COMMISSION OF THE EUROPEAN COMMUNITIES

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2006/0144 (COD)

Amended 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 of the European Parliament and of the Council, ~~and~~ Council Directive 2001/112/EC <u>and Regulation (EC) No 258/97 of the European Parliament and of the Council</u>

(presented by the Commission pursuant to article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

I. PROCEDURE

1. On 28th July 2006, the Commission adopted the proposal for a European Parliament and Council Regulation 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 [Document (COM (2006)0425 final)] as part of a package of four proposals on food improvement agents. The proposal was submitted to the Council and the European Parliament on 28th July 2006.

2. The Economic and Social Committee adopted its opinion on 25th April 2007

3. The Council has agreed a 'general approach' on the proposal at the EPSCO meeting on 31st May 2007.

4. The European Parliament has given in first reading a favourable opinion on the proposal on 9 July 2007.

5. The present proposal amends the original proposal [COM (2006)0425 – 2006/0144(COD)] so as to take into account the amendments of the European Parliament that were accepted by the Commission.

With regard to the original proposal, the European Parliament adopted 33 amendments. Commissioner Kyprianou had indicated to the plenary meeting on 9 July 2007 that the Commission could accept most of the amendments, wholly or in part, and subject to rewording. From the adopted amendments the following cannot be accepted by the Commission: 6, 9, 13, 16, 32, 37, 38.

The amendments in the revised proposal are in **bold and underlined**. A number of amendments have been reformulated so as to ensure consistency of the terminology used throughout the proposal and the other proposals of the package, or to bring the text in line with the approach of the Council with regard to similar amendments.

The numbering of the Articles has been adapted to take into account a number of amendments. Within certain Articles, the numbering of the paragraphs has been adapted in order to take into account the addition or deletion of elements in the Commission proposal.

II. OBJECTIVES OF THE PROPOSAL

6. The Commission announced in the White Paper on Food Safety a proposal amending the framework Directive 89/107/EEC on food additives to lay down specific provisions in respect of food enzymes. In-depth assessment of the situation has led to the development of a specific proposal for food enzymes.

7. Currently the scope of Directive 89/107/EEC only covers enzymes used as food additives. The remaining enzymes are not regulated at all or are regulated as processing aids under the legislation of the Member States, which is diverse. 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. The proposal aims to establish harmonised rules for food enzymes at Community level, in order to promote fair trading and effective functioning of the internal market and to ensure protection of human health and consumers' interest.

III. OVERVIEW OF THE AMENDMENTS OF THE EUROPEAN PARLIAMENT

8. Technical/editorial amendments

Amendments 2, 8, 10 and 17 aim to improve the proposal from a technical and editorial point of view and have been taken over by the Commission, in some cases subject to some editorial changes. Amendment 19 was partially accepted.

Amendment 31 amends Regulation (EC) No 258/97 on novel foods in order to clarify that food enzymes which are covered by the proposed Regulation on food enzymes will be excluded from the scope of the novel food Regulation.

9. Legal basis

Amendment 35 deletes Article 37 of the Treaty from the legal basis of the proposed Regulation. Since the agricultural aspects of the proposal (amendments to vertical agricultural texts) are only secondary objectives of the proposed Regulation, the deletion of Article 37 has been endorsed in the amended proposal.

10. Scope (Article 2)

Amendments 3, 11 and 12 aim to clarify that the proposal does not apply to food enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids. The principle of these amendments is in line with the Commission proposal. As these enzymes are not added to food to perform a technological function, they are not covered by the definition of food enzymes. However, the text proposed under amendment 11 is not well placed under Article 2 (2) and the proposed exclusion is better covered by amendment 12. Therefore, amendment 11 is redundant and not taken on board in the amended proposal.

With regard to amendment 12, the Commission retains the exclusion of cultures that are ‘traditionally’ used in the production of foods such as cheese, wine etc. and which may incidentally produce enzymes. The deletion of the word 'traditionally' would enlarge the scope of the exclusion and could result in cultures, which are added to food for the technological function of the enzyme that they produce (e.g. preservation), not being regulated.

11. Definitions (Article 3)

Amendment 14 introduces some new definitions. The definitions of '*enzyme'* and 'food enzyme *preparation'* are incorporated with some editorial changes in the amended proposal.

