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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting 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, Council Directive 2001/112/EC and Regulation (EC) No 258/97
(16676/1/2007 – C6-0140/2008 – 2006/0144(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Avril Doyle

PR_COD_2am

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*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. 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). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting 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, Council Directive 2001/112/EC and Regulation (EC) No 258/97
(16676/1/2007 – C6-0140/2008 – 2006/0144(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (16676/1/2007 – C6-0140/2008),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2006)0425),

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 62 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0176/2008),

1. Approves the common position as amended;

2. Instructs its President to forward its position to the Council and the Commission.

Amendment 1

Council common position – amending act
Recital 4

Council common position	*Amendment*
(4) This Regulation should only cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids (hereinafter referred to as "food enzymes"). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function but are	(4) This Regulation should only cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids (hereinafter referred to as "food enzymes"). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function but are

[1] Texts Adopted, 10.7.2007, P6_TA(2007)0322.

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

Justification

Amendment agreed by Parliament at first reading (amendment 3). It should be made explicitly 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

Council common position – amending act
Recital 6

Council common position	*Amendment*
(6) Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes must be safe when used, there must be a technological need for their use and their use must not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. The approval of food enzymes should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors ***and*** the feasibility of controls.	(6) Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes must be safe when used, there must be a technological need for their use***,*** and their use must not mislead the consumer ***and 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. The approval of food enzymes should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors***,*** the feasibility of controls ***and, if necessary, the precautionary principle.***

Justification

Based on amendments adopted by Parliament at first reading (amendment 4 and 6). Parliament's view is that the precautionary principle should be at the centre of the assessment of food enzymes. 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.

Amendment 3

Council common position – amending act
Recital 9

Council common position	*Amendment*
(9) In order to ensure harmonisation, the risk assessment of food enzymes and their inclusion in the Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No …/… of the European Parliament and of the Council of … establishing a common authorisation procedure for food additives, food enzymes and food flavourings.	(9) In order to ensure harmonisation, the risk assessment of food enzymes and their inclusion in the Community list should be carried out in accordance ***with the 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 food additives, food enzymes and food flavourings.

Justification

Amendment agreed by Parliament at first reading (amendment 6). The precautionary principle should be at the centre of the risk assessment of food enzymes.

Amendment 4

Council common position – amending act
Recital 11

Council common position	*Amendment*
(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 ***subject to the authorisation procedure under*** that Regulation ***with regard to the safety assessment of the genetic modification, while the final authorisation of the food enzyme should be granted*** under this Regulation.	(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 ***as well as*** under this Regulation.

Justification

Reintroduces in part amendment 7 from the first reading. Any GM product used for the production of a food enzyme already approved in the EU in accordance with this Regulation on Enzymes must also be approved in accordance with Regulation 1829/2003. This amendment brings the Enzymes Regulation into line with the other proposals in the package.

Amendment 5

Council common position – amending act
Recital 14

Council common position	*Amendment*
(14) In order to ensure fair and equal conditions for all applicants, the Community list should be drawn up in a single step. That list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period.	(14) In order to ensure fair and equal conditions for all applicants, the Community list should be drawn up in a single step. That list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period. ***However, the risk assessments of the Authority for individual enzymes should be published as soon as they are completed.***

Justification

Amendment agreed by Parliament at first reading (amendment 8). It should be clarified that "single-step-approach" does not delay the publication of the risk assessment for individual enzymes.

Amendment 6

Council common position – amending act
Article 3 - paragraph 2 - point (b b) (new)

Council common position	*Amendment*
	(bb) "quantum satis" means that no maximum level is specified. However, enzymes 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.

Justification

This is based on the amendment moved by Parliament at first reading (amendment 14). Quantum satis: A definition for 'quantum satis', referred to in Article 12 (f) of the Commission Proposal, should be included in this article with the other definitions.

Amendment 7

Council common position – amending act
Article 6 - point (a)

Council common position	*Amendment*
(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed and	(a) it does not, on the basis of the scientific evidence available ***and the precautionary principle***, pose a safety concern to the health of the consumer at the level of use proposed and

Justification

Partly reintroduces amendment adopted by Parliament at the first reading (amendment 16). Parliament holds the view that the Precautionary Principle should be at the centre of the assessment and should therefore be included in an article.

