consumer. All food additives that are to continue to be authorised in the Community should be transferred to the Community lists in Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and food enzymes as well as carriers for nutrients and their conditions of use in accordance with Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings]. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives and food additives in flavourings, should not apply until 1 January 2011.
- (26) Until the future Community lists of food additives are established, it is necessary to provide for a simplified procedure allowing the current lists of food additives contained in the existing Directives to be updated.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

⁽²⁾ OJ L 268, 18.10.2003, p. 24.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁴⁾ OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.

(27) Without prejudice to the outcome of the review referred to in recital 25, within one year following the adoption of this Regulation the Commission should set up an evaluation programme for the Authority to re-evaluate the safety of the food additives that were already approved in the Community. That programme should define the needs and the order of priorities according to which the approved food additives are to be examined.

(28) This Regulation repeals and replaces the following acts: Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption ⁽¹⁾, Council Directive 65/66/EEC of 26 January 1965 laying down specific criteria of purity for preservatives authorised for use in foodstuffs intended for human consumption ⁽²⁾, Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs ⁽³⁾, Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption ⁽⁴⁾, 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 ⁽⁵⁾, Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽⁶⁾, Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ⁽⁷⁾, Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs ⁽⁸⁾, Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽⁹⁾, Decision No 292/97/EC of the European Parliament and of the Council of 19 December 1996 on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs ⁽¹⁰⁾ and Commission Decision 2002/247/EC of 27 March 2002 suspending the placing on the market and import of jelly confectionary containing the food additive E 425 konjac ⁽¹¹⁾. However, it is appropriate that certain provisions of those acts remain in force during a transitional period to allow time for the preparation of the Community lists in the Annexes to this Regulation,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules on food additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

For those purposes, this Regulation provides for:

- (a) Community lists of approved food additives as set out in Annexes II and III;
- (b) conditions of use of food additives in foods, including in food additives and in food enzymes as covered by Regulation (EC) No 1332/2008 [on food enzymes], and in food flavourings as covered by Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods ⁽¹²⁾;
- (c) rules on the labelling of food additives sold as such.

Article 2

Scope

1. This Regulation shall apply to food additives.
2. This Regulation shall not apply to the following substances unless they are used as food additives:
 - (a) processing aids;
 - (b) substances used for the protection of plants and plant products in accordance with Community rules relating to plant health;
 - (c) substances added to foods as nutrients;
 - (d) substances used for the treatment of water for human consumption falling within the scope of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽¹³⁾;

⁽¹⁾ OJ 115, 11.11.1962, p. 2645/62.

⁽²⁾ OJ 22, 9.2.1965, p. 373.

⁽³⁾ OJ L 223, 14.8.1978, p. 7.

⁽⁴⁾ OJ L 223, 14.8.1978, p. 30.

⁽⁵⁾ OJ L 257, 10.9.1981, p. 1.

⁽⁶⁾ OJ L 40, 11.2.1989, p. 27.

⁽⁷⁾ OJ L 237, 10.9.1994, p. 3.

⁽⁸⁾ OJ L 237, 10.9.1994, p. 13.

⁽⁹⁾ OJ L 61, 18.3.1995, p. 1.

⁽¹⁰⁾ OJ L 48, 19.2.1997, p. 13.

⁽¹¹⁾ OJ L 84, 28.3.2002, p. 69.

⁽¹²⁾ See page 34 of this Official Journal.

⁽¹³⁾ OJ L 330, 5.12.1998, p. 32.

(e) flavourings falling within the scope of Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods].

3. This Regulation shall not apply to food enzymes falling within the scope of Regulation (EC) No 1332/2008 [on food enzymes], with effect from the date of adoption of the Community list of food enzymes in accordance with Article 17 of that Regulation.

4. This Regulation shall apply without prejudice to any specific Community rules concerning the use of food additives:

(a) in specific foods;

(b) for purposes other than those covered by this Regulation.

Article 3

Definitions

1. For the purposes of this Regulation, the definitions laid down in Regulations (EC) No 178/2002 and (EC) No 1829/2003 shall apply.