However the definition of 'produced by GMOs' is not necessary for the scope of the proposed Regulation which covers all food enzymes regardless of falling or not within the scope of Regulation (EC) No 1829/2003. Such definition relates to genetically modified (GM) food in general and it is therefore not appropriate to add this definition in the proposed sector specific Regulation on food enzymes.

The definition of '*quantum satis*' is laid down in the definitions of the proposal on food additives. Since all definitions of food additives apply also for food enzymes, its repetition in the proposal on food enzymes is not necessary.

12. Prohibition of non-compliant food enzymes (Article 5)

Amendment 15 aims to clarify that a food enzyme or a food in which an enzyme is used should not be placed on the market, if the enzyme or its use do not comply with the proposed regulation. This clarification is endorsed in the amended proposal.

13. General criteria for inclusion and use of food enzymes in the Community list (Article 6)

The Commission proposal sets criteria for the authorisation of food enzymes. Enzymes must be safe; there must be a technological need for their use; and their use must not mislead the consumer.

Amendment 4, second part introduces clarification of what is meant by misleading the consumer. This part of amendment 4 is included in the amended proposal.

Amendments 6 and 16 require the authorisation of food enzymes to be based on the precautionary principle. The precautionary principle and the conditions for its application are already laid down in the General Food Law (Regulation (EC) No 178/2002) and it should not be repeated here.

Amendments 4 and 16 also require food enzymes to bring a clear benefit to the consumer in order to be authorised. Most enzymes are used as processing aids. Such uses can improve the environmental performance of production processes, through lower energy consumption, less raw materials, fewer waste and better biodegradability. This cannot always be translated into a direct benefit to the consumer, although there is an indirect benefit from the environmental advantage. These provisions have not been taken over by the Commission.

14. Relation with Regulation (EC) No 1829/2003 on GM food and feed (Article 9) and Regulation (EC) No 1830/2003 (Article 7)

The Commission proposal aimed to cover all food enzymes including those produced from genetically modified organisms (GMOs) or by fermentation using genetically modified micro-organisms (GMMs). Food enzymes which fall within the scope of Regulation (EC) No 1829/2003, i.e. enzymes produced from GMOs, will be also subject to that Regulation with regard to the safety assessment of the genetic modification, while the other aspects of safety and the final authorisation will be dealt with under the enzymes Regulation. The two evaluations and authorisations can run in parallel.

Amendments 7 and 34 clarify that the two procedures can run simultaneously in accordance with good administrative practice. The proposed clarification is endorsed by the Commission, subject to some drafting changes in order to make the provision more compatible with Regulation (EC) No1829/2003.

The Commission proposal also aimed to ensure that the unique identifier attributed to a GMO in accordance with Regulation (EC) No 1830/2003 should be included in the specifications of the enzyme produced from the GMO.

Amendments 18 and 38 aim to clarify this provision, however the proposed wording is not compatible with Regulation (EC) No 1830/2003. The Commission accepted in principle the proposed clarification, however the wording was changed in order to make it consistent with that Regulation.

15. Comitology (Article 2§5, Article 15 and Article 17)

Since the proposal was adopted around the time that Decision 2006/512/EC amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission was adopted, the Commission proposal referred to the normal regulatory procedure. Therefore the alignment of the amended proposal with Decision 2006/512/EC is generally endorsed by the Commission. Amendments 10, 28 and 30 are acceptable.

However amendment 13 introduces the regulatory procedure with scrutiny for deciding whether or not a given substance falls within the scope of the Regulation. The application of this provision is an implementation of the rules contained in the basic act ('food enzyme' definition) and therefore does not fall within the regulatory procedure with scrutiny. The normal regulatory procedure should therefore apply.

16. 10-year review

Amendment 9 introduces a regular review of the evaluation and authorisation of all food enzymes every 10 years. Such requirement would impose a significant administrative burden. For reasons of proportionality and since the proposal already provides that substances will be under continuous observation and be evaluated whenever necessary in the light of new scientific or technological information, this amendment was not taken up in the amended proposal.

17. Fast track authorisation (Article 17)

Amendment 29 provides for enzymes which are currently on the market to be transferred directly to the Community list, if the European Food Safety Authority (EFSA) is satisfied with the previous safety assessment carried out at Community or national level.

