EUROPEAN PARLIAMENT

2004 *2009*

Session document

FINAL
A6-0177/2007

11.5.2007

***I
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

PR_COD_1am

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.

CONTENTS

Page

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)[1],

– 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 the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rules 51 and 35 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 (A6-0177/2007),

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	Amendments by Parliament
	Amendment 1 CITATION 1
Having regard to the Treaty establishing the European Community, and in particular Articles ***37 and*** 95 thereof,	Having regard to the Treaty establishing the European Community, and in particular Articles 95 ***and 153*** thereof,

[1] OJ C ... / Not yet published in OJ.

Justification

Use of enzymes in the context of agricultural legislation is just a very minor aspect of the proposed regulation. Article 37 should therefore not be used as legal base.

The proposal is aiming at a high level of consumer protection, which shall be achieved by harmonising regulations of the Member States within the internal market. Article 153 should therefore be used as legal base.

Amendment 2
RECITAL 3

(3) 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.	(3) 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 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.

Justification

Legal clarity. There is a need for harmonised rules in the single market. This reinforces the legal basis of Article 95 (internal market) of this proposal.

Amendment 3
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	(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 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.	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 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 4
RECITAL 6

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

Justification

This is required so there is an improved common understanding of the meaning of the phrase 'misleading the consumer'.

Amendment 5
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	(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.	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 6
RECITAL 9

(9) With a view to 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 […] of the European Parliament and of the Council of […] establishing a common authorisation procedure for the food additives, food enzymes and food flavourings.	(9) With a view to harmonisation, the risk assessment of food enzymes and their inclusion in the Community list should be carried out in accordance ***with the precautionary principle and*** with the procedure laid down in Regulation (EC) No […] of the European Parliament and of the Council of […] establishing a common authorisation procedure for the food additives, food enzymes and food flavourings.

Justification

The precautionary principle should be in the centre of the risk assessment of food enzymes.

Amendment 7
RECITAL 11

(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 should be authorised in accordance with that Regulation, prior to ***its approval*** under this Regulation.	(11) A food enzyme ***derived from an organism*** 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 should be authorised in accordance with that Regulation, prior to ***or simultaneously with authorisation*** under this Regulation.

Justification

It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food enzyme to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in the Community list of the proposed food enzymes Regulation appears to go against this approach and may result in the enzyme having to undergo two separate authorisation procedures. While in practice EFSA may look at a GMO-derived enzyme in light of both pieces of legislation, in accordance with good administrative practice, it is better to make this clear from the outset.

Amendment 8
RECITAL 14

(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 the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period has been completed.	(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 the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period has been completed. ***However, the opinions of the Authority should be published as soon as the scientific assessment is completed.***

Justification

It should be clarified that "single-step-approach" does not delay the publication of the risk assessment for individual enzymes.

Amendment 9
RECITAL 19

(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.	(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. ***However, a fresh scientific evaluation and classification should be performed at least every 10 years.***

Amendment 10
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[1]. [1] 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[1]. [1] 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 11
ARTICLE 2, PARAGRAPH 2, POINT (C A) (new)

	(ca) digestive aids;

Justification

Legal clarification. It should be clear that, as stated in Recital 4, this Regulation should only cover enzymes that are added to food to perform a technological function and not enzymes intended for human consumption, such as enzymes fort digestive aids.

Amendment 12
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***:*** ***(a)*** microbial cultures that are used in the production of food and which may ***incidentally produce*** enzymes but which are not specifically used to produce them; ***(b) enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids.***

Justification

The Commission has confirmed that the scope of this regulation shall not apply to enzymes intended for human consumption such as enzymes for nutritional purposes or enzymes used as digestive aids. This is covered by Recital 4 of the Commission's proposal. However, in order to make this clear, a reference is need within the main text of the proposed regulation. Article 2.4 is the most appropriate place to make such a reference.

The deletion of word "traditionally" is a legal clarification, as it is not clear what it means.

