# EUROPEAN PARLIAMENT

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

30.3.2007 PE 386.660v01-00

**AMENDMENTS 19-65**

**Draft report** **(PE 386.295v03-00)**
**Avril Doyle**
Food enzymes

Proposal for a regulation (COM(2006)0425 – C6-0257/2006 – 2006/0144(COD))

| Text proposed by the Commission | Amendments by Parliament |
|---|---|

Amendment by Carl Schlyter, Bart Staes

Amendment 19
CITATION 1

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| 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, |

Or. en

*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 by Avril Doyle

Amendment 20
CITATION 1

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| 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 ***Article*** 95 thereof, |

Or. en

*Justification*

*There is no valid justification for recourse to dual legal basis in this case. Enzymes are not agricultural products. This is purely an internal market proposal, which aims to harmonise legislation and remove barriers to trade. Therefore, Article 95 is the correct legal basis.*

Amendment by Avril Doyle

Amendment 21
RECITAL 3

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| (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. |

Or. en

*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 by Carl Schlyter, Bart Staes

Amendment 22
RECITAL 6

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| (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 and their use should not mislead the consumer ***concerning freshness, nutritional quality of the ingredients and naturalness of a food product. On the contrary, they should bring a clear benefit to the consumer***. |

Or. en

*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.*

Amendment by David Martin, Åsa Westlund

Amendment 23
RECITAL 6

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| (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 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.*** |

Or. en

*Justification*

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

Amendment by John Bowis

Amendment 24
RECITAL 6

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| (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 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.*** |

Or. en

*Justification*

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

Amendment by Karin Scheele

Amendment 25
RECITAL 6

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|---|---|
| (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***. |

Or. de

Amendment by Carl Schlyter, Bart Staes

Amendment 26
RECITAL 8

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| (8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes, specify any conditions governing their use and be supplemented by specifications, in particular on their origin and purity criteria. Where the food enzyme ***contains or consists of*** a genetically modified organism ("GMO") within the meaning of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, the unique identifier assigned to the GMO under that Regulation should also be included in the specifications. | (8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes, specify any conditions governing their use and be supplemented by specifications, in particular on their origin and purity criteria. Where the food enzyme ***is produced from or by*** 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. |

Or. en

*Justification*

*A protein is per definition a part of an organism and cannot contain or consist of an organism. The wording should be consistent with the definitions used in the specific regulations 1829/2003/EC and 1830/2003/EC.*

Amendment by Carl Schlyter, Bart Staes

Amendment 27
RECITAL 9

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| (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 | (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 |

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| enzymes and food flavourings. | authorisation procedure for the food additives, food enzymes and food flavourings. |

Or. en

*Justification*

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

Amendment by Avril Doyle

Amendment 28
RECITAL 11

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| (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. |

Or. en

*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 by Urszula Krupa

Amendment 29
RECITAL 13

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| (13) Since many food enzymes are already on the Community market, provision should | (13) Since many food enzymes are already on the Community market, provision should |

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| 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 enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period. | 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 ***in Member States' domestic markets***. 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 enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period. |

Or. pl

*Justification*

*The aim of this amendment is to protect the EU market against an influx of cheaper foods from outside the Union, as well as food components and additives. Article 1 of this regulation alludes to this.*

Amendment by Carl Schlyter, Bart Staes

Amendment 30
RECITAL 14

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| (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 | (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.

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.***

Or. en

*Justification*

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

Amendment by Karin Scheele

Amendment 31
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. ***Nonetheless, every opinion delivered by the EFSA should be published as soon as a risk assessment has been completed.***

Or. de

Amendment by Carl Schlyter, Bart Staes

Amendment 32
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. ***In addition a review of their authorisation should be foreseen after 10 years, especially regarding their benefit for consumers.***

Or. en

*Justification*

*While it should be possible to review an authorisation at any time when necessary, a general review should be foreseen after 10 years.*

Amendment by Karin Scheele

Amendment 33
RECITAL 19

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|---|---|
| (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.*** |

Or. de

Amendment by Urszula Krupa

Amendment 34
ARTICLE 1, POINT (B)

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|---|---|
| (b) conditions of use of food enzymes in foods; | (b) conditions of use of food enzymes in foods ***and permissible content levels thereof***; |

Or. pl

*Justification*

*A high level of human health and consumer protection is dependent not only on the conditions of use of enzymes but also, and above all, on setting enzyme content levels for consumer goods, in order to avoid any adverse effects on human health (e.g. disruption of the hormone system).*

Amendment by Avril Doyle

Amendment 35
ARTICLE 2, PARAGRAPH 4

| | |
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| 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 traditionally 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.*** |

Or. en

*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.*

Amendment by Ria Oomen-Ruijten, Lambert van Nistelrooij

Amendment 36
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 traditionally used in the production of food but which are not specifically used to produce them; |
| | ***(b) enzymes intended for direct human consumption, such as enzymes for nutritional purposes (digestive aids).*** |