EFSA is the risk assessment body in the Community. An automatic transfer of food enzymes into the Community list, without a previous evaluation by EFSA is not appropriate. As part of usual practice, when EFSA evaluates substances they consider any relevant scientific assessments undertaken by other bodies. The Commission has introduced in the amended proposal wording to clarify that EFSA could consider existing opinions as part of their evaluation.

18. Labelling (Articles 10 to 13 and Article 22)

Labelling of food enzymes sold from business to business or to the final consumer

Amendments 21-27 aim to ensure a new presentation and simplification of the labelling provisions for food enzymes sold from business to business or to the final consumer. The Commission has taken over the main ideas of these amendments but re-drafted the text so as to take into account similar amendments of the Council and to ensure coherence with the other proposals of the Food Improvement Agents package.

However, the provision of amendment 21 requiring information on the "side-effects of their use in excessive quantities" is not relevant, as food enzymes will be evaluated for their safety by EFSA and any side effects would be taken into account when authorising the food enzyme, if necessary, with appropriate conditions of use that should be respected by all operators. This provision is therefore not accepted.

In addition, amendment 21 requires that food enzymes should be added to foods only in a dose which is strictly necessary in order to achieve the purpose for which they are used. This is the *quantum satis* principle which is in line with the Commission proposal. It was therefore introduced in the amended proposal, subject to redrafting and under Article 7 relating to the content of the Community list of food enzymes.

With regard to the labelling of food enzymes intended for sale to the final consumer, these are considered food and must comply with the relevant labelling provisions of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs. Therefore, Article 12 was further simplified so as not to repeat the provisions of Directive 2000/13/EC.

Amendment 37 requires labelling of the technological function of food enzymes sold directly to the final consumer. Directive 2000/13/EC already provides that on the label of a food, including a food enzyme, instructions for use should be included. This information will be more useful for the consumer than a technical description of the function of the enzyme which could lead to confusion and misunderstanding. Therefore, this amendment is not accepted.

Labelling of food enzymes in food

Most food enzymes are used as processing aids in the production of food and they are present in food in the form of a residue, if at all, and have no technological function on the finished product. Taking into account that all food enzymes will be assessed for their safety, the Commission proposal provided for an exception from labelling of food enzymes which are used as processing aids. Food enzymes used to exert a technological function in the final food would be labelled with their function (e.g. stabiliser etc.) and specific name.

Amendment 32 introduces labelling of all food enzymes present in the final food, irrespective of the level of residues and whether they continue to function or not. The labelling should also indicate whether the enzymes are still active or not in the final product.

Amendment 37 requires information about all food enzymes used in the production process to be made available to consumers, if not on the label at least through other information channels. Both amendments are not compatible with Directive 2000/13/EC which excludes from labelling processing aids, i.e. substances which are present in the final product only as technically unavoidable residues and do not have any technological effect on the finished product. Labelling of food enzymes used as processing aids would be therefore disproportionate. In addition labelling of food enzymes on food as 'active' or 'inactive', may give misleading information to the consumer as to what is meant by 'active' or 'inactive', e.g. it could be associated with a nutritional effect.

With regard to labelling of GMOs, Article 12 of Regulation 1829/2003 already provides for labelling of food, including food enzymes, produced from GMOs. Therefore the inclusion here is redundant.

Therefore, amendments 32 and 37 are not accepted by the Commission.

19. Transitional measures (Article 18)

Amendment 36 introduces transitional measures for food enzymes, food enzyme preparations and food containing food enzymes which were put on the market or labelled before the date of application of the proposed Regulation. Such provision is appropriate and the amendment has been endorsed in the Commission amended proposal.

20. **<u>Changes in production process or starting materials of a food enzyme (Article 8)</u>**

The amended Commission proposal includes a new Article 8 introducing requirements for food enzymes already included in the Community list which are prepared by production methods or starting materials significantly different from those included in the risk assessment of the Authority. This Article reflects the principle in recital (12) of the Commission proposal and keeps consistency with the proposal on food additives, where the same text has been introduced in order to address an amendment concerning 'nano' substances.

21. Pursuant to Article 250(2) of the EC-Treaty, the Commission amends it proposal in accordance with the lines set out above.