Amendment 8

Council common position – amending act
Article 6 - point (c)

Council common position	*Amendment*
(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 and quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product.***

Justification

Amendment based on amendment 16 adopted at first reading. What is meant by the concept 'misleading the consumer' should be made clear and transparent.

Amendment 9

Council common position – amending act
Article 6 - point (c a) (new)

Council common position	*Amendment*
	(ca) its use has a clear benefit for the consumer.

Justification

Amendment agreed by Parliament at first reading (amendment 16). 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.

Amendment 10

Council common position – amending act
Article 7 - paragraph 2 - points (c) and (d)

Council common position	*Amendment*
(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; where appropriate, no maximum level shall be fixed for a food enzyme. In that case, the food enzyme shall be used in accordance with the principle of quantum satis;	(d) the conditions under which the food enzyme may be used; where appropriate, no maximum level shall be fixed for a food enzyme. In that case, the food enzyme shall be used in accordance with the principle of quantum satis;

Justification

This amendment is based on an amendment adopted at first reading (amendment 19). It is Parliament's view that the authorisation of a food enzyme should be more specific in relation to conditions of use and labelling requirements.

Amendment 11

Council common position – amending act
Article 7 - paragraph 2 - point (f)

Council common position	*Amendment*
(f) ***where necessary,*** specific requirements in respect of the labelling of food in which the food enzymes have been used in order to ensure that the final consumer is informed of the physical condition of the food or the specific treatment it has undergone.	(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 treatment it has undergone.

Justification

Amendment agreed by Parliament at first reading. The authorisation of a food enzyme should specify all conditions of use and labelling requirements. Therefore this paragraph needs to be clarified.

Amendment 12

Council common position – amending act
Article 8

Council common position	*Amendment*
A food enzyme falling within the scope of Regulation (EC) No 1829/2003 may be included in ***the Community*** list in accordance with this Regulation only ***when*** it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.	A food enzyme falling within the scope of Regulation (EC) No 1829/2003 ***and not already included in the Community list*** may be included in ***that*** list in accordance with this Regulation only ***if*** it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.

Justification

Reintroduces amendment 34 from the first reading. Any GM product used for the production of a food enzyme already approved in the EU in accordance with this Regulation on Enzymes must also be approved in accordance with Regulation 1829/2003.This amendment brings the Enzyme Regulation into line with the other proposals in the package.

Amendment 13

Council common position – amending act
Article 10 - paragraph 1

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

Justification

To eliminate confusion between enzymes or enzyme preparations and ingredients to which enzymes or enzyme preparations have been added, the latter category should be treated separately. Therefore the text of the EP first reading should be reintroduced.

Amendment 14

Council common position – amending act
Article 11 - paragraph 1 - point (a)

Council common position	*Amendment*
(a) the name laid down under this Regulation in respect of each food enzyme or ***a sales description which includes the name of each food enzyme or*** in the absence of a name, ***a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused;***	(a) the name laid down under this Regulation in respect of each food enzyme or***,*** in the absence of ***such*** a name, ***the accepted name laid down in the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB);***

Justification

Amendment is a compromise between the Common position and amendment 21 of Parliament's first reading. The wording 'a sales description which includes the name of each food enzyme' is not clear and should be replaced by the enzyme names laid down in the IUBMB, which are internationally recognised and should therefore be used as long as the positive list has not been published. (The deletion of 'a description sufficiently precise' is in

line with the proposal for a Food Additive Regulation.)

Amendment 15

Council common position – amending act
Article 12, paragraph 1, point (a)

Council common position	*Amendment*
(a) the name laid down under this Regulation in respect of each food enzyme or ***a sales description which includes the name of each food enzyme or*** in the absence of a name, ***a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused;***	(a) the name laid down under this Regulation in respect of each food enzyme or***,*** in the absence of ***such*** a name, ***the accepted name laid down in the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB);***

Justification

See amendment 20.