Or. en

*Justification*

*Legal clarification ; It should be clear that, as stated in Recital 4, that this Regulation should only cover enzymes that are added to perform a technological function and not enzymes*

*intended for human consumption (digestive aids). The exemption should therefore be legally clarified in the scope of this Article and therefore not refer to enzymes that are used in the production of digestive aids, but enzymes that are digestive aids.*

Amendment by Avril Doyle

Amendment 37
ARTICLE 3, PARAGRAPH 2

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| 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;*** |
| '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.*** |

Or. en

*Justification*

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

*between these three situations.*

Amendment by Avril Doyle, Marios Matsakis

Amendment 38
ARTICLE 3, PARAGRAPH 2, DEFINITION -1 (NEW)

***'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;***

Or. en

*Justification*

*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.*

Amendment by Carl Schlyter, Bart Staes

Amendment 39
ARTICLE 3, PARAGRAPH 2, DEFINITION 1 A (NEW)

***'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***;

Or. en

*Justification*

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

Amendment by Avril Doyle

Amendment 40
ARTICLE 3, PARAGRAPH 2, DEFINITION 1 A (NEW)

***'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)***

Or. en

*Justification*

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

Amendment by Avril Doyle

Amendment 41
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.***

Or. en

*Justification*

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

Amendment by Carl Schlyter, Bart Staes

Amendment 42
ARTICLE 5

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|---|---|
| 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 proposed; | (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; |
| (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***;*** |
| | ***(ca) its use has a clear benefit for the consumer.*** |

Or. en

*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.*

Amendment by Urszula Krupa

Amendment 43
ARTICLE 5, POINT (A)

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|---|---|
| (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; | (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***, subject to the setting of a permissible content level in products***; |

Or. pl

*Justification*

*Scientific evidence pointing to the harmlessness of the use of such substances (enzymes) is not enough to ensure that they are not harmful to consumer health. Their use in excessive and unjustified quantities in food products can lead to health problems among Europeans (e.g. endocrine system).*

Amendment by Karin Scheele

Amendment 44
ARTICLE 5, POINT (C) AND POINT (CA) (new)

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| (c) its use does not mislead the consumer. | (c) its use does not mislead the consumer ***with regard, inter alia, to freshness, the quality of the ingredients in the product, the naturalness of the product and the fruit and vegetable content;*** ***(ca) its use is of benefit to the consumer.*** |

Or. de

Amendment by Kartika Tamara Liotard

Amendment 45
ARTICLE 5, POINT (C)

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|---|---|
| (c) its use does not mislead the consumer. | (c) its use does not mislead the consumer***, for example concerning freshness, quality of the ingredients used, naturalness of a product, nutritional quality and fruit and vegetable content***. |

Or. en

*Justification*

*Transparent criteria are needed for how a decision will be made about "misleading consumers".*

Amendment by David Martin, Åsa Westlund

Amendment 46
ARTICLE 5, POINT (C)

| | |
|---|---|
| (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, or the nutritional quality of the product.*** |

Or. en

*Justification*

*This is required so there is an improved common understanding of the meaning of the phrase*

*'misleading the consumer'.*

Amendment by Avril Doyle

Amendment 47
ARTICLE 6, PARAGRAPH 2, POINT (B)

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|---|---|
| (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; |

Or. en

*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 by Urszula Krupa

Amendment 48
ARTICLE 6, PARAGRAPH 2, POINT (B)

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| (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 | (b) the specifications of the food enzyme, including its origin, purity criteria and any other necessary information ***(e.g. quantity)***; 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 |

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| Regulation shall be included in the specifications; | pursuant to that Regulation shall be included in the specifications; |

Or. pl

*Justification*

*In addition to the essential information set out in Article 6 (e.g. the country of origin), a quantity indication is of fundamental importance (content, concentration in the product or a recommended daily intake of the foodstuff) with a view to avoiding any damage to consumer health.*

Amendment by Carl Schlyter, Bart Staes

Amendment 49
ARTICLE 6, PARAGRAPH 2, POINTS (C) TO (F)

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| (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 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. |

Or. en

*Justification*

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

Amendment by Kartika Tamara Liotard

Amendment 50
ARTICLE 6, PARAGRAPH 2, POINTS (C) TO (F)

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| (c) ***if necessary,*** the foods to which the food | (c) the foods to which the food enzyme may |

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| enzyme may be added; | 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 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. |

Or. en

*Justification*

*"If necessary" should be deleted to avoid any legal uncertainties.*

Amendment by Karin Scheele

Amendment 51
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 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. |

