

# EUROPEAN PARLIAMENT

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*Committee on the Environment, Public Health and Food Safety*

PROVISIONAL  
**2006/0144(COD)**

7.3.2007

**\*\*\*I**

## **DRAFT REPORT**

on the proposal for a regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC  
(COM(2006)0425 – C6-0257/2006 – 2006/0144(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Avril Doyle

### ***Symbols for procedures***

- \* Consultation procedure  
*majority of the votes cast*
- \*\*I Cooperation procedure (first reading)  
*majority of the votes cast*
- \*\*II Cooperation procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\* Assent procedure  
*majority of Parliament's component Members except in cases  
covered by Articles 105, 107, 161 and 300 of the EC Treaty and  
Article 7 of the EU Treaty*
- \*\*\*I Codecision procedure (first reading)  
*majority of the votes cast*
- \*\*\*II Codecision procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\*III Codecision procedure (third reading)  
*majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

### ***Amendments to a legislative text***

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC (COM(2006)0425 – C6-0257/2006 – 2006/0144(COD))**

**(Codecision procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2006)0425)<sup>1</sup>,
  - having regard to Article 251(2) and Articles 37 and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0257/2006),
  - having regard to Rule 51 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Industry, Research and Energy (A6-0000/2007),
1. Approves the Commission proposal as amended;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

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Amendments by Parliament

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### Amendment 1 RECITAL 4

(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 ('food enzymes'). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function

(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 ('food enzymes'). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function

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<sup>1</sup> OJ C ... / Not yet published in OJ.

but are intended for human consumption, such as enzymes for nutritional purposes. Microbial cultures traditionally used in the production of food, such as cheese and, wine and which may contain enzymes but are not specifically used to produce them should not be considered food enzymes.

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 contain enzymes but are not specifically used to produce them should not be considered food enzymes.

#### *Justification*

*It should be made clear that the scope of this Regulation should not cover enzymes intended for human consumption such as enzymes for nutritional purposes or enzymes used as digestive aids.*

#### Amendment 2 RECITAL 8

(8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes, specify any conditions governing their use and be supplemented by specifications, in particular on their origin and purity criteria. Where the food enzyme ***contains or consists of*** a genetically modified organism (“GMO”) within the meaning of 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 and amending Directive 2001/18/EC, the unique identifier assigned to the GMO under that Regulation should also be included in the specifications.

(8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes, specify any conditions governing their use and be supplemented by specifications, in particular on their origin and purity criteria. Where the food enzyme ***is derived from*** a genetically modified organism (“GMO”) within the meaning of 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 and amending Directive 2001/18/EC, the unique identifier assigned to the GMO under that Regulation should also be included in the specifications.

#### *Justification*

*The text in the Commission's proposal is misleading. Genetically modified organisms cannot be enzymes in themselves, but can be used to produce an enzyme.*

Amendment 3  
RECITAL 20

(20) The measures necessary for the implementation of this Regulation should be 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>1</sup>.

<sup>1</sup> OJ L 184, 17.7.1999, p. 23.

(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>1</sup>.

<sup>1</sup> OJ L 184, 17.7.1999, p. 23. *Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p.1)*

*Justification*

*This amendment is needed to align the text to the provisions of the new comitology decision.*

Amendment 4  
ARTICLE 2, PARAGRAPH 4

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

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

*Justification*

*The term 'traditionally' is vague and not further explained. The paragraph allows for more legal certainty without this term.*

Amendment 5  
ARTICLE 2, PARAGRAPH 5

5. Where necessary, it may be decided in accordance with the procedure referred to in ***Article 16(2)*** whether or not a given substance falls within the scope of this Regulation.

5. Where necessary, it may be decided in accordance with the ***regulatory*** procedure ***with scrutiny*** referred to in ***Article 16(2a)*** whether or not a given substance falls within the scope of this Regulation.