Amendment 13
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 14
ARTICLE 3, PARAGRAPH 2

The following ***definition*** shall ***also*** apply:	The following ***definitions*** shall 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; this definition should for the purposes of this Regulation also include "pro-enzymes", i.e. compounds that are inactive or nearly inactive precursors of enzymes and can be converted to active enzymes if subjected to a specific catalytic change;
'food enzyme' means a product obtained by extraction from plants ***or*** animals or by a fermentation process using micro-organisms:	***(2)*** 'food enzyme' means a product obtained by extraction from plants***,*** animals***, micro-organisms or products thereof,*** or by a fermentation process using micro-organisms:
(a) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and	(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.	(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 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;
	(4) 'produced by GMOs' means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;
	(5) 'quantum satis' means [1]that no maximum level is specified. However, additives 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.
	[1] Text from Article 2(5) of Directive 94/35/EC (sweeteners).

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.

This is necessary for the sake of completeness in order to cover the possibility of the use of pro-enzymes, which are not enzymes but precursors to enzymes, in food preparation.

The regulation should be consistent with GMO definitions used in other relevant legislation in order not to confuse terminology.

Quantum satis: A definition for 'quantum satis', referred to in Article 12 (f), should be included in this article with the other definitions.

Amendment 15
ARTICLE 4, PARAGRAPH 1 A (NEW)

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

Justification

This new point ensures that all eligible food enzymes are covered by this Regulation.

Amendment 16
ARTICLE 5

A food enzyme may be included in the Community list only if it meets the following conditions:	A food enzyme may be included in the Community list only if it meets the following conditions:
(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	(a) it does not, on the basis of the scientific evidence available ***and the precautionary principle***, pose a safety concern to the health

proposed;	of the consumer at the level of use proposed;
(b) there is a reasonable technological need;	(b) there is a reasonable technological need;
(c) its use does not mislead the consumer.	(c) its use does 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, the nutritional quality of the product or the fruit and vegetable content;***
	(ca) its use has a clear benefit for the consumer.

Justification

As in the current legislation on food additives, a clear benefit for the consumer must be a central requirement in the authorisation process for food enzymes.

There should be an improved common understanding of the meaning of the phrase 'misleading the consumer'.

Amendment 17
ARTICLE 6, PARAGRAPH 2, POINT (A)

(a) the ***name*** of the food enzyme;	(a) the ***definition*** of the food enzyme***, including its common or recommended name, systematic name and synonyms, if possible according to the nomenclature of the International Union of Biochemistry and Molecular Biology and, in the case of complex enzymes, selected on the basis of the enzyme activity that determines the enzyme's function***;

Justification

If possible, the most accurate enzyme name, based on the International Union of Biochemistry (IUB)'s Nomenclature should be used. In cases of complex enzymes, the name should be based on the enzyme activity (active principle) that is exerting the functionality in the food processing.

Amendment 18
ARTICLE 6, PARAGRAPH 2, POINT (B)

(b) the specifications of the food enzyme, including its origin, purity criteria and any other necessary information; where the food enzyme ***falls*** within the scope of Regulation (EC) No 1830/2003, a reference to the unique identifier attributed to the genetically modified organism pursuant to that Regulation shall be included in the specifications;	(b) the specifications of the food enzyme, including its origin, purity criteria and any other necessary information; where the food enzyme ***is derived from an organism falling*** within the scope of Regulation (EC) No 1830/2003, a reference to the unique identifier attributed to the genetically modified organism pursuant to that Regulation shall be included in the specifications;

Justification

It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food enzyme to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in the Community list of the proposed food enzymes Regulation appears to go against this approach and may result in the enzyme having to undergo two separate authorisation procedures. While in practice EFSA may look at a GMO-derived enzyme in light of both pieces of legislation, in accordance with good administrative practice, it is better to make this clear from the outset.

Amendment 19
ARTICLE 6, PARAGRAPH 2, POINTS (C) TO (F)

(c) ***if necessary,*** the foods to which the food enzyme may be added;	(c) the foods to which the food enzyme may be added;
(d) ***if necessary,*** the conditions under which the food enzyme may be used;	(d) the conditions under which the food enzyme may be used;
(e) if appropriate, whether there are any restrictions on the sale of the food enzyme directly to consumers;	(e) if appropriate, whether there are any restrictions on the sale of the food enzyme directly to consumers;
(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	(f) 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

specific treatment it has undergone.	treatment it has undergone.