Amendment 16

Council common position – amending act
Article 12 - paragraph 1 - point (b a) (new)

Council common position	*Amendment*
	(ba) where applicable, an indication that the food enzyme product contains or was produced from genetically modified organisms as required by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[1] and according to the requirements 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[2].

[1] OJ L 268, 18.10.2003, p. 1. Regulation as last

amended by Regulation (EC) No 298/2008 of the European Parliament and of the Council (OJ L 97, 9.4.2008, p.64.

[2] OJ L 268, 18.10.2003, p. 24.

Justification

This amendment is based on amendment adopted at first reading (amendment 37). Council's position on GM labelling is not satisfactory. Parliament would like to see clearer labelling where a food enzyme product contains or was produced from genetically modified organisms.

EXPLANATORY STATEMENT

Objective of Proposal:

There is currently no safety evaluation of food enzymes at European level and no authorisation procedure, except for those considered as food additives. Industry has been pressing for harmonised legislation with a Community procedure for authorisation of food enzymes as the absence of EU legislation in this field has led to unfair commercial practices, hindered growth and led to 'reverse discrimination' against domestic food producers in countries with more restrictive rules.

The objective of the proposed Regulation is to harmonise legislation controlling the use of enzymes in food processing in the EU in order to protect human health, and to promote fair trade and competition.

Rapporteur's view on the Common Position:

I welcome recital 13 of the Council's text, which accepts Parliament's suggestion to have a provision to allow EFSA to decide on a "fast track" authorisation procedure for food enzymes which are currently on the market, as many enzymes have already been evaluated in Member States where well-established national authorisation procedures exist, notably in Denmark, France or the UK. I also welcome the simplified labelling provisions introduced by the Council which will apply horizontally across the food improvement package of Regulations on food additives, flavourings and enzymes.

However, Parliament's first reading adopted several important amendments to the draft Regulation proposed by the Commission which the Parliament would like to see maintained in the text. I have reinstated Parliament's view that the 'precautionary principle' should be at the centre of any risk assessment and therefore needs to be emphasised in this proposal. At the first reading Parliament also strengthened the provisions for consumer protection to ensure a food enzyme should not mislead consumers as to the nature, quality and substance of a product and this concept is reintroduced.

Food enzymes are not, and cannot, be genetically modified micro-organisms. However, it is likely that an increasing amount of food enzymes could be *derived from* GMOs in the future. It is important to stress this distinction in order to avoid misunderstandings or creating unnecessary concern while still ensuring transparency for the consumer. I have therefore reintroduced some relevant amendments from the first reading.

I hope that this proposal is adopted without further delay so that harmonised rules can be introduced and a high level of food safety can be guaranteed.

PROCEDURE

Title	Food enzymes
References	16676/1/2007 – C6-0140/2008 – 2006/0144(COD)
Date of Parliament's first reading – P number	10.7.2007 T6-0322/2007
Commission proposal	COM(2006)0425 - C6-0257/2006
Amended Commission proposal	COM(2007)0670
Date receipt of common position announced in plenary	13.3.2008
Committee responsible Date announced in plenary	ENVI 13.3.2008
Rapporteur(s) Date appointed	Avril Doyle 14.9.2006
Date adopted	6.5.2008
Result of final vote	+: 51 –: 0 0: 1
Members present for the final vote	Georgs Andrejevs, Pilar Ayuso, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Mojca Drčar Murko, Jill Evans, Anne Ferreira, Karl-Heinz Florenz, Matthias Groote, Françoise Grossetête, Satu Hassi, Jens Holm, Caroline Jackson, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Marie-Noëlle Lienemann, Jules Maaten, Linda McAvan, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Kathy Sinnott, Bogusław Sonik, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Åsa Westlund, Anders Wijkman, Glenis Willmott
Substitute(s) present for the final vote	Anne Laperrouze, Kartika Tamara Liotard, Miroslav Mikolášik, Alojz Peterle, Lambert van Nistelrooij
Substitute(s) under Rule 178(2) present for the final vote	Armando França, Raül Romeva i Rueda