### *Justification*

*This amendment is needed to align the text to the provisions of the new comitology decision.*

#### Amendment 6

#### ARTICLE 3

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 [...] [Regulation on food additives] shall apply. The following *definition* shall also apply:

‘food enzyme’ means a product obtained by extraction from plants or animals or by a fermentation process using micro-organisms:

(a) containing one or more enzymes capable of *catalyzing* a specific biochemical reaction; and

(b) added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of foods.

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 [...] [Regulation on food additives] shall apply. The following *definitions* shall also apply:

**(1) ‘enzyme’ means any protein of vegetable, animal or microbial origin, capable of catalysing a specific biochemical reaction, without changing its own structure in the process;**

(2) ‘food enzyme’ means a product obtained by extraction from plants or animals or by a fermentation process using micro-organisms:

(a) containing one or more enzymes capable of *catalysing* a specific biochemical reaction; and

(b) added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of foods;

**(3) ‘food enzyme preparation’ means a food enzyme formulated with other substances to facilitate the storage, sale, standardisation, dilution or dissolution of the food enzyme.**

### *Justification*

*There may be different perceptions of what is meant by the term 'enzyme'. In some cases the term is used to describe the pure enzyme protein, whereas in others it is used to describe the product obtained by extraction or fermentation which does not only include the enzyme protein, but also some residues from the process. Finally, the term enzyme may also be used to describe the ready-to-sell product to which other ingredients have been added. For the*

*sake of legal certainty and good science, separate definitions are needed to distinguish between these three situations.*

Amendment 7  
ARTICLE 5, POINT (B)

(b) there is a reasonable technological need;

(b) there is a reasonable technological need ***in terms of advantages and benefits provided to the consumer;***

*Justification*

*Transparent criteria are needed to determine whether there is a technological need for the use of an enzyme in food production. The use of a food enzyme should always have advantages and benefits for the consumer.*

Amendment 8  
ARTICLE 5, POINT (C)

(c) its use does not mislead the consumer.

(c) its use does not mislead the consumer ***as to the nature, quality or substance of a product.***

*Justification*

*Food enzymes must not be approved if their use could mislead consumers as to the nature, quality and substance of a product.*

Amendment 9  
ARTICLE 7, TITLE

*Inclusion of genetically modified **enzymes** on the Community list*

*Inclusion of **enzymes derived from genetically modified organisms (GMOs)** on the Community list*

*Justification*

*Clarity is needed on the GMO issue. Food enzymes can be derived from or produced by GMO's: they are not GMO's themselves.*

Amendment 10  
ARTICLE 8

Food enzymes not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with other ingredients as defined in Article 6(4) of Directive 2000/13/EC, may be marketed only where the packaging or containers bear the information provided for in **Articles 9 to 12 of this Regulation**, which must be easily visible, clearly legible and indelible.

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

**2. The packaging or containers shall provide the following information:**

**(a) the name laid down in this Regulation; or**

**(b) in the absence of a name, as referred to in point (a), a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused.**

**Where food enzymes or food enzyme preparations are sold mixed with each other, the information provided for in point (a) or (b) shall be given in respect of each food enzyme, in descending order of its percentage by weight of the total;**

**(c) the net quantity;**

**(d) the statement either 'for use in food' or 'restricted use in food' or a more specific reference to its intended food use;**

**(e) if necessary, the special conditions of storage and use.**

**3. In addition, the following information shall be provided, either on the packaging or container, or in the documents relating to the product which are to be supplied with or prior to the delivery, on condition that the indication "intended for the manufacture of food and not for retail**

*sale" is visible on the packaging or container of the product in question:*

*(a) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;*

*(b) a mark identifying the batch or lot;*

*(c) directions for use, if the omission thereof would preclude appropriate use of the food enzyme;*

*(d) where applicable, sufficient information on the composition of the food enzyme or food enzyme preparation to enable the user to comply with quantitative limitations in food: the limit on quantity shall be expressed either numerically or by the quantum satis principle;*

*(e) sufficient information to enable the user to comply with Directive 2000/13/EC, in particular the provisions relating to allergen labelling.*