Justification

The authorisation of a food enzyme should specify all conditions of use and labelling requirements. Therefore this paragraph needs to be clarified.

Amendment 20
ARTICLE 7

Inclusion of genetically modified ***enzymes*** on the Community list	Inclusion of ***enzymes derived from*** genetically modified ***organisms (GMOs)*** on the Community list
A food enzyme falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community list ***only after*** it has been authorised in accordance with the procedure referred to in Article 7 of that Regulation.	***Without prejudice to Article 4 of this Regulation,*** a food enzyme ***derived from an organism*** falling within the scope of Regulation (EC) No 1829/2003 may ***only*** be included in the Community list ***once*** it has been authorised in accordance with the procedure referred to in Article 7 of that Regulation.

Justification

It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food enzyme to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in the Community list of the proposed food enzymes Regulation appears to go against this approach and may result in the enzyme having to undergo two separate authorisation procedures. While in practice EFSA may look at a GMO-derived enzyme in light of both pieces of legislation, in accordance with good administrative practice, it is better to make this clear from the outset.

Amendment 21
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 ***and food enzyme preparations*** not intended for sale to the final consumer, whether sold singly or mixed with each other, 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, and the description according to the nomenclature of the International Union of Biochemistry and Molecular Biology; and
(b) 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 expiry date beyond which use of the food enzyme would be inappropriate;

(e) the statement either 'for use in food' or 'restricted use in food' or a more specific reference to its intended food use;
(f) if necessary, the special conditions of transport, 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; when enzymes are added to foods, this shall be done only in a dose which is strictly necessary in order to attain the purpose for which they are being used. This will minimise the quantity of enzymes ingested and afford better protection to sensitive population groups;
(e) sufficient information to enable the user to comply with Directive 2000/13/EC, in particular the provisions relating to allergen labelling;
(f) the side-effects of their use in excessive quantities.

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.

The labelling intended to professional users should give precise information regarding the nature and activity of the enzyme. It is important for food producers to know the durability of food enzymes in order to ensure food safety. The conditions under which specific enzymes sensitive to changes in temperature, humidity levels, etc. are transported can have an effect on the quality of the end product.

Information on the effects of a potential overdose of enzymes can protect consumers against avoidable diseases. Excessive use of enzymes is not harmless to the human organism.

Amendment 22
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 23
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 24
ARTICLE 11

Where food enzymes not intended for sale to the final consumer are mixed with other	Where food enzymes ***or food enzyme preparations*** not intended for sale to the

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.	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 seperate 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 25
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 26
ARTICLE 13, PARAGRAPH 1, POINT (B)

(b) the information required in accordance with ***Articles 9, 10,*** and 11 ***and points (a) to (e) and (g) and (h) of Article 12(1).***	(b) the information required in accordance with ***Articles 8*** and 11.

Justification

For the labelling of food enzymes intended for sale to the final consumer, all information should be made available. Especially the provisions from Article 8(3) point (d) concerning maximum quantities of food enzymes in the final food product should not be excluded.

Amendment 27
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 28
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 29
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 30
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 ***regulatory*** procedure ***with scrutiny*** referred to in ***Article 16(2a).***

Justification

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

Amendment 31
ARTICLE 20 A (NEW)

Article 20a

Amendment to Regulation (EC) No 258/1997

In Article 2(1) of Regulation (EC) No 258/1997, the following point (d) shall be added:

"(d) food enzymes falling within the scope of Regulation (EC) No ……. [on food enzymes]."

Justification

This brings the Novel Food Regulation in line with this proposal.

Amendment 32
ARTICLE 22, POINT 2
Article 6, paragraph 6, new indent (Directive 2001/13/EC)

− enzymes ***other than as referred to in paragraph 4(c)(ii)*** must be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name**,**	− enzymes ***present in the food product*** must be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name ***and an indication of whether they are still active in the final product or not; for enzymes produced from GMOs the indication "produced from GMOs" shall be given on the label***;

Justification

Consumers must be aware of whether a given product contains active enzymes. Labelling provisions must also be clarified regarding enzymes produced from GMOs. This is in line with the concept of "last living organism" ruling the labelling provisions of Regulation 1829/2003/EC on GM food and feed. In addition, information on all enzymes used in food

processing should be provided, if not on the label then at least through other media, preferably at the point of purchase as well as in a format that could be consulted at home.