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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 and Regulation (EC) No 258/97 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular ~~**Articles 37** and~~ **Article** 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(3) 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.

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1 OJ C […],[…], p. […].

2 OJ C **168, 20.7.2007. p 34.**

(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 **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.

(5) Food enzymes used exclusively in the production of food additives falling within the scope of the Regulation […] on food additives, flavourings falling within the scope of the Regulation […] on flavourings […] and novel foods falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[3] should be excluded from the scope of this Regulation, since the safety of these foods is already assessed and regulated. However, when these food enzymes are used as such in food, they are covered by this Regulation.

(6) Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes should be safe when used, there should be a technological need for their use and their use should 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.**

(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[4], 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[5] and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine[6] should therefore be amended accordingly. **Since all food enzymes should be covered by this Regulation, Regulation (EC) 258/1997 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[7] should be amended accordingly.**

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3 OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

4 OJ L 10, 12.1.2002, p. 58.

5 OJ L 237, 26.8.1983, p. 25. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

6 OJ L 179, 14.7.1999, p. 1. Regulation as last amended by Regulation (EC) No 2165/2005 (OJ L 345, 28.12.2005, p. 1).

7 **OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).**

(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~~ **is produced 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[8], the unique identifier assigned to the GMO ~~under~~ **in accordance with** that Regulation should also be included in the specifications.

(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].

(10) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[10], the European Food Safety Authority ('the Authority') is to be consulted on matters likely to affect public health.

(11) A food enzyme which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[11] should be ~~authorised in accordance with that Regulation, prior to its approval under this Regulation~~ **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.**

(12) A food enzyme already included in the Community list under this Regulation and prepared by production methods or from starting materials significantly different from those covered by the Authority's risk assessment, or different from those covered by the authorisation and the specifications under this Regulation should be submitted to the Authority for an evaluation with emphasis on the specifications. Significantly different production methods or starting materials could mean a change in the production method from extraction from plants to production by fermentation using a micro-organism or genetic modification of the original micro-organism.

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8 OJ L 268, 18.10.2003, p. 24.

9 OJ L […], […], p. […].

10 OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

11 OJ L 268, 18.10.2003, p. 1.

(13) Since many food enzymes are already on the Community market, provision should be made to ensure that the switchover to a Community list of food enzymes takes place smoothly and does not disturb the existing food enzyme market. Sufficient time should be allowed for applicants to make available the information necessary for the risk assessment of these products. An initial two-year period should therefore be allowed following the date of application of the implementing measures to be laid down in accordance with Article 9(1) of Regulation (EC) No […] [establishing a common authorisation procedure for the food additives, food enzymes and food flavourings], in order to give applicants sufficient time to submit the information on existing **food** enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new **food** enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period. **For food enzymes which are already on the Community market and have undergone an adequate safety assessment by a competent Community or national body, the Authority may decide to take into account this safety assessment.**

(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.**

(15) A significant number of applications is expected to be submitted during the initial two-year period. A lengthy period may therefore be needed before the risk assessment of these has been completed and the Community list is drawn up. In order to ensure equal access to the market for new food enzymes after the initial two-year period, a transitional period should be provided for during which food enzymes and food using food enzymes may be placed on the market and used, in accordance with the existing national rules in the Member States, until the Community list has been drawn up.

(16) The food enzymes E 1103 Invertase and E 1105 Lysozyme, that have been authorised as food additives under Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners[12], and the conditions governing their use should be carried over from Directive 95/2/EC to the Community list when it is drawn up by this Regulation. In addition, Council Regulation (EC) No 1493/1999 authorises the use of urease, beta-glucanase and lysozyme in wine subject to the conditions laid down in Commission Regulation (EC) No 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[13]. 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.

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12 OJ L 61, 18.3.1995 p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

13 OJ L 194, 31.7.2000, p. 1. Regulation as last amended by Regulation (EC) No 1163/2005 (OJ L 188, 20.7.2005, p. 3).

(17) Food enzymes remain subject to the general labelling obligations provided for in **Directive 2000/13/EC and, as the case may be,** in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 ~~as applicable~~. In addition, specific labelling provisions for food enzymes sold as such to the manufacturer or to the consumer should be laid down in this Regulation.