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

(a) 'food additive' shall mean 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 such foods;

The following are not considered to be food additives:

- (i) monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties;
- (ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect;
- (iii) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods;
- (iv) products containing pectin and derived from dried apple pomace or peel of citrus fruits or quinces, or from a mixture of them, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (liquid pectin);

(v) chewing gum bases;

(vi) 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;

(vii) ammonium chloride;

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

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

(x) caseinates and casein;

(xi) inulin;

(b) 'processing aid' shall mean any substance which:

(i) is not consumed as a food by itself;

(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;

(c) 'functional class' shall mean one of the categories set out in Annex I based on the technological function a food additive exerts in the foodstuff;

(d) 'unprocessed food' shall mean a food which has not undergone any treatment resulting in a substantial change in the original state of the food, for which purpose the following in particular are not regarded as resulting in substantial change: dividing, parting, severing, boning, mincing, skinning, paring, peeling, grinding, cutting, cleaning, trimming, deep-freezing, freezing, chilling, milling, husking, packing or unpacking;

(e) 'food with no added sugars' shall mean a food without the following:

(i) any added monosaccharides or disaccharides;

(ii) any added food containing monosaccharides or disaccharides which is used for its sweetening properties;

(f) 'energy-reduced food' shall mean a food with an energy value reduced by at least 30 % compared with the original food or a similar product;

(g) 'table-top sweeteners' shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugars;

(h) 'quantum satis' shall mean that no maximum numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.

CHAPTER II

COMMUNITY LISTS OF APPROVED FOOD ADDITIVES

Article 4

Community lists of food additives

1. Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods under the conditions of use specified therein.

2. Only food additives included in the Community list in Annex III may be used in food additives, in food enzymes and in food flavourings under the conditions of use specified therein.

3. Food additives in Annex II shall be listed on the basis of the categories of food to which they may be added.

4. Food additives in Annex III shall be listed on the basis of the food additives, food enzymes, food flavourings and nutrients or categories thereof to which they may be added.

5. Food additives shall comply with the specifications as referred to in Article 14.

Article 5

Prohibition of non-compliant food additives and/or non-compliant food

No person shall place on the market a food additive or any food in which such a food additive is present if the use of the food additive does not comply with this Regulation.

Article 6

General conditions for inclusion and use of food additives in Community lists

1. A food additive may be included in the Community lists in Annexes II and III only if it meets the following conditions and, where relevant, other legitimate factors, including environmental factors:

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;

(b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and

(c) its use does not mislead the consumer.

2. To be included in the Community lists in Annexes II and III a food additive must have advantages and benefits for the consumer and therefore serve one or more of the following purposes:

(a) preserving the nutritional quality of the food;

(b) providing necessary ingredients or constituents for foods manufactured for groups of consumers with special dietary needs;

(c) enhancing the keeping quality or stability of a food or improving its organoleptic properties, provided that the nature, substance or quality of the food is not changed in such a way as to mislead the consumer;

(d) aiding in the manufacture, processing, preparation, treatment, packing, transport or storage of food, including food additives, food enzymes and food flavourings, provided that the food additive is not used to disguise the effects of the use of faulty raw materials or of any undesirable practices or techniques, including unhygienic practices or techniques, during the course of any such activities.

3. By way of derogation from paragraph 2(a), a food additive which reduces the nutritional quality of a food may be included in the Community list in Annex II provided that:

(a) the food does not constitute a significant component of a normal diet; or

(b) the food additive is necessary for the production of foods for groups of consumers with special dietary needs.

*Article 7***Specific conditions for sweeteners**

A food additive may be included in the Community list in Annex II for the functional class of sweetener only if, in addition to serving one or more of the purposes set out in Article 6(2), it serves one or more of the following purposes:

- (a) replacing sugars for the production of energy-reduced food, non-cariogenic food or food with no added sugars; or
- (b) replacing sugars where this permits an increase in the shelf-life of the food; or
- (c) producing food intended for particular nutritional uses as defined in Article 1(2)(a) of Directive 89/398/EEC.