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.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

Mr Miroslav Ouzký
Chairman
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis of the Proposal for a Regulation of the European Parliament and of the Council on food enzymes (COM(2006)0425 – C6-0257/2006 – 2006/0144(COD))[1]

Dear Mr Chairman,

By letter of 28 March 2007 you asked the Committee on Legal Affairs pursuant to Rule 35(2), to consider whether the legal basis of the above Commission proposal was valid and appropriate.

The committee considered the above question at its meeting of 2 May 2007.

The committee noted that whereas the proposal has a dual legal basis, Article 37 and Article 95 of the EC Treaty, the rapporteur, Mrs Doyle, proposes to delete Article 37 as she considers that Article 95 provides an appropriate and sufficient legal base.

Furthermore, Mr Schlyter and Mr Staes, taking into consideration the regulation's aim of providing a high level of consumer protection, propose not only to delete the reference to Article 37 but also to add a reference to Article 153, so that the legal bases would be Articles 95 and 153.

The legal bases under consideration

Article 37

1. In order to evolve the broad lines of a common agricultural policy, the Commission shall, immediately this Treaty enters into force, convene a conference of the Member States with a view to making a comparison of their agricultural policies, in particular by producing a statement of their resources and needs.

2. Having taken into account the work of the Conference provided for in paragraph 1, after consulting the Economic and Social Committee and within two years of the entry into force of

[1] Not yet published in OJ.

this Treaty, the Commission shall submit proposals for working out and implementing the common agricultural policy, including the replacement of the national organisations by one of the forms of common organisation provided for in Article 34(1), and for implementing the measures specified in this title.
These proposals shall take account of the interdependence of the agricultural matters mentioned in this title.

The Council shall, on a proposal from the Commission and after consulting the European Parliament, acting by a qualified majority, make regulations, issue directives, or take decisions, without prejudice to any recommendations it may also make.

3. The Council may, acting by a qualified majority and in accordance with paragraph 2, replace the national market organisations by the common organisation provided for in Article 34(1) if:

(a) the common organisation offers Member States which are opposed to this measure and which have an organisation of their own for the production in question equivalent safeguards for the employment and standard of living of the producers concerned, account being taken of the adjustments that will be possible and the specialisation that will be needed with the passage of time;

(b) such an organisation ensures conditions for trade within the Community similar to those existing in a national market.

4. If a common organisation for certain raw materials is established before a common 2organisation exists for the corresponding processed products, such raw materials as are used for processed products intended for export to third countries may be imported from outside the Community.

Article 95

1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a

Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.

Article 153

1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.

2. Consumer protection requirements shall be taken into account in defining and implementing other Community policies and activities.

3. The Community shall contribute to the attainment of the objectives referred to in paragraph 1 through:

(a) measures adopted pursuant to Article 95 in the context of the completion of the internal market;

(b) measures which support, supplement and monitor the policy pursued by the Member States.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, shall adopt the measures referred to in paragraph 3 (b).

5. Measures adopted pursuant to paragraph 4 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them.

Content of the draft Regulation

According to the explanatory memorandum, the aim and purpose of the proposal for a regulation is as follows:

The legislation controlling the use of enzymes in food processing is not fully harmonised in the EU. The national regulatory context for enzymes used as processing aids in food production differs significantly among Member States. Only a few Member States have a mandatory or voluntary authorisation procedure, the majority have none at all. Moreover, there are divided opinions among Member States in relation to the categorisation of enzymes into food additives or processing aids according to their function in the food process or in the final food. This lack of harmonised rules in the Community created barriers to the trade of food enzymes and has hindered growth in this field.

With respect to safety, there is neither safety evaluation nor authorisation of food enzymes at European level, except for those that are considered as food additives. Historically, food enzymes were considered to be non-toxic. However, the food enzyme industry is continually striving to develop improved technology resulting in the development of food enzymes which became through the years more complex and sophisticated. There could be some potential hazards arising from their chemical nature and source such as allergenicity, activity-related toxicity, residual microbiological activity, and chemical toxicity. Therefore safety evaluation of all food enzymes, including those produced by genetically modified micro-organisms (GMOs), is essential in order to ensure consumer safety.

