

Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (Text with EEA relevance)

CHAPTER II

COMMUNITY LIST OF APPROVED FOOD ENZYMES

Article 4

Community list of food enzymes

Only food enzymes included in the Community list may be placed on the market as such and used in foods, in accordance with the specifications and conditions of use provided for in Article 7(2).

Article 5

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

No person shall place on the market a food enzyme or any food in which such a food enzyme has been used if the use of the food enzyme does not comply with this Regulation and its implementing measures.

Article 6

General conditions for inclusion of food enzymes in the Community list

A food enzyme may be included in the Community list only if it meets the following conditions and, where relevant, other legitimate 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, and
- (c) its use does not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness and quality of the ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product.

Article 7

The content of the Community list of food enzymes

1 A food enzyme which complies with the conditions set out in Article 6 may, in accordance with the procedure referred to in Regulation (EC) No 1331/2008 [establishing a

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common authorisation procedure for food additives, food enzymes and food flavourings], be included in the Community list.

- 2 The entry of a food enzyme in the Community list shall specify:
 - a the name of the food enzyme;
 - b the specifications of the food enzyme, including its origin, purity criteria and any other necessary information;
 - c the foods to which the food enzyme may be added;
 - d the conditions under which the food enzyme may be used; where appropriate, no maximum level shall be fixed for a food enzyme. In that case, the food enzyme shall be used in accordance with the *quantum satis* principle;
 - e if appropriate, whether there are any restrictions on the sale of the food enzyme directly to the final consumer;
 - f where necessary, specific requirements in respect of the labelling of food in which the food enzymes have been used in order to ensure that the final consumer is informed of the physical condition of the food or the specific treatment it has undergone.
- 3 The Community list 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 8

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

- 1 A food enzyme falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community list 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 enzyme 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 enzyme complies with the specifications established under this Regulation.

Article 9

Interpretation decisions

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 15(2) whether or not:

- (a) a given substance meets the definition of food enzyme in Article 3;
- (b) a particular food belongs to a category of food in the Community list of food enzymes.

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