

**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)

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 <sup>(1)</sup>,

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

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 enzymes other than those used as food additives are not currently regulated or are regulated as processing aids under the legislation of the Member States. Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of food enzymes may hinder their free movement, creating conditions for unequal and unfair competition. It is therefore necessary to adopt Community rules harmonising national provisions relating to the use of enzymes in foods.

(4) This Regulation should only cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids (hereinafter referred to as food enzymes). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function but are intended for human consumption, such as enzymes for nutritional or digestive purposes. Microbial cultures traditionally used in the production of food such as cheese and wine, and which may incidentally produce enzymes but are not specifically used to produce them, should not be considered food enzymes.

(5) Food enzymes used exclusively in the production of food additives falling within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(3)</sup> should be excluded from the scope of this Regulation, since the safety of these foods is already assessed and regulated. However, when these food enzymes are used as such in food, they are covered by this Regulation.

(6) Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes must be safe when used, there must be a technological need for their use and their use must not mislead 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. The approval of food enzymes 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.

(7) Some food enzymes are permitted for specific uses, such as in fruit juices and certain similar products and certain lactoproteins intended for human consumption, and for certain authorised oenological practices and processes. The use of such food enzymes should comply with this

<sup>(1)</sup> OJ C 168, 20.7.2007, p. 34.

<sup>(2)</sup> Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 162), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 32), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

<sup>(3)</sup> See page 16 of this Official Journal.

Regulation and with the specific provisions laid down in the relevant Community legislation. Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption <sup>(1)</sup>, Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption <sup>(2)</sup> and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine <sup>(3)</sup> should therefore be amended accordingly. Since all food enzymes should be covered by this Regulation, Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(4)</sup> should be amended accordingly.

- (8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes and specify any conditions governing their use, including where necessary information on their function in the final food. This list should be supplemented by specifications, in particular on their origin, including where relevant information about allergenic properties, and purity criteria.
- (9) In order to ensure harmonisation, the risk assessment of food enzymes and their inclusion in the Community list 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 <sup>(5)</sup>.
- (10) 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 <sup>(6)</sup>, the European Food Safety Authority (hereinafter referred to as the Authority) is to be consulted on matters likely to affect public health.
- (11) A food enzyme 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 <sup>(7)</sup> should be authorised in accordance with that Regulation as well as under this Regulation.
- (12) A food enzyme already included in the Community list 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 authorisation and the specifications under this Regulation, 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.
- (13) Since many food enzymes are already on the Community market, provision should be made to ensure that the switchover to a Community list of food enzymes takes place smoothly and does not disturb the existing food enzyme market. Sufficient time should be allowed for applicants to make available the information necessary for the risk assessment of these products. An initial two-year period should therefore be allowed following the date of application of the implementing measures to be laid down in accordance with Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], in order to give applicants sufficient time to submit the information on existing enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period.
- (14) In order to ensure fair and equal conditions for all applicants, the Community list should be drawn up in a single step. That list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period. However, the risk assessments of the Authority for individual enzymes should be published as soon as they are completed.
- (15) A significant number of applications is expected to be submitted during the initial two-year period. A lengthy period may therefore be needed before the risk assessment of these has been completed and the Community list is drawn up. In order to ensure equal access to the market for new food enzymes after the initial two-year period, a transitional period should be provided for during which food enzymes and food using food enzymes may be placed on the market and used, in accordance with the existing national rules in the Member States, until the Community list has been drawn up.

<sup>(1)</sup> OJ L 10, 12.1.2002, p. 58.

<sup>(2)</sup> OJ L 237, 26.8.1983, p. 25.

<sup>(3)</sup> OJ L 179, 14.7.1999, p. 1.

<sup>(4)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(5)</sup> See page 1 of this Official Journal.

<sup>(6)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(7)</sup> OJ L 268, 18.10.2003, p. 1.