The content of the regulation may be analysed as follows:

Chapter I - Subject matter, scope and definitions.

The proposed Regulation is to apply to enzymes used for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including those used as processing aids. Food enzymes are to be subject to safety evaluation and approval by means of a Community list.

Chapter II - Community list of approved food enzymes
All food enzymes and their use in food will be evaluated for safety, technological need, benefit to the consumer and to ensure that the consumer is not misled by their use. In line with the decision to separate risk management and risk assessment, the European Food Safety Authority (EFSA) will carry out the safety evaluations. The inclusion of a food enzyme in the Community list will be considered by the Commission on the basis of the opinion from EFSA, taking into account the other general criteria (technological need, consumer aspects). For every food enzyme included in the positive list specifications, including the criteria relating to the purity and the origin of the food enzyme, are to be laid down.

Chapter III - Labelling
The proposed Regulation will introduce labelling requirements for food enzymes sold to the manufacturer or directly to the consumer. For the purpose of labelling, enzymes used in food should be considered as ingredients in a similar way to additives in accordance with Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs. In most cases food enzymes will be used as processing aids, *i.e.* they will be present in food in the form of a residue, if at all, and will have no technological effect on the finished product. Taking into account that all food enzymes will be assessed for their safety, it is proposed that food enzymes which are used as processing aids should be exempted from labelling. Food enzymes used to exert a technological function in the final food will be labelled with their function (*e.g.* stabiliser, etc) and specific name.

Chapter IV - Procedural provisions and implementation
Wherever necessary, producers or users of food enzymes will be obliged to inform the Commission of any new information which may affect the safety assessment of the food enzyme.

Implementation of the measures proposed in the Regulation will be effected by the Commission in accordance with the regulatory procedure laid down in Council Decision 1999/468/EC.

Chapter V -Transitional and final provisions
Since many food enzymes are already on the market in the Community, the transition to a Community positive list should be smooth and should not lead to unfair conditions for enzyme producers. Therefore, the proposal provides for an initial period of 24 months, after the date of application of the implementing measures foreseen in the common procedure Regulation, during which applications can be submitted. The establishment of the Community list will take place in a single-step procedure after the EFSA has expressed opinions on all products for which sufficient information has been submitted during the 24-month period. Until such time as the Community list has been established, food enzymes and food produced with food enzymes may be placed on the market and used in accordance with existing national rules. A transitional period is also laid down for the proposed labelling requirements.

Appraisal

All Community acts must be founded upon a legal basis laid down in the Treaty (or in another legal act which they are intended to implement). The legal basis defines the Community's competence *ratione materiae* and specifies how that competence is to be exercised, namely the legislative instrument(s) which may be used and the decision-making procedure.

It is clear from settled case-law of the Court of Justice that the choice of legal basis is not at the discretion of the Community legislator but must be determined by objective factors which can be subject to judicial review[1], such as the aim and content of the measure in question[2]. Furthermore, the decisive factor should be the main object of a measure[3].

According to the case-law of the Court of Justice, a general Treaty article constitutes a sufficient legal basis even though the measure in question also seeks, in a subordinate manner, to attain an aim sought by a specific Treaty article[4].

However, where a measure has several contemporaneous objectives which are indissolubly linked with each other without one being secondary and indirect in respect to the others, the measure must be based on the various relevant Treaty provisions[5], unless this is impossible on account of the mutual incompatibility of the decision-making procedures laid down by the provisions[6].

In the light of the above, it is to be established whether Article 37 together with Article 95, Article 95 alone or Article 95 together with Article 153 of the EC Treaty should constitute the proper legal basis of the proposed regulation.