*Article 8***Specific conditions for colours**

A food additive may be included in the Community list in Annex II for the functional class of colour only if, in addition to serving one or more of the purposes set out in Article 6(2), it serves one of the following purposes:

- (a) restoring the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;
- (b) making food more visually appealing;
- (c) giving colour to food otherwise colourless.

*Article 9***Functional classes of food additives**

1. Food additives may be assigned in Annexes II and III to one of the functional classes in Annex I on the basis of the principal technological function of the food additive.

Allocating a food additive to a functional class shall not preclude it from being used for several functions.

2. Where necessary, as a result of scientific progress or technological development, the measures, designed to amend non-essential elements of this Regulation, relating to additional functional classes which may be added to Annex I shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).

*Article 10***The content of the Community lists of food additives**

1. A food additive which complies with the conditions set out in Articles 6, 7 and 8 may, in accordance with the procedure referred to in Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] be included in:

- (a) the Community list in Annex II to this Regulation; and/or
- (b) the Community list in Annex III to this Regulation.

2. The entry for a food additive in the Community lists in Annexes II and III shall specify:

- (a) the name of the food additive and its E number;
- (b) the foods to which the food additive may be added;
- (c) the conditions under which the food additive may be used;
- (d) if appropriate, whether there are any restrictions on the sale of the food additive directly to the final consumer.

3. The Community lists in Annexes II and III shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

*Article 11***Levels of use of food additives**

1. When establishing the conditions of use referred to in Article 10(2)(c):

- (a) the level of use shall be set at the lowest level necessary to achieve the desired effect;
- (b) the levels shall take into account:
 - (i) any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources;
 - (ii) where the food additive is to be used in foods eaten by special groups of consumers, the possible daily intake of the food additive by consumers in those groups.

2. Where appropriate, no maximum numerical level shall be fixed for a food additive (quantum satis). In that case, the food additive shall be used in accordance with the principle of quantum satis.

3. The maximum levels of food additives set out in Annex II shall apply to the food as marketed, unless otherwise stated. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted the maximum levels shall apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor.

4. The maximum levels for colours set out in Annex II shall apply to the quantities of colouring principle contained in the colouring preparation unless otherwise stated.

Article 12

Changes in the production process or starting materials of a food additive already included in a Community list

When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.

Article 13

Food additives falling within the scope of Regulation (EC) No 1829/2003

1. A food additive falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community lists in Annexes II and III in accordance with this Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.

2. When a food additive already included in the Community list is produced from a different source falling within the scope of Regulation (EC) No 1829/2003, it will not require a new authorisation under this Regulation, as long as the new source is covered by an authorisation in accordance with Regulation (EC) No 1829/2003 and the food additive complies with the specifications established under this Regulation.

Article 14

Specifications of food additives

The specifications of food additives relating, in particular, to origin, purity criteria and any other necessary information, shall be adopted when the food additive is included in the Community lists in Annexes II and III for the first time, in accordance with the procedure referred to in Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

CHAPTER III

USE OF FOOD ADDITIVES IN FOODS

Article 15

Use of food additives in unprocessed foods

Food additives shall not be used in unprocessed foods, except where such use is specifically provided for in Annex II.

Article 16

Use of food additives in foods for infants and young children

Food additives shall not be used in foods for infants and young children as referred to in Directive 89/398/EEC, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to this Regulation.

Article 17

Use of colours for markings

Only food colours listed in Annex II to this Regulation may be used for the purpose of health marking as provided for in Council Directive 91/497/EEC of 29 July 1991 amending and consolidating Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat ⁽¹⁾ and other markings required on meat products, for the decorative colouring of eggshells and for the stamping of eggshells as provided for in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ⁽²⁾.

Article 18

Carry-over principle

1. The presence of a food additive shall be permitted:
 - (a) in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food;
 - (b) in a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:
 - (i) is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and

⁽¹⁾ OJ L 268, 24.9.1991, p. 69.

⁽²⁾ OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.

(ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and

(iii) has no technological function in the final food;

(c) in a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with this Regulation.