(18) Food enzymes are covered by the definition of food in Regulation (EC) No 178/2002 and are therefore, when used in food, required to be indicated as ingredients in the labelling of the food in compliance with Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[14]. Food enzymes should be designated by their technological function in food, followed by the specific name of the food enzyme. However, provision should be made for a derogation from the provisions on labelling in cases where the **food** enzyme performs no technological function in the final product but is present in the foodstuff only as a result of carry-over from one or more of the ingredients of the foodstuff or where it is used as a processing aid. Directive 2000/13/EC should be amended accordingly.

(19) Food enzymes should be kept under continuous observation and should be re-evaluated whenever necessary in the light of changing conditions governing their use and new scientific information.

(20) The measures necessary for the implementation of this Regulation should be **adopted** in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[15].

(21) In particular power should be conferred on the Commission to adopt appropriate transitional measures. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, and/or to supplement it by the addition of new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(22) In order to develop and update Community legislation on food enzymes in a proportionate and effective way, it is necessary to collect data, share information and coordinate work between Member States. For that purpose, it may be useful to undertake studies to address specific issues with a view to facilitating the decision-making process. It is appropriate that the Community may finance such studies as part of its budgetary procedure. The financing of such measures is covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[16] and consequently the legal basis for the financing of the above measures will be Regulation (EC) No 882/2004.

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14 OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

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

16 OJ L 165, 30.4.2004, p. 1. Corrected version (OJ L 191, 28.5.2004, p. 1).

(23) Member States are to carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.

(24) Since the objective of the action to be taken, namely to lay down Community rules on food enzymes cannot be sufficiently achieved by the Member States and can therefore, by reason of market unity and high level of consumer protection be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION

Chapter I
Subject matter, scope and definitions

Article 1
Subject matter

This Regulation lays down rules on food enzymes used in foods, including such enzymes used as processing aids, to ensure the effective functioning of the internal market and a high level of human health protection and consumer protection.

For those purposes, this Regulation provides for:

(a) a Community list of approved food enzymes;

(b) conditions of use of food enzymes in foods;

(c) rules on labelling of food enzymes sold as such.

Article 2
Scope

1. This Regulation shall apply to food enzymes.

2. This Regulation shall not apply to food enzymes used exclusively in the production of:

   (a) food additives falling within the scope of Regulation (EC) No …[on food additives];

   (b) flavourings falling within the scope of Regulation (EC) No …[on flavourings];

   (c) novel foods falling within the scope of Regulation (EC) No 258/97.

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

(a) in specific foods ;

(b) for purposes other than those covered by this Regulation.

4. This Regulation shall not apply to:

(a) microbial cultures that are traditionally used in the production of food and which may **incidentally produce** ~~contain~~ 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.

5. Where necessary, it may be decided in accordance with the procedure referred to in Article **15**~~16~~(2) whether or not a given substance falls within the scope of this Regulation.

Article 3
Definitions

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

The following definition**s** shall also apply:

1. **'enzyme' means any protein of vegetable, animal or microbial origin, capable of catalysing a specific biochemical reaction, without changing its own structure in the process, including "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.**

2. 'food enzyme' means a product obtained ~~by extraction~~ from plants, ~~or~~ animals **or micro-organisms or products thereof, including a product obtained** by a fermentation process using micro-organisms:

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

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

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.

Chapter II
Community list of approved food enzymes

Article 4
Community list of food enzymes

Only food enzymes included in the Community list may be placed on the market as such and used in foods, in compliance with the specifications and conditions of use provided for in Article ~~6~~ **7**(2).

Article 5
Prohibition of non-compliant food enzymes and/or non-compliant foodstuffs

No food enzyme and/or any food in which such a food enzyme has been used may be placed on the market, if the food enzyme or its use does not comply with this Regulation and its implementing measures.

*Article ~~5~~ **6***
General conditions for inclusion and use of food enzymes in the Community list

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 proposed;

(b) there is a reasonable technological need;

(c) its use does not mislead the consumer.

*Article ~~6~~ **7***
The content of the Community list of food enzymes

1. A food enzyme which complies with the conditions set out in Article ~~5~~ **6** may, in accordance with the procedure laid down in Regulation (EC) No […][establishing a common authorisation procedure for food additives, food enzymes and food flavourings], be included in the Community list.