As far as *Article 37*, is concerned, it is noted that, even though that article is mentioned in the first citation in the preamble to the proposed regulation, the explanatory memorandum mentions only Article 95 as the legal basis. When in addition, it is considered that the only positive mentions of agricultural products are very ancillary indeed, namely in recitals 7[7] and

---

[1] Case 45/86, *Commission* v. *Council* [1987] ECR 1439, para. 5.
[2] Case C-300/89, *Commission* v. *Council* [1991] ECR I-287, para. 10, and Case C-42/97, *European Parliament* v. *Council* [1999] ECR I-869, para. 36.
[3] Case C-377/98, *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, para. 27.
[4] Case C-377/98 *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, paras 27-28; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paras 93-94.
[5] Case C-165/87 *Commission* v. *Council* [1988] ECR 5545, para. 11.
[6] See, *e.g.*, Case C-300/89 *Commission* v. *Council* [1991] ECR I-2867, paras 17-21 (*Titanium dioxide* case), Case C-388/01 *Commission* v. *Council* [2004] ECR I-4829, para. 58 and Case C-491/01 *British American Tobacco* [2002] ECR I-11453, paras 103-111.
[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. Those food enzymes should be used in accordance with this 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, 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 and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine should therefore be amended*

16[1], and that recital 4 makes it clear that "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", it is hard to see how Article 37 could constitute the legal basis. Consequently, given the proposed regulation's emphasis on the internal market and the protection of health as evinced in recitals 1, 2 and 3[2], it is considered that Article 37 does not qualify as joint legal basis on the basis of the criteria laid down in the case-law.

It should also be observed that Article 37 and Article 95 do not seem to be compatible - the former provides for the mere consultation of Parliament whilst the latter provides for the codecision procedure.

When it comes to the question whether *Article 153* may be added to the legal basis of Article 95, it is undeniable that the proposed regulation is concerned with the protection of the health of consumers and with their social and economic interests, of which mention is made in Article 153. It is indeed possible to take the view that the two aims of achieving the internal market and consumer protection within the meaning of Article 153 are equally balanced and that therefore both legal bases may be used.

However, in view of the wording of paragraph 3(a) of Article 153, which provides that the Community shall contribute to the attainment of the objective of, i*nter alia*, protecting the health and economic interests of consumers through measures adopted pursuant to Article 95 in the context of the completion of the internal market, there is, strictly speaking, no need to consider whether the proposed measure has "several contemporaneous objectives which are indissolubly linked with each other without one being secondary and indirect in respect to the others", since Article 95 may be used as the legal basis by itself, either on the ground that paragraph 3 of that article provides that internal market measures concerning consumer protection are to take as a base a high level of protection or on the ground of the explicit reference made to Article 95 in Article 153.

Articles 95 and 153 are intrinsically compatible and the addition of the latter article has no procedural or substantive implications.

---

accordingly.

[1] *... 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 1622/2000 of 24 July 2000 laying down certain detailed rules for implementing Regulation (EC) No 1493/1999 on the common organisation of the market in wine and establishing a Community code of oenological practices and processes. Those substances are food enzymes and they should fall within the scope of this Regulation. They should therefore be also 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 1622/2000.*

[2] *(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) 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.

Accordingly, where, as in this case, a measure seeks to attain consumer protection objectives in equal measure and at the same time as objectives relating to the completion of the internal market, it may be safely based on both Article 95 and Article 153.

At its meeting of 2 May 2007 the Committee on Legal Affairs accordingly decided, unanimously[1], to recommend as follows:

(a) Article 37 of the EC Treaty does not constitute an appropriate legal basis for the proposal for a regulation;

(b) the appropriate legal basis is Article 95 and Article 153 of the EC Treaty.

Yours sincerely,

Giuseppe Gargani

[1] The following were present for the final vote: Giuseppe Gargani (chairman), Cristian Dumitrescu, Francesco Enrico Speroni (vice-chairmen), Manuel Medina Ortega (draftsman), Sharon Bowles, Mogens N.J. Camre, Carlo Casini, Bert Doorn, Monica Frassoni, Klaus-Heiner Lehne, Eva Lichtenberger, Antonio Masip Hidalgo, Aloyzas Sakalas, Gary Titley, Jaroslav Zvěřina.

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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

on the proposal for a regulation of the European Parliament and of the Councilon 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))

Draftswoman: Erna Hennicot-Schoepges

SHORT JUSTIFICATION

For thousands of years, man has used naturally occurring micro-organisms - bacteria, yeasts and moulds - and the enzymes they produce to make foods such as bread, cheese, beer and wine. The second half of the 20th century has seen a significant growth in the use of enzymes in food processing (like baked goods, wine and juices, brewing, dairy products, starch and sugar) and increasing sophistication in the methods of processing and preparing food will demand an ever wider-range of enzymes.