- (16) The food enzymes E 1103 Invertase and E 1105 Lysozyme, that have been authorised as food additives under Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners <sup>(1)</sup>, and the conditions governing their use should be carried over from Directive 95/2/EC to the Community list when it is drawn up by this Regulation. In addition, Council Regulation (EC) No 1493/1999 authorises the use of urease, beta-glucanase and lysozyme in wine subject to the conditions laid down in Commission Regulation (EC) No 423/2008 of 8 May 2008 on laying down certain detailed rules for implementing Council Regulation (EC) No 1493/1999 and establishing a Community code of oenological practices and processes <sup>(2)</sup>. Those substances are food enzymes and they should fall within the scope of this Regulation. They should therefore also be added to the Community list when it is drawn up for their use in wine in accordance with Regulation (EC) No 1493/1999 and Regulation (EC) No 423/2008.
- (17) Food enzymes remain subject to the general labelling obligations 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 <sup>(3)</sup> 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 <sup>(4)</sup>. In addition, specific provisions on the labelling of food enzymes sold as such to the manufacturer or to the consumer should be contained in this Regulation.
- (18) Food enzymes are covered by the definition of food in Regulation (EC) No 178/2002 and are therefore, when used in food, required to be indicated as ingredients in the labelling of the food in compliance with Directive 2000/13/EC. Food enzymes should be designated by their technological function in food, followed by the specific name of the food enzyme. However, provision should be made for a derogation from the provisions on labelling in cases where the enzyme performs no technological function in the final product but is present in the foodstuff only as a result of carry-over from one or more of the ingredients of the foodstuff or where it is used as a processing aid. Directive 2000/13/EC should be amended accordingly.
- (19) Food enzymes should be kept under continuous observation and should be re-evaluated whenever necessary in the light of changing conditions governing their use and new scientific information.
- (20) 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 <sup>(5)</sup>.
- (21) In particular the Commission should be empowered 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.
- (22) In order to develop and update Community law on food enzymes 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 <sup>(6)</sup>.
- (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 enzymes, 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,

<sup>(1)</sup> OJ L 61, 18.3.1995, p. 1.

<sup>(2)</sup> OJ L 127, 15.5.2008, p. 13.

<sup>(3)</sup> OJ L 109, 6.5.2000, p. 29.

<sup>(4)</sup> OJ L 268, 18.10.2003, p. 24.

<sup>(5)</sup> OJ L 184, 17.7.1999, p. 23.

<sup>(6)</sup> OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1.

HAVE ADOPTED THIS REGULATION:

Article 3

### Definitions

#### CHAPTER I

#### SUBJECT MATTER, SCOPE AND DEFINITIONS

##### Article 1

#### Subject matter

This Regulation lays down rules on food enzymes used in foods, including such enzymes used as processing aids, 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) a Community list of approved food enzymes;
- (b) conditions of use of food enzymes in foods;
- (c) rules on the labelling of food enzymes sold as such.

##### Article 2

#### Scope

1. This Regulation shall apply to food enzymes as defined in Article 3.

2. This Regulation shall not apply to food enzymes when and insofar as they are used in the production of:

- (a) food additives falling within the scope of Regulation (EC) No 1333/2008 [on food additives];
- (b) processing aids.

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

- (a) in specific foods;
- (b) for purposes other than those covered by this Regulation.

4. This Regulation shall not apply to microbial cultures that are traditionally used in the production of food and which may incidentally produce enzymes, but which are not specifically used to produce them.

1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002, Regulation (EC) No 1829/2003 and Regulation (EC) No 1333/2008 [on food additives] shall apply.

2. The following definitions shall also apply:

- (a) 'food enzyme' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms:
  - (i) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and
  - (ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods;
- (b) 'food enzyme preparation' means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

#### 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 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.

## CHAPTER III

**LABELLING**

## Article 10

**Labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer**

1. Food enzymes and food enzyme preparations not intended for sale to the final consumer, whether sold singly or mixed with each other and/or other food ingredients, as defined in Article 6(4) of Directive 2000/13/EC, may only be marketed with the labelling provided for in Article 11 of this Regulation, which must be easily visible, clearly legible and indelible. The information provided for in Article 11 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 11 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 11

#### **General labelling requirements for food enzymes and food enzyme preparations not intended for sale to the final consumer**

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

- (a) the name laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme or in the absence of such a name, the accepted name laid down in the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB);
- (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 enzyme;
- (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 activity of the food enzyme(s);
- (j) the date of minimum durability or use-by-date;
- (k) where relevant, information on a food enzyme or other substances as referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC.

2. Where food enzymes and/or food enzyme preparations 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. The packaging or containers of food enzyme preparations shall bear a list of all components 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 enzymes and food enzyme preparations 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 12

#### **Labelling of food enzymes and food enzyme preparations 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 <sup>(1)</sup> and Regulation (EC) No 1829/2003, food enzymes and food enzyme preparations 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 laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme or in the absence of such a name, the accepted name laid down in the nomenclature of the IUBMB;

<sup>(1)</sup> OJ L 186, 30.6.1989, p. 21.

(b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use.