*4. This Article 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.*

*5. The information provided for in this Article shall be given in a language easily understandable to purchasers. Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that this information shall be made available upon request 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.***

*Justification*

*To simplify the Business to Business labelling by replacing Articles 8, 9, 10, 12 and 14 with one single Article containing all the requirements for labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer. This improves the logic of the text and makes it easier to read and understand.*

Amendment 11  
ARTICLE 9

***Article 9***

***deleted***

***Information requirements concerning the identification of food enzymes***

***1. Where food enzymes not intended for sale to the final consumer are sold singly or mixed with each other, their packaging or containers shall bear the following information in respect of each food enzyme:***

***(a) the name laid down in this Regulation;  
or***

***(b) in the absence of a name, as referred to in point (a), a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused.***

***2. Where food enzymes are sold mixed with each other, the information provided for in paragraph 1 shall be given in respect of each food enzyme in descending order of its percentage by weight of the total.***

*Justification*

*See amendment to Article 8 which contains all the above provisions for the labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer.*

Amendment 12  
ARTICLE 10

*Article 10*

*deleted*

*Information requirements where other substances, materials or food ingredients are incorporated in food enzymes*

*Where substances, materials or food ingredients other than food enzymes are incorporated in food enzymes not intended for sale to the final consumer to facilitate their storage, sale, standardisation, dilution or dissolution, the packaging, containers or accompanying documents of the food enzyme shall bear the information provided for in Article 9 and an indication of each component in descending order of its percentage by weight of the total.*

*Justification*

*See amendment to Article 8 which contains all the above provisions for the labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer.*

Amendment 13  
ARTICLE 11

Where food enzymes not intended for sale to the final consumer are mixed with other food ingredients, the packaging or containers of the **food enzymes** shall bear a list of all components in descending order of their percentage by weight of the total.

Where food enzymes **or food enzyme preparations** not intended for sale to the final consumer are mixed with other food ingredients, the packaging or containers of the **resulting product** shall bear a list of all components in descending order of their percentage by weight of the total.

*Justification*

*According to the definitions contained in the amendment to article 3, a food enzyme that is mixed with other food ingredients is defined as a food enzyme preparation. The term 'food enzyme preparation' covers the meaning of article 10 - i.e. 'Information requirements where other substances, materials or food ingredients are incorporated in food enzymes' - and so removes the need for two separate articles. The term food enzyme is incorrect here and could be misleading; if food enzymes are mixed with other ingredients, they can no longer be*

*described as purely a food enzyme. The 'resulting product' is a more accurate definition.*

Amendment 14  
ARTICLE 12

*Article 12*

*deleted*

*General information requirements for  
food enzymes*

*1. The packaging or containers of food enzymes not intended for sale to the final consumer shall bear the following information:*

*(a) the statement either 'for use in food' or the statement 'restricted use in food' or a more specific reference to its intended food use;*

*(b) if necessary, the special conditions of storage and use;*

*(c) instructions for use, if the omission thereof would preclude appropriate use of the food enzyme;*

*(d) a mark identifying the batch or lot;*

*(e) the name or business name and address of the manufacturer, packager or seller;*

*(f) where a component of the food enzyme is subject to a limit on quantity in food, an indication of that component's percentage of the food enzyme or sufficient information on the composition of the food enzyme to enable the purchaser to ensure compliance with the limit on quantity in food; 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;*

***(g) the net quantity;***

***(h) where relevant, information on a food enzyme or other substances as referred to in Articles 9, 10 and 11 of the present Regulation and listed in Annex IIIa to Directive 2000/13/EC.***

***2. By way of derogation from paragraph 1, the information required in points (c) to (f) and (h) of that paragraph may appear merely on the documents relating to the consignment which are to be supplied with or prior to delivery, provided that the indication “intended for the manufacture of food and not for retail sale” appears on a easily visible part of the packaging or container of the product in question.***

*Justification*

*See amendment to Article 8 which contains all the above provisions for the labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer.*