Enzymes are extremely useful in the food industry. Acting as biocatalysts, they facilitate the biochemical reactions through which all biological material is built up and ultimately broken down. Enzymes can break down complex molecules (e.g. carbohydrates) into smaller units, they can catalyse structural changes within one molecule (e.g. isomerisation of sugar), or join substrate molecules to other specific molecules (e.g. the building of proteins or cell wall materials). Furthermore, enzymes are very efficient, being able to accelerate reactions by factors of at least a million without modifying themselves. Compared to chemically catalysed reactions, enzymatic reactions offer some major advantages in terms of lower energy consumption, lower waste production, and biodegradability. Enzymes can be compared to a key to an individual lock, rather than to a chemical axe to break down the door. The increased use of enzymes triggered the emergence of "commercial" enzymes, produced from the fermentation of specially selected micro-organisms.

The legislation controlling the use of enzymes in food processing in the EU is nowadays not fully harmonised. Enzymes used in food processing are considered to be either food additives or processing aids. Food additives are essentially substances that are added to food and have a technological function in that food, while processing aids are essentially substances that are added during food processing for technical reasons and may end up in the food but do not have a technological function in the final food.

The use of enzymes as food additives is regulated by Directive 89/107/EEC. However, at the moment, this Directive only covers and authorises two enzymes as food additives (lysozyme and invertase). The use of enzymes as processing aids is not regulated at all at European level, but merely at national level. National legislation in this area differs from country to country as far as the number and type of permitted enzymes (whether or not produced by genetically modified micro-organisms) in various applications is concerned, and also as far as pre-market approval is concerned.

In order to create a level playing field and ensure the proper functioning of the internal market, the harmonisation of rules at Community level is necessary. This proposed Regulation aims at harmonizing the safety evaluation and authorisation of all food enzymes, including those produced by GMOs, and requires their labelling.

Your draftswoman welcomes this proposal that will introduce a harmonised system of safety evaluation of enzymes at Community level. However, in order to make the proposal more workable, your draftswoman would like to introduce a "fast track" procedure for food enzymes already evaluated and authorized by Member States (such as Denmark, France or the UK). Also, your draftswoman would like to propose certain amendments to enhance legal clarity.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
ARTICLE 2, PARAGRAPH 2, POINT (C A) (new)

	(ca) digestive aids;

Justification

Legal clarification. It should be clear that, as stated in Recital 4, this Regulation should only cover enzymes that are added to food to perform a technological function and not enzymes intended for human consumption, such as enzymes fort digestive aids.

Amendment 2
ARTICLE 2, PARAGRAPH 4

4. This Regulation shall not apply to	4. This Regulation shall not apply to

[1] Not yet published in OJ.

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.	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

Legal clarification. It is not clear what the word "traditionally" covers.

Amendment 3
ARTICLE 3, PARAGRAPH 2, SUBPARAGRAPH 1 A (new)

	'food enzyme preparation' means a food enzyme formulated with substances that facilitate the storage, sale, standardisation, dilution or dissolution of the food enzyme.

Justification

A definition of 'food enzyme preparation' is lacking from this proposal. In order to simplify the business to business labelling of food enzymes, this term is introduced in Article 8.

Amendment 4
ARTICLE 6, PARAGRAPH 2, POINT (A)

(a) the ***name*** of the food enzyme;	(a) the ***definition*** of the food enzyme***, including its common or recommended name, systematic name and synonyms, if possible according to the nomenclature of the International Union of Biochemistry and Molecular Biology and, in the case of complex enzymes, selected on the basis of the enzyme activity that determines the enzyme's function***;

Justification

If possible, the most accurate enzyme name, based on the International Union of Biochemistry (IUB)'s Nomenclature should be used. In cases of complex enzymes, the name should be based on the enzyme activity (active principle) that is exerting the functionality in the food processing.

Amendment 5
ARTICLE 7, TITLE

Inclusion of genetically modified ***enzymes*** on the Community list	Inclusion ***in the Community list*** of ***food enzymes from*** genetically modified ***micro organisms***

Justification

The term "genetically modified enzymes" could lead to misunderstandings.