Or. de

Amendment by Carl Schlyter, Bart Staes

Amendment 52
ARTICLE 7, TITLE

| | |
|---|---|
| Inclusion of genetically modified ***enzymes*** on the Community list | Inclusion of ***enzymes produced from or by*** genetically modified ***organisms (GMOs)*** on the Community list |

Or. en

*Justification*

*Clarity is needed on the GMO issue. Food enzymes can be derived from or produced by GMO's: they are not GMO's themselves. The wording should be consistent with the definitions used in the specific regulations 1829/2003/EC and 1830/2003/EC.*

Amendment by Avril Doyle

Amendment 53
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. |

Or. en

*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 by Carl Schlyter, Bart Staes

Amendment 54
ARTICLE 9, PARAGRAPH 1, POINTS (A) AND (B)

| | |
|---|---|
| (a) the name laid down in this Regulation; ***or*** | (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) ***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) a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused. |

Or. en

*Justification*

*The labelling intended to professional users should give precise information regarding the nature and activity of the enzyme.*

Amendment by Kartika Tamara Liotard

Amendment 55
ARTICLE 9, PARAGRAPH 1, POINTS (A) AND (B)

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|---|---|
| (a) the name laid down in this Regulation; ***or*** | (a) the name laid down in this Regulation; ***and*** |
| (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. | (b) a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused. |

Or. en

*Justification*

*The name of an enzyme should always be indicated.*

Amendment by Urszula Krupa

Amendment 56
ARTICLE 12, PARAGRAPH 1, POINT (B)

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

Or. pl

*Justification*

*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.*

Amendment by Carl Schlyter, Bart Staes

Amendment 57
ARTICLE 12, PARAGRAPH 1, POINT (C)

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

Or. en

*Justification*

*Food enzymes should not be put on the market without instructions for use being given on the label.*

Amendment by Karin Scheele

Amendment 58
ARTICLE 12, PARAGRAPH 1, POINT F

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| (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, | (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, |

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| 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; | 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; |
| | ***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.*** |

Or. de

Amendment by Urszula Krupa

Amendment 59
ARTICLE 12, PARAGRAPH 1, POINT (H) A (NEW)

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|---|---|
| | ***(ha) the side-effects of their use in excessive quantities.*** |

Or. pl

*Justification*

*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 by Karin Scheele

Amendment 60
ARTICLE 13

| | |
|---|---|
| Without prejudice to Directive 2000/13/EC, food enzymes 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: | Without prejudice to Directive 2000/13/EC, food enzymes ***or foods containing food enzymes*** 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 under which the food enzyme is sold; that name shall be constituted by the name laid down by any Community | (a) the name under which the food enzyme is sold ***or both that name and the technological function in the food***; that |

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| provisions applying to the food enzyme in question; | name shall be constituted by the name laid down by any Community provisions applying to the food enzyme in question; |
| (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 9, 10, and 11 and points (a) to (e) and (g) and (h) of Article 12(1)***;*** |
| | ***(ba) where applicable, an indication that the product contains genetically modified organisms or substances produced from them.*** |
| | ***In addition, information about all enzymes used in the production process should be made available to consumers, if not on the label then at least through other information channels, with priority assigned to those at the point of sale. Moreover, provision should also be made for consumers to access this information from home, for example over the Internet or by means of telephone hotlines.*** |

Or. de

Amendment by Carl Schlyter, Bart Staes

Amendment 61
ARTICLE 13, PARAGRAPH 1, POINT (B)

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|---|---|
| (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 9, 10 and 11 and Article 12(1). |

Or. en

*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 12(1) point (f) concerning maximum quantities of food enzymes in the final food product should not be excluded.*

Amendment by Kartika Tamara Liotard

Amendment 62
ARTICLE 15 A (NEW)

***Monitoring and reporting by Member States***

***Member States shall establish systems to monitor the consumption and use of food enzymes and report their findings each year to the Commission and the Authority. These findings shall be considered before inclusion of a food enzyme on the Community list.***

Or. en

*Justification*

*Information on use shall not only be provided by the producer. Production and consumption data provided by industry are often insufficient and should be complemented by data collected by national authorities.*

*Similar provisions are already required in the proposal on food additives as well as in the proposal on flavourings and certain food ingredients with flavouring properties.*

Amendment by Urszula Krupa

Amendment 63
ARTICLE 18, PARAGRAPH 3

| | |
|---|---|
| 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 | 3. The Commission shall establish a Register of all food enzymes***, together with their permissible concentrations,*** 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. | The Commission shall submit the applications to the Authority for its opinion. |

Or. pl

*Justification*

*In addition to listing all enzymes, it is essential for the register to indicate their permissible concentrations, with a view to protecting consumer health.*

Amendment by Avril Doyle

Amendment 64
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]."***

Or. en

*Justification*

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

Amendment by Carl Schlyter, Bart Staes

Amendment 65
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***; |

Or. en

*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.*