2. Paragraph 1 shall not apply to infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children as referred to in Directive 89/398/EEC, except where specifically provided for.

3. Where a food additive in a food flavouring, food additive or food enzyme is added to a food and has a technological function in that food, it shall be considered a food additive of that food and not a food additive of the added flavouring, food additive or food enzyme, and must then comply with the conditions of use for that food as provided for.

4. Without prejudice to paragraph 1, the presence of a food additive used as a sweetener shall be permitted in a compound food with no added sugars, in an energy-reduced compound food, in compound dietary foods intended for low-calorie diets, in non-cariogenic compound foods, and in a compound food with an increased shelf-life, provided that the sweetener is permitted in one of the ingredients of the compound food.

Article 19

Interpretation decisions

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 28(2) whether or not:

- (a) a particular food belongs to a category of food referred to in Annex II; or
- (b) a food additive listed in Annexes II and III and permitted at 'quantum satis' is used in accordance with the criteria referred to in Article 11(2); or
- (c) a given substance meets the definition of food additive in Article 3.

Article 20

Traditional foods

The Member States listed in Annex IV may continue to prohibit the use of certain categories of food additives in the traditional foods produced on their territory as listed in that Annex.

CHAPTER IV

LABELLING

Article 21

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

1. Food additives not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with food ingredients, as defined in Article 6(4) of Directive 2000/13/EC, may only be marketed with the labelling provided for in Article 22 of this Regulation, which must be easily visible, clearly legible and indelible. The information shall be in a language easily understandable to purchasers.

2. Within its own territory, the Member State in which the product is marketed may, in accordance with the Treaty, stipulate that the information provided for in Article 22 shall be given in one or more of the official languages of the Community, to be determined by that Member State. This shall not preclude such information from being indicated in several languages.

Article 22

General labelling requirements for food additives not intended for sale to the final consumer

1. Where food additives not intended for sale to the final consumer are sold singly or mixed with each other and/or other food ingredients and/or with other substances added to them, their packaging or containers shall bear the following information:

- (a) the name and/or E-number laid down in this Regulation in respect of each food additive or a sales description which includes the name and/or E-number of each food additive;
- (b) the statement 'for 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/or use;
- (d) a mark identifying the batch or lot;
- (e) instructions for use, if the omission thereof would preclude appropriate use of the food additive;
- (f) the name or business name and address of the manufacturer, packager or seller;

- (g) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the quantum satis principle;
- (h) the net quantity;
- (i) the date of minimum durability or use-by-date;
- (j) where relevant, information on a food additive or other substances referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC as regards the indication of the ingredients present in foodstuffs.

2. Where food additives are sold mixed with each other and/or with other food ingredients, their packaging or containers shall bear a list of all ingredients in descending order of their percentage by weight of the total.

3. Where substances (including food additives or other food ingredients) are added to food additives to facilitate their storage, sale, standardisation, dilution or dissolution, their packaging or containers shall bear a list of all such substances in descending order of their percentage by weight of the total.

4. By way of derogation from paragraphs 1, 2 and 3, the information required in paragraph 1 points (e) to (g) and in paragraphs 2 and 3 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 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question.

5. By way of derogation from paragraphs 1, 2 and 3, where food additives are supplied in tankers, all of the information may appear merely on the accompanying documents relating to the consignment which are to be supplied with the delivery.

Article 23

Labelling of food additives intended for sale to the final consumer

1. Without prejudice to Directive 2000/13/EC, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs ⁽¹⁾ and Regulation (EC) No 1829/2003, food additives sold singly or mixed with each

other and/or other food ingredients intended for sale to the final consumer may be marketed only if their packaging contains the following information:

- (a) the name and E-number laid down in this Regulation in respect of each food additive or a sales description which includes the name and E-number of each food additive;
- (b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use.

2. By way of derogation from paragraph 1(a), the sales description of a table-top sweetener shall include the term '...-based table-top sweetener', using the name(s) of the sweetener(s) used in its composition.