Amendment 6
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.	Food enzymes ***and food enzyme preparations*** not intended for sale to the final consumer, whether sold singly or mixed with each other, 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.

Justification

In order to facilitate the business to business labelling of food enzymes.

Amendment 7
ARTICLE 9, PARAGRAPH 2

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***.	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.

Justification

In order to facilitate the business to business labelling of food enzymes.

Amendment 8
ARTICLE 12, PARAGRAPH 1, POINT (G A) (new)

	(ga) the expiry date beyond which use of the food enzyme would be inappropriate;

Justification

It is important for food producers to know the durability of food enzymes in order to ensure food safety.

Amendment 9
ARTICLE 18, PARAGRAPH 4, POINT (B A) (new)

(ba) the Commission may include in the Community list any food enzyme already authorised in Denmark, France or the United Kingdom, or already evaluated by the Joint Expert Committee on Food Additives, without requiring an application under paragraph 2 or the opinion of the Authority.

Justification

Food enzymes already evaluated by JECFA or already authorized in Denmark, France or the UK should be allowed a "fast track" procedure. This will alleviate the work of EFSA.

PROCEDURE

Title	Food enzymes
References	COM(2006)0425 - C6-0257/2006 - 2006/0144(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ITRE 5.9.2006
Drafts(wo)man Date appointed	Erna Hennicot-Schoepges 4.10.2006
Discussed in committee	28.11.2006 27.2.2007 27.3.2007
Date adopted	27.3.2007
Result of final vote	+: 47 –: 0 0: 0
Members present for the final vote	Jan Březina, Renato Brunetta, Jerzy Buzek, Jorgo Chatzimarkakis, Giles Chichester, Silvia Ciornei, Pilar del Castillo Vera, Den Dover, Lena Ek, Nicole Fontaine, Adam Gierek, Norbert Glante, András Gyürk, Fiona Hall, Rebecca Harms, Erna Hennicot-Schoepges, Mary Honeyball, Ján Hudacký, Romana Jordan Cizelj, Anne Laperrouze, Eugenijus Maldeikis, Angelika Niebler, Reino Paasilinna, Atanas Paparizov, Francisca Pleguezuelos Aguilar, Miloslav Ransdorf,

	Vladimír Remek, Herbert Reul, Mechtild Rothe, Paul Rübig, Andres Tarand, Britta Thomsen, Radu Ţîrle, Patrizia Toia, Catherine Trautmann, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras
Substitute(s) present for the final vote	Alexander Alvaro, Philip Dimitrov Dimitrov, Avril Doyle, Robert Goebbels, Matthias Groote, Satu Hassi, Eija-Riitta Korhola, Esko Seppänen, Hannes Swoboda, Lambert van Nistelrooij

PROCEDURE

Title	Food enzymes
References	COM(2006)0425 - C6-0257/2006 - 2006/0144(COD)
Date submitted to Parliament	28.7.2006
Committee responsible Date announced in plenary	ENVI 5.9.2006
Committee(s) asked for opinion(s) Date announced in plenary	ITRE IMCO AGRI 5.9.2006 5.9.2006 5.9.2006
Not delivering opinions Date of decision	IMCO AGRI 13.9.2006 11.9.2006
Rapporteur(s) Date appointed	Avril Doyle 5.10.2006
Legal basis disputed Date of JURI opinion	JURI 3.5.2007
Discussed in committee	22.3.2007
Date adopted	8.5.2007
Result of final vote	+: 43 –: 0 0: 1
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Jill Evans, Satu Hassi, Gyula Hegyi, Jens Holm, Marie Anne Isler Béguin, Dan Jørgensen, Christa Klaß, Urszula Krupa, Marie-Noëlle Lienemann, Peter Liese, Jules Maaten, Linda McAvan, Alexandru-Ioan Morţun, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Daciana Octavia Sârbu, Karin Scheele, Carl Schlyter, Horst Schnellhardt, Kathy Sinnott, Antonios Trakatellis, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Anders Wijkman, Glenis Willmott
Substitute(s) present for the final vote	Christofer Fjellner, Adam Gierek, Alojz Peterle, Andres Tarand