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Working document



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28 August 2003

Working Document WGA/003/03

Draft proposal for a

EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC) No .../..

of [...]

on enzymes used or intended for use in foods

(Text with EEA relevance)

Working document

EXPLANATORY MEMORANDUM

As part of the framework to improve Community legislation in the area of foods, 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 enzymes. However, in-depth assessment of the situation has led to the development of a proposal amending the framework Directive and of a specific proposal for enzymes.

The scope of Directive 89/107/EEC only covers enzymes used as food additives. Currently, only two enzymes are authorised under this Directive. The remaining enzymes are considered as processing aids and fall under the legislation of the Member States.

The current situation in the Member States concerning the authorisation of enzymes as processing aids is diverse. Only a few Member States have a mandatory or voluntary authorisation procedure, the majority have none at all. Thus, there is a need for harmonisation at Community level.

In order to ensure a high level of protection of human health and protection of consumers' interest, as well as to ensure fair trade practice, this proposal covers all enzymes used or intended for use in food, whether used as additives or used as processing aids (hereinafter called food enzymes). The objective of the present proposal is to establish Community procedures for the risk assessment, the authorisation and the labelling of these food enzymes.

The food enzymes for which no health concern is revealed during evaluation and their conditions of use will be included in a positive list of products authorised to the exclusion of all others in the Community.

It is proposed to grant the authorisations for a period of 10 years after which the authorisations will need to be renewed. This provision ensures that food enzymes are regularly re-evaluated according to the latest scientific and technical knowledge and ensures also that authorised products that are no longer used will disappear from the Community positive list.

For an application for authorisation of a food enzyme, detailed information on the their production method, the intended uses in specific food or food categories, chemical specifications and toxicological studies have to be provided by the applicant. The evaluation will be done by the European Food Safety Authority according to a defined time limited and transparent procedure. The Authority has to inform the Commission and the Member States about the receipt of an application and has to provide a summary thereof or the whole dossier. Confidentiality for sensitive data is provided if requested by the applicant, except for information of direct relevance to the assessment of the safety of the product.

After the European Food Safety Authority has completed its scientific evaluation, the Commission will propose a risk management decision to be adopted by the regulatory procedure laid down by Council Decision 1999/468/EC [Council Directive 89/107/EEC].

A food enzyme which is produced from a genetically modified organism ('GMO'), should be authorised under Regulation No [...] on genetically modified food and feed prior to its authorisation under this Regulation.

Since many food enzymes are already on the market in the Community, the transition to a Community positive list should be smooth and should not lead to unfair conditions for enzyme producers. Therefore, the proposal foresees an initial period of 18 months during which applications for existing and new products can be submitted to the European Food Safety Authority. The establishment of the Community list will take place in a single step procedure after the European Food Safety Authority has expressed opinions on all products for which applications have been submitted during the 18-month period. This procedure will ensure that all companies are subject to the same conditions. After the initial establishment of the list, new products may be added following evaluation by the European Food Safety Authority.

Concerning the labelling requirements for enzymes, it should be distinguished if they are not intended for sale to the final consumer, i.e. sold to the food industry, or used in food. For enzymes sold as such, this Regulation sets out labelling requirements similar to those laid down for food additives sold as such in Directive 89/107/EEC.

For the purpose of labelling, enzymes used in food should be considered as additives (which are ingredients) according to Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Consequently, for food enzymes the same labelling regime would apply than for any other additive. If still present in the finished food, even if in an altered form, enzymes would be subject to the labelling provisions of the Directive. Like for any other additive, there are only two exemptions to that: first, if the additive/enzyme is only present in the foodstuff as a result of carry-over from one or more of the ingredients of the foodstuff, and second, if used as processing aid and consequently only present in the form of a residue, if at all. In both cases, the enzyme may not have a technological effect on the finished product.

For the sake of clarity and simplification of the labelling, it is proposed that enzymes may be designated by the name of the category "enzymes" rather than by their specific name. Accordingly, this Regulation proposes that enzymes are considered as ingredients according to Directive 2000/13/EC and included among the categories of ingredients which may be designated by the name of the category listed in Annex I of the Directive.

This Proposal intends to ensure a high level of protection of human health and the protection of consumers' interests with respect to enzymes used or intended for use in food and to ensure market unity while abiding by the principle of proportionality.

This Proposal has no financial implications for the budget of the European Community.

Draft proposal for a

EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC) No .../..

of [...]

on enzymes used or intended for use in food

(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 Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption³, and in particular Article 3(1) thereof,

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

Whereas:

- (1) Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption⁴, and in particular Article 3 thereof, provides for the adoption of particular provisions in respect of the additives in the categories given in Annex 1 of the same Directive, enzymes being one of these categories.
- (2) 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.
- (3) A high level of protection of human life and health should be assured in the pursuit of Community policies.

¹ (...)

² (...)

³ OJ L 40, 11.2.1989, p. 27

⁴ OJ L 40, 11.2.1989, p. 27

- (4) In order to protect human health enzymes used or intended for use in food ('food enzymes') should undergo a risk assessment through a Community procedure before being placed on the market or used in food within the Community.
- (5) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of food enzymes may hinder their free movement, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level.
- (6) The scope of Directive 89/107/EEC currently only covers enzymes used as food additives. The remaining enzymes are considered as processing aids and fall under the legislation of the Member States. In order to ensure a high level of protection of human health and protection of consumers' interest, as well as to ensure fair trade practice, this proposal covers all enzymes used or intended for use in food, whether used as additives or used as processing aids.
- (7) Provision should be made for the establishment, on the basis of the risk assessment, of a list of food enzymes authorised for use within the Community. That list should clearly describe the enzymes specifying conditions of their use and the dates from which the authorisations are valid.
- (8) In order to ensure harmonisation, risk assessments should be carried out by the European Food Safety Authority ('the Authority'), established by 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 safety⁵.
- (9) The risk assessment of a specific food enzyme should be followed by a risk management decision as to whether the product should be entered on the Community list of authorised food enzymes; that decision should be adopted in accordance with a regulatory procedure so as to ensure close co-operation between the Commission and the Member States.
- (10) A food enzyme which is produced from a genetically modified organism ('GMO'), should be authorised under Regulation No [...] on genetically modified food and feed prior to its authorisation under this Regulation in accordance with Article 5(6).
- (11) It is appropriate that the person ('the applicant') who intends to place on the market food enzymes should submit all the information necessary for the risk assessment.
- (12) Since many food enzymes are already on the market in the Member States, provision should be made to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing enzyme market. Sufficient time should be allowed for the applicant to make available to the Authority the information necessary for the risk assessment of these products. Therefore, a certain time period, hereinafter referred to as the 'first phase', should be fixed during which the information for existing enzymes should be submitted by the applicant to the Authority. Applications for authorisation of new enzymes may also be submitted during the first phase. The

⁵ OJ L 31, 1.2.2002, p. 1.

Authority should evaluate without delay all applications for existing as well as new enzymes for which sufficient information has been submitted during the first phase.

- (13) The Community positive list should be established by the Commission after the completion of the risk assessment of all food enzymes for which sufficient information was submitted during the first phase. In order to ensure fair and equal conditions for all applicants, this initial establishment of the list should be done in a single step. After the initial establishment of the list of authorised enzymes, it should be possible for additional enzymes to be added thereto by decision of the Commission, following the risk assessment by the Authority.
- (14) Whenever the risk assessment by the Authority indicates that an existing food enzyme already on the market in the Member States constitutes an unacceptable risk to human health, this product should be removed from the market without delay.
- (15) Concerning the labelling requirements for enzymes, it should be distinguished if they are sold as such or used in food. For enzymes sold as such, this Regulation sets out labelling requirements similar to those laid down for additives in the framework Directive 89/107/EEC. Enzymes used in food should fall under the labelling requirements set out for additives (which are ingredients) in Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁶. According to Article 6.4 of this Directive, enzymes would be subject to the labelling provisions of the Directive if still present in the finished food, even if in an altered form. There are only two exemptions to that: first, if the enzyme is only present in the foodstuff as a result of carry-over from one or more of the ingredients of the foodstuff, and second, if used as processing aid and consequently only present in form of a residue, if at all. In both cases, the enzyme may not have a technological effect on the finished product.
- (16) For the sake of clarity and simplification of the labelling, it is proposed that enzymes are included amongst the categories of ingredients which may be designated by the name of the category “enzymes” rather than by their specific name.
- (17) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to food of Community origin or imported from a third country. They allow the Commission to adopt such measures in situations where food is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.
- (18) In order to ensure equal access of existing and new food enzymes to the market, an interim period should be established during which national measures continue to apply in the Member States.
- (19) Provision should be made for the Annexes to this Regulation to be adapted to scientific and technical progress.

⁶ O.J.L 109, 6.5.2000, p. 29

- (20) Since these Annexes, which are necessary for the implementation of this Regulation, are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁷, amendments thereto should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.
- (21) The Commission shall be assisted by the Committee referred to in Article 58 (1) of Regulation (EC) No 178/2002.

HAS ADOPTED THIS REGULATION

Article 1
Subject matter

1. This Regulation seeks to ensure the effective functioning of the internal market in relation to enzymes used or intended for use in food, whilst providing the basis for securing a high level of protection for human health and the interests of consumers.
2. To this end, this Regulation lays down
 - a Community procedure for the evaluation and authorisation of enzymes used or intended for use in food;
 - a Community procedure for the establishment of a list of enzymes used or intended for use in food to the exclusion of all others in the Community and their conditions of use in food.

Article 2
Scope

This Regulation shall apply to all enzymes used or intended for use in food, hereinafter referred to as 'food enzymes', notwithstanding if they are used as food additives or as processing aids.

This Regulation shall not apply to enzymes already naturally present in food or added to them as live organism.

Article 3
Definitions

For the purposes of this Regulation, the definitions laid down in Directive 89/107/EEC and Regulation (EC) No 178/2002 shall apply.

⁷ O.J.L 184, 17.7.1999, p. 23.

The following definitions shall also apply:

1. 'Enzyme' means any protein, obtained by extraction from plant or animal source materials or by a fermentation process using micro-organisms, capable of catalysing a specific biochemical reaction;
2. ['Enzyme preparation' means any substance, (other than a natural food substance or a live organism,) which contains one or more enzymes in combination with a carrier or carrier solvent in sufficient quantity to be capable of performing a technological function in food;]
3. 'Genetically modified organism ("GMO")' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC⁸, with the exclusion of organisms obtained through the techniques of genetic modification listed in Annex I B of Directive 2001/18/EC;
4. 'Processing aid' as defined in Article 1 (3) (a) footnote 1 of Directive 89/107/EEC.

*Article 4
General use and safety requirements*

1. The use of an enzyme in food shall only be authorised if it is sufficiently demonstrated that
 - it does not present a risk to the health of the consumer so far as can be judged on the scientific evidence available;
 - it does not mislead consumers.

Each authorisation may be subject to specific conditions of use.

2. No person shall place on the market an enzyme or any food in which such an enzyme has been used if the enzyme has not been authorised in accordance with Article 5 and if the conditions of use laid down in the authorisation in accordance with this Regulation are not adhered to.

*Article 5
Community list of authorised enzymes*

1. A list of enzymes used or intended for use in food, authorised to the exclusion of all others in the Community, shall be established in accordance with the procedure referred to in Article 18 (2).
2. In respect of each authorised enzyme, the list referred to in paragraph 1 shall give a unique code for that product, the name of the enzyme, [the name and address of the authorisation holder,] a clear description and characterisation of the enzyme, the conditions of its use in specific foods or food categories and the date from which the enzyme is authorised.

⁸ OJ L 106, 17.4.2001, p. 1.

3. Following the establishment of the list referred to in paragraph 1, enzymes may be added to that list in accordance with the procedure referred to in Article 18 (2).

Article 6
Application for authorisation

1. To obtain the authorisation referred to in Article 6 (1), an application shall be submitted in accordance with the following provisions.
2. The application shall be sent to the national competent authority of a Member State.
 - (a) The national competent authority:
 - (i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
 - (ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the "Authority"); and
 - (iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.
 - (b) The Authority shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.
3. The application shall be accompanied by the following:
 - the name and address of the applicant;
 - the information listed in Annex [...];
 - a reasoned statement affirming that the product complies with Article 4 (1);
 - a summary of the dossier in a standardised form.
 - for food enzymes produced from GMOs and covered by Regulation (EC) No [.../...] on GM food and feed, a copy of the Community authorisation [details of the application for authorisation] granted in accordance with this Regulation.
4. The Authority shall publish detailed guidance concerning the preparation and the submission of the application. Pending such publication, applicants shall consult the ‘Guidelines for the presentation of data on food enzymes’⁹ in conjunction with the

⁹ “Guidelines for the presentation of data on food enzymes” by the Scientific Committee on Food, expressed on 11 April 1991 or its latest update

‘Guidance on submissions for food additive evaluations’¹⁰ drawn up by the Scientific Committee on Food.

Article 7
Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application as to whether the product and its intended use complies with Article 4 (1). The Authority may extend the said period. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority, which in no event shall exceed 12 months. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that this information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.
3. In order to prepare its opinion, the Authority shall:
 - (a) verify that the particulars and documents submitted by the applicant are in accordance with Article 6 (3) in which case the application shall be regarded as valid;
 - (b) inform the applicant, the Commission and the Member States if an application is not valid.
4. In the event of an opinion in favour of authorising the evaluated enzyme, the opinion shall include, where appropriate, any conditions or restrictions which should be attached to the use of the enzyme in specific foods or food categories.
5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.
6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 15.

Article 8
Community authorisation

1. Within three months of receiving the opinion of the Authority, the Commission shall prepare a draft of the measure to be taken in respect of the application for inclusion of a substance in the list referred to in Article 5 (1), taking into account the requirements of Article 4 (1), Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with

¹⁰ “Guidance on submissions for food additive evaluations” by the Scientific Committee on Food, expressed on 11 July 2001 or its latest update:
http://europa.eu.int/comm/food/fs/sc/scf/out98_en.pdf

the opinion of the Authority, the Commission shall provide an explanation for the reasons for the differences.

The measure referred to in paragraph 1 shall be

- a draft decision amending the list referred to in Article 5 (1), including the food enzyme on the list of authorised products, in accordance with the requirements under Article 5 (2) or
 - a draft decision, addressed to the applicant, refusing authorisation.
2. The measure shall be adopted in accordance with the procedure laid down in Article 18 (2). The Commission shall inform the applicant of its adoption without delay.
 3. Without prejudice to Article 10, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 11.
 4. After an authorisation has been issued in accordance with this Regulation, the authorisation holder or any other food business operator using the food enzyme shall comply with any condition or restriction attached to such authorisation.
 5. The authorisation holder shall inform the Commission immediately of any new scientific or technical information, which might affect the risk assessment of the authorised food enzyme in relation to human health. If necessary, the Authority shall then review the assessment.
 6. The granting of an authorisation shall not diminish the general civil and criminal liability of any food business operator in respect to the authorised food enzyme or food containing the authorised enzyme.

Article 9

Initial establishment of the Community list of authorised enzymes

1. During the 18 months following the entry into force of this Regulation, business operators shall submit an application in accordance with Article 6 in view of the establishment of an initial Community list of authorised food enzymes. Without prejudice to Article 8 (1), this initial list shall be established after the Authority has issued an opinion on each enzyme for which a valid application has been submitted during this period.

Applications for which the Authority could not issue an opinion owing to the applicant's failure to comply with the time limits specified for submission of supplementary information in accordance with Article 7 (2) shall be excluded from consideration for inclusion in the initial Community list.

2. Within six months of receiving all the opinions referred to in paragraph 1, the Commission shall prepare a draft regulation for the initial establishment of the list referred to in Article 5 (1), having regard to the requirements of Article 5 (2).
3. The list referred to in Article 5 (1) shall be established in accordance with the procedure referred to in Article 18 (2).

Article 10
Modification, suspension and revocation of authorisations

1. The authorisation holder may, in accordance with the procedure laid down in Article 6, apply for a modification of the existing authorisation.
2. On its own initiative or following a request from a Member State or the Commission, the Authority shall deliver an opinion on whether an authorisation is still in accordance with this Regulation, following the procedure laid down in Article 7, where applicable.
3. The Commission shall examine the opinion of the Authority without delay and prepare a draft of the decision to be taken.
4. A draft measure modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attaching to that authorisation.
5. The final measure, i.e. the modification, suspension or revocation of the authorisation shall be adopted in accordance with the procedure referred to in Article 18 (2).
6. The Commission shall without delay inform the authorisation holder of the measure taken.

Article 11
Renewal of authorisations

1. Without prejudice to Article 10, authorisations under this Regulation shall be renewable for ten-year periods on application to the Commission by the authorisation holder, at the latest, 18 months before the expiry date of the authorisation.
2. The application shall be accompanied by the following particulars and documents:
 - (a) a reference to the original authorisation;
 - (b) any available information which supplements the information already provided to the Authority in the course of the previous evaluation(s) and updates this in the light of the most recent scientific and technical developments;
 - (c) a reasoned statement affirming that the product complies with Article 4 (1), first indent.
3. Articles 6 to 8 shall apply mutatis mutandis.
4. Where, for reasons beyond the control of the authorisation holder, no decision is taken on the renewal of an authorisation until one month before its expiry date, the period of authorisation of the product shall automatically be extended by 6 months. The Commission shall inform the authorisation holder and the Member States about the delay.

Article 12
Labelling of enzymes

1. Food enzymes not intended for sale to the final consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:
 - (a)
 - for food enzymes sold singly or mixed with each other, for each enzyme, the name laid down by this Regulation applying to the product, or in the absence of such provisions, by a description of the products that is sufficiently precise to enable it to be distinguished from products with which it could be confused, in descending order of the proportion by weight in the total;
 - when other substances or materials or food ingredients to facilitate storage, sale, standardization, dilution or dissolution of a food enzyme or food enzymes are incorporated in the enzyme, the name of the enzyme in accordance with the first indent and an indication of each component in descending order of the proportion by weight in the total;
 - (b)
 - either the statement 'for use in 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 use;
 - (d) directions for use, if the omission thereof would preclude appropriate use of the enzyme;
 - (e) a mark identifying the batch or lot;
 - (f) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;
 - (g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any Community provisions, or in their absence national provisions, applying to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the combined percentage may be given as a single figure;
 - (h) the net quantity;

- (i) an indication of the presence of an enzyme or other substances as listed in paragraph (a) second indent, that consist, contain or are produced from a genetically modified organism in accordance with Article [12 to 14] of the [proposal for a] Regulation of the European Parliament and of the Council on genetically modified food and feed.
2. By way of derogation from paragraph 1, the information required in point (a