3. The labelling of a table-top sweetener containing polyols and/or aspartame and/or aspartame-acesulfame salt shall bear the following warnings:

- (a) polyols: 'excessive consumption may induce laxative effects';
- (b) aspartame/aspartame-acesulfame salt: 'contains a source of phenylalanine'.

4. Manufacturers of table-top sweeteners shall make available by appropriate means the necessary information to allow their safe use by consumers. Guidance for the implementation of this paragraph may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).

5. For the information provided for in paragraphs 1 to 3 of this Article, Article 13(2) of Directive 2000/13/EC shall apply accordingly.

Article 24

Labelling requirement for foods containing certain food colours

1. Without prejudice to Directive 2000/13/EC, the labelling of food containing the food colours listed in Annex V to this Regulation shall include the additional information set out in that Annex.

2. In relation to the information provided in paragraph 1 of this Article, Article 13(2) of Directive 2000/13/EC shall apply accordingly.

3. Where necessary as a result of scientific progress or technical development, Annex V shall be amended by measures, designed to amend non-essential elements of this Regulation, in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).

⁽¹⁾ OJ L 186, 30.6.1989, p. 21.

*Article 25***Other labelling requirements**

Articles 21, 22, 23 and 24 shall be without prejudice to 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 applying to the transport of such substances and preparations.

CHAPTER V

PROCEDURAL PROVISIONS AND IMPLEMENTATION*Article 26***Information obligation**

1. A producer or user of a food additive shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive.
2. A producer or user of a food additive shall, at the request of the Commission, inform it of the actual use of the food additive. Such information shall be made available to Member States by the Commission.

*Article 27***Monitoring of food additive intake**

1. Member States shall maintain systems to monitor the consumption and use of food additives on a risk-based approach and report their findings with appropriate frequency to the Commission and the Authority.
2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community shall be adopted in accordance with the regulatory procedure referred to in Article 28(2).

*Article 28***Committee**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be 2 months, 2 months and 4 months respectively.

*Article 29***Community financing of harmonised policies**

The legal basis for the financing of measures resulting from this Regulation shall be Article 66(1)(c) of Regulation (EC) No 882/2004.

CHAPTER VI

TRANSITIONAL AND FINAL PROVISIONS*Article 30***Establishment of Community lists of food additives**

1. Food additives which are permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC, as amended on the basis of Article 31 of this Regulation, and their conditions of use shall be entered in Annex II to this Regulation after a review of their compliance with Articles 6, 7 and 8 thereof. The measures relating to the entry of such additives in Annex II, which are designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by 20 January 2011.

Food additives and uses which are no longer needed shall not be entered in Annex II.

2. Food additives authorised for use in food additives in Directive 95/2/EC and their conditions of use shall be entered in Part I of Annex III to this Regulation after a review of their compliance with Article 6 thereof. The measures relating to the entry of such additives in Annex III, which are designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by 20 January 2011.

Food additives and uses which are no longer needed shall not be entered in Annex III.

3. Food additives authorised for use in food flavourings in Directive 95/2/EC and their conditions of use shall be entered in Part 4 of Annex III to this Regulation after a review of their compliance with Article 6 thereof. The measures relating to the entry of such additives in Annex III, which are designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by 20 January 2011.

Food additives and uses which are no longer needed shall not be entered in Annex III.

4. Specifications of the food additives covered under paragraphs 1 to 3 of this Article shall be adopted, in accordance with Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], at the moment those food additives are entered in the Annexes in accordance with those paragraphs.

5. The measures relating to any appropriate transitional measures, which are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).

Article 31

Transitional measures

Until the establishment of the Community lists of food additives as provided for in Article 30 is completed, the Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC shall be amended, where necessary, by measures, designed to amend non-essential elements of those Directives, adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).

Foods placed on the market or labelled before 20 January 2010 which do not comply with Article 22(1)(i) and (4) may be marketed until their date of minimum durability or use-by-date.

Foods placed on the market or labelled before 20 July 2010 which do not comply with Article 24 may be marketed until their date of minimum durability or use-by-date.