Amendment 15  
SECTION 3 AND ARTICLE 14

**SECTION 3**

***deleted***

**OTHER LABELLING  
REQUIREMENTS**

**Article 14**

***Other labelling requirements***

***1. Articles 8 to 13 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.***

***2. The information provided for in Articles 8 to 13 shall be in a language***

*easily understandable to purchasers.*

*Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that this information shall be given in one or more of the official languages of the Community, to be determined by that Member State.*

*The first and second subparagraph of this paragraph shall not preclude such information from being indicated in several languages.*

*Justification*

*See amendment to Article 8 which contains all the above provisions for the labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer.*

Amendment 16

ARTICLE 16, PARAGRAPH 2 A (new)

***2a. 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.***

*Justification*

*This amendment is needed in order to align the text to the provisions of the new comitology decision.*

Amendment 17

ARTICLE 18, PARAGRAPH 4, POINT (A A) (new)

***(aa) the Authority shall be allowed to decide on a “fast track” authorisation procedure for food enzymes which are currently on the market if the Authority is satisfied that they have undergone an adequate safety assessment at national or Community level within the EU so that such enzymes could be directly transposed to the Community list of food enzymes.***

*Justification*

*EFSA's resources are already limited and therefore should not be wasted in performing risk assessments of food enzymes which have already been appropriately evaluated within the EU, specifically in Denmark, France or the UK where well-established national authorisation procedures exist for food enzymes.*

Amendment 18  
ARTICLE 18, PARAGRAPH 5

5. If necessary, any appropriate transitional measures for the purposes of this Article may be adopted in accordance with the procedure referred to in *Article 16(2)*.

5. If necessary, any appropriate transitional measures for the purposes of this Article may be adopted in accordance with the procedure referred to in *Article 16(2a)*.

*Justification*

*This amendment is needed to align the text to the provisions of the new comitology decision.*

## EXPLANATORY STATEMENT

At present, there is a lack of harmonised rules at Community level controlling the use of enzymes in food processing. This creates not only barriers to trade and legal uncertainty, but also differing standards of health and consumer protection among the Member States.

Enzymes have been used in food production for hundreds of years with the most common use being in bakery, cheese-making, starch processing and the production of beer, fruit juices and other drinks. They perform many useful functions such as improving texture, appearance and nutritional values.

Currently EU legislation only covers enzymes used as food additives under the scope of Directive 89/107/EEC and just two enzymes, E 1103 Invertase and E1105 Lysozyme, are authorised under this Directive.

In recent years the use of food enzymes in food production has significantly increased, and improved technology has allowed the development of new and more complex enzymes. This raises issues about the potential risks to human health such as allergenicity, toxicity and residual microbiological activity. Enzymes are also being produced from genetically modified micro-organisms. There is therefore a clear need for uniform safety evaluation at European level to ensure effective protection for consumers.

As Rapporteur, I therefore welcome the proposal from the Commission, and note that both industry and consumer associations also welcome the prospect of harmonising legislation for food enzyme use in the EU.

The main focus of my amendments has been on clarification and coherence, particularly in relation to the definitions of food enzymes and food enzyme preparations, labelling requirements for products not intended for sale to the final consumer and on food enzymes derived from genetically modified micro-organisms.

I am concerned about the possible system of double authorisation that this regulation will create for food enzymes falling under the scope of Regulation 1829/2003 on genetically modified food and feed, i.e. food enzymes derived from genetically modified organisms. Under the current Commission proposal, food enzymes under the scope of Regulation 1829/2003 will have to be authorised in accordance with that Regulation before they may be assessed under this regulation for inclusion in the Community list of food enzymes. This may result in such enzymes having to undergo two separate authorisation procedures and therefore needs further clarification.

This concern notwithstanding, I think this legislation is a good example of the European Institutions, industry and consumer groups working together in the interest of both the free movement of goods within the EU and the right of EU citizens to a uniformly high standard of health and consumer protection.