2. The entry of a food enzyme in the Community list shall specify:

(a) the ~~name~~ **description** 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 food enzymes, selected on the basis of the enzyme activity that determines the enzyme's function;**

(b) the specifications of the food enzyme, including its origin, purity criteria and any other necessary information; where the food enzyme ~~falls~~ **is produced from a genetically modified organism ("GMO") within the meaning** ~~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;

(c) ~~if necessary,~~ 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.***

(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 specific treatment it has undergone.

3. The Community list shall be amended in accordance with the procedure referred to in Regulation (EC) No […] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

Article 8

Changes in production process or starting materials of a food enzyme already included in a Community list

When, as regard a food enzyme already included in a Community list, there is a significant change in the production methods or the starting materials, the food enzyme prepared by these new methods or materials shall be considered as a different enzyme and a new entry in the Community lists or change in the specifications shall be required before it can be placed on the market.

*Article ~~7~~ **9***

Food enzymes falling within the scope of Regulation (EC) No 1829/2003 ~~*Inclusion of genetically modified enzymes on the Community list*~~

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.** ~~after it has been authorised in accordance with the procedure referred to in Article 7 of that Regulation~~.

Chapter III
Labelling

~~SECTION 1~~
~~LABELLING OF FOOD ENZYMES NOT INTENDED FOR SALE TO THE FINAL CONSUMER~~

*Article ~~8~~ **10***

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

1. Food enzymes **and food enzyme preparations** not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with other **food** ingredients as defined in Article 6(4) of Directive 2000/13/EC, may be marketed only ~~where the packaging or containers bear~~ **if they comply with the labelling** ~~the information~~ provided for in Article~~s~~ **11** ~~9 to 12~~ of this Regulation, which must be easily visible, clearly legible and indelible. **The information provided for in Article 11 shall be in a language easily understandable to purchasers.**

2. Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that this information shall be given in one or more official languages of the Community, to be determined by that Member State. This shall not preclude such information from being indicated in several languages.

*Article ~~9~~**11***

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

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

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

(a) the name laid down ~~in~~ **under** this Regulation **in respect of each food enzyme**, **and the description according to the nomenclature of the International Union of Biochemistry and Molecular Biology;** or 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.

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

(c) if necessary, the special conditions of storage and/or use;

(d) a mark identifying the batch or lot;

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

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

(g) where applicable, an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community legislation; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the *quantum satis* principle;

(h) the net quantity;

(i) the activity of the food enzyme(s);

(j) the date of minimum durability;

(k) where relevant, information on a food enzyme or other substances as referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC to enable the purchaser to ensure compliance with that Directive.

2. Where food enzymes **and/or food enzyme preparations** are sold mixed with each other **and/or with other food ingredients**, **the packaging or containers of the resulting product shall bear a list of all ingredients** ~~all the information provided for in paragraph 1 shall be given in respect of each food enzyme~~ in descending order of ~~its~~ **their** percentage by weight of the total.

3. The packaging or containers of food enzyme preparations shall bear a list of all components in descending order of their percentage by weight of the total.

4. By way of derogation from paragraphs 1, 2 and 3, the information required in paragraph 1 points (e) to (g), (i), (k) and in paragraphs 2 and 3 may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication "intended for the manufacture of food and not for retail sale" is easily visible on the packaging or container of the product in question.

5. By way of derogation from paragraphs 1, 2 and 3, where food enzymes are supplied in tankers all of the information may appear merely on the accompanying documents relating to the consignment which are to be supplied with the delivery.

~~*Article 10*~~

~~*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.~~

~~*Article 11*~~

~~*Information requirement where food enzymes are mixed with other food ingredients*~~

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

~~*Article 12*~~

~~*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.~~

~~SECTION 2~~
~~LABELLING OF FOOD ENZYMES INTENDED FOR SALE TO THE FINAL CONSUMER~~

*Article ~~13~~ **12***
*Labelling of food enzymes **and food enzyme preparations** intended for sale to the final consumer*

1. Without prejudice to Directive 2000/13/EC, **Directive 89/396/EEC and to Regulation (EC) 1829/2003,** food enzymes **and food enzyme preparations sold singly or mixed with each other and/or other food ingredients** intended for sale to the final consumer may be marketed only if their packaging contains the following information ~~which must be easily visible, clearly legible and indelible~~:

   (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** ~~under which the food enzyme is sold; that name shall be constituted by the name laid down by any Community provisions applying to the food enzyme in question~~;

   (b) **the statement either 'for food ' or the statement 'restricted use in food' or a more specific reference to its intended food use** ~~the information required in accordance with Articles 9, 10, and 11 and points (a) to (e) and (g) and (h) of Article 12(1)~~.

