

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance)

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;

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Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- 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.

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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.

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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].

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