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

#### Article 13

### Other labelling requirements

Articles 10 to 12 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 IV

### PROCEDURAL PROVISIONS AND IMPLEMENTATION

#### Article 14

### Information obligation

1. A producer or user of a food enzyme shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food enzyme.

2. For a food enzyme 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 European Food Safety Authority (hereinafter referred to as the Authority), a producer or user shall, before marketing the food enzyme, submit to the Commission the necessary data to allow an evaluation of the food enzyme with regard to the modified production method or characteristics to be undertaken by the Authority.

3. A producer or user of a food enzyme shall, at the request of the Commission, inform it of the actual use of the food enzyme. Such information shall be made available to Member States by the Commission.

#### Article 15

### 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.

#### Article 16

### 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 V

### TRANSITIONAL AND FINAL PROVISIONS

#### Article 17

### Establishment of the Community list of food enzymes

1. The Community list of food enzymes shall be drawn up on the basis of applications made pursuant to paragraph 2.

2. Interested parties may submit applications for the inclusion of a food enzyme in the Community list.

The deadline for submitting such applications shall be 24 months after the date of application of the implementing measures to be laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

3. The Commission shall establish a Register of all food enzymes to be considered for inclusion in the Community list in respect of which an application complying with the validity criteria to be laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] has been submitted in accordance with paragraph 2 of this Article (hereinafter referred to as the Register). The Register shall be made available to the public.

The Commission shall submit the applications to the Authority for its opinion.

4. The Community list shall be adopted by the Commission in accordance with the procedure laid down in Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], once the Authority has issued an opinion on each food enzyme included in the Register.

However, by way of derogation from that procedure:

(a) Article 5(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] shall not apply to the Authority's adoption of its opinion;

(b) the Commission shall adopt the Community list for the first time after the Authority has delivered its opinion on all the food enzymes listed in the Register.

5. If necessary, any appropriate transitional measures for the purposes of this Article 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 15(3).

## Article 18

**Transitional measures**

1. Notwithstanding Articles 7 and 17 of this Regulation, the Community list shall, when drawn up, include the following food enzymes:

- (a) E 1103 Invertase and E 1105 Lysozyme, stating the conditions governing their use as specified in Annex I and Part C of Annex III to Directive 95/2/EC;
- (b) Urease, beta-glucanase and lysozyme for use in wine in accordance with Regulation (EC) No 1493/1999 and the implementing rules for that Regulation.

2. Food enzymes, food enzyme preparations and food containing food enzymes placed on the market or labelled before 20 January 2010 which do not comply with the provisions of Articles 10 to 12 may be marketed until their date of minimum durability or use-by-date.

## Article 19

**Amendments to Directive 83/417/EEC**

In Directive 83/417/EEC, in Annex I, Section III(d), the indents shall be replaced by the following:

- rennet meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (\*);
- other milk-coagulating enzymes meeting the requirements of Regulation (EC) No 1332/2008.

(\* ) OJ L 354, 31.12.2008, p. 7.'

## Article 20

**Amendment to Regulation (EC) No 1493/1999**

In Regulation (EC) No 1493/1999, the following paragraph shall be added to Article 43:

'3. Enzymes and enzymatic preparations used in the authorised oenological practices and processes listed in Annex IV shall meet the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (\*).

(\* ) OJ L 354, 31.12.2008, p. 7.'

## Article 21

**Amendments to Directive 2000/13/EC**

Directive 2000/13/EC is hereby amended as follows:

1. Article 6(4) shall be amended as follows:

(a) point (a) shall be replaced by the following:

'(a) "Ingredient" shall mean any substance, including additives and enzymes, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.';

(b) in point (c)(ii), the introductory word 'additives' shall be replaced by 'additives and enzymes';

(c) in point (c)(iii), the words 'additives or flavouring' shall be replaced by 'additives or enzymes or flavourings';

2. the following indent shall be added to Article 6(6):

— enzymes other than as referred to in paragraph 4(c)(ii) shall be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name,'.

## Article 22

**Amendments to Directive 2001/112/EC**

In Directive 2001/112/EC, in Annex I, Section II(2), the fourth, fifth and sixth indents shall be replaced by the following:

— Pectolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (\*);

— Proteolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008;

— Amylolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008.

(\* ) OJ L 354, 31.12.2008, p. 7.'

*Article 23***Amendment to Regulation (EC) No 258/97**

In Regulation (EC) No 258/97, the following point shall be added to Article 2(1):

- (d) food enzymes falling within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (\*).

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(\* OJ L 354, 31.12.2008, p. 7.

*Article 24***Entry into force**

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

Article 4 shall apply from the date of application of the Community list. Until that date, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes shall continue to apply in the Member States.

Articles 10 to 13 shall apply from 20 January 2010.

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