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

~~**SECTION 3**~~

~~**OTHER LABELLING REQUIREMENTS**~~

*Article ~~14~~ **13***
Other labelling requirements

Articles ~~8~~ **10 to 12**~~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.~~

Chapter IV
Procedural provisions and implementation

*Article ~~15~~ **14***
Information obligation

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

2. A producer or user of a food enzyme shall, at the request of the Commission, inform it of the actual use of the food enzyme.

*Article ~~16~~ **15***
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health (hereinafter referred to as "the Committee").

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. **Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.** ~~The Committee shall adopt its Rules of Procedure.~~

*Article ~~17~~ **16***
Community financing of harmonised policies

The legal basis for the financing of measures resulting from this Regulation is Article 66(1)(c) of Regulation (EC) No 882/2004.

CHAPTER V
Transitional and final provisions

*Article ~~18~~ **17***
Establishment of the Community list of food enzymes

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

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

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

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

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

4. The Community list shall be adopted by the Commission in accordance with the procedure laid down in Regulation (EC) No […][establishing a common authorisation procedure for food additives, food enzymes and food flavourings], once the Authority has issued an opinion on each food enzyme included in the Register. **For those food enzymes, the Authority in preparing its opinion may consider, where relevant, scientific assessments undertaken by the national competent organisations in the Member States.**

However, by way of derogation from that procedure:

(a) Article 5(1) of Regulation (EC) No […] [establishing a common authorisation procedure] shall not apply to the Authority's adoption of its opinion;

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

5. If necessary, any appropriate transitional measures for the purposes of this Article **which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it shall** ~~may~~ be adopted in accordance with the **regulatory** procedure **with scrutiny** referred to in Article **15 (3)**~~16 (2~~).

*Article ~~19~~ **18***
*Transitional measures ~~**for certain food enzymes already covered by Community legislation**~~*

1. Notwithstanding Articles ~~6~~ **7** and ~~18~~ **17** of the present Regulation, the Community list shall, when drawn up, include the following food enzymes:

(a) E 1103 Invertase and E 1105 Lysozyme, stating the conditions governing their use as specified in Annexes I and Part C of Annex III to Directive 95/2/EC;

(b) Urease, beta-glucanase and lysozyme for use in wine in accordance with Regulation (EC) No 1493/1999 and the implementing rules for that Regulation.

2. Food enzymes, food enzyme preparations and food containing food enzymes which do not comply with the provisions of Articles 10 to 13 and were legally placed on the market or labelled prior to [12 months after the date of publication of this Regulation] may continue to be marketed until their date of minimum durability.

*Article ~~20~~ **19***
Amendments to Directive 83/417/EEC

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

"– rennet meeting the requirements of [the proposal for a] Regulation […/..] on food enzymes

– other milk-coagulating enzymes meeting the requirements of [the proposal for a] Regulation […/..] on food enzymes".

Article 20
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] ".**

Article 21
Amendment to Regulation (EC) No 1493/1999

In Article 43 of Regulation (EC) No 1493/1999, the following paragraph 3 shall be added:

"3. Enzymes and enzymatic preparations used in the authorised oenological practices and processes listed in Annex IV shall meet the requirements of [the proposal for a] Regulation […/..] on food enzymes."

Article 22
Amendments to Directive 2000/13/EC

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

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

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

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

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

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

   "– 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,";

Article 23
Amendments to Directive 2001/112/EC

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

"– Pectolytic enzymes meeting the requirements of [the proposal for a] Regulation […/..] on food enzymes

– Proteolytic enzymes meeting the requirements of [the proposal for a] Regulation […/..] on food enzymes

– Amylolytic enzymes meeting the requirements of [the proposal for a] Regulation […/..] on food enzymes".

Article 24
Entry into force

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

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

Articles **10 to 13** ~~8 to 14~~ shall apply from [12 months after the date of publication of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President