Article 32

Re-evaluation of approved food additives

1. Food additives which were permitted before 20 January 2009 shall be subject to a new risk assessment carried out by the Authority.

2. After consultation of the Authority, an evaluation programme for those additives shall be adopted by 20 January 2010, in accordance with the regulatory procedure referred to in Article 28(2). The evaluation programme shall be published in the *Official Journal of the European Union*.

Article 33

Repeals

1. The following acts shall be repealed:
 - (a) Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption;
 - (b) Directive 65/66/EEC;
 - (c) Directive 78/663/EEC;
 - (d) Directive 78/664/EEC;
 - (e) Directive 81/712/EEC;
 - (f) Directive 89/107/EEC;
 - (g) Directive 94/35/EC;
 - (h) Directive 94/36/EC;
 - (i) Directive 95/2/EC;
 - (j) Decision No 292/97/EC;
 - (k) Decision 2002/247/EC.
2. References to the repealed acts shall be construed as references to this Regulation.

Article 34

Transitional provisions

By way of derogation from Article 33, the following provisions shall continue to apply until the transfer under Article 30(1), (2) and (3) of this Regulation of food additives already permitted in Directives 94/35/EC, 94/36/EC and 95/2/EC has been completed:

- (a) Article 2(1), (2) and (4) of Directive 94/35/EC and the Annex thereto;
- (b) Article 2(1) to (6), (8), (9) and (10) of Directive 94/36/EC and Annexes I to V thereto;
- (c) Articles 2 and 4 of Directive 95/2/EC and Annexes I to VI thereto.

Notwithstanding point (c), the authorisations for E 1103 Invertase and E 1105 Lysozyme laid down in Directive 95/2/EC shall be repealed with effect from the date of application of the Community list on food enzymes in accordance with Article 17 of Regulation (EC) No 1332/2008 [on food enzymes].

Article 35

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 20 January 2010.

However, Article 4(2) shall apply to Parts 2, 3 and 5 of Annex III from 1 January 2011 and Article 23(4) shall apply from 20 January 2011. Article 24 shall apply from 20 July 2010. Article 31 shall apply from 20 January 2009.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

ANNEX I

Functional classes of food additives in foods and of food additives in food additives and food enzymes

1. 'sweeteners' are substances used to impart a sweet taste to foods or in table-top sweeteners;
2. 'colours' are substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible 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 foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms;
4. 'antioxidants' are substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;
5. 'carriers' are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its 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' 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;
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 foods 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' are substances which form chemical complexes with metallic ions;
 24. 'stabilisers' are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food;
 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.
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ANNEX II

Community list of food additives approved for use in foods and conditions of use.

ANNEX III

Community list of food additives approved for use in food additives, food enzymes and food flavourings, and their conditions of use.

Community list of carriers in nutrients and their conditions of use.

- Part 1 Carriers in food additives
 - Part 2 Food additives other than carriers in food additives
 - Part 3 Food additives including carriers in food enzymes
 - Part 4 Food additives including carriers in food flavourings
 - Part 5 Carriers in nutrients and other substances added for nutritional and/or for other physiological purposes
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ANNEX IV

Traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives

Member State	Foods	Categories of additives which may continue to be banned
Germany	Traditional German beer (Bier nach deutschem Reinheitsgebot gebraut)	All except propellant gases
France	Traditional French bread	All
France	Traditional French preserved truffles	All
France	Traditional French preserved snails	All
France	Traditional French goose and duck 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 'Mortadella'	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas
Italy	Traditional Italian 'Cotechino e zamponi'	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas

ANNEX V

List of the food colours referred to in Article 24 for which the labelling of foods shall include additional information

Foods containing one or more of the following food colours	Information
Sunset yellow (E 110) (*)	‘name or E number of the colour(s)’: may have an adverse effect on activity and attention in children.
Quinoline yellow (E 104) (*)	
Carmoisine (E 122) (*)	
Allura red (E 129) (*)	
Tartrazine (E 102) (*)	
Ponceau 4R (E 124) (*)	

(*) With the exception of foods where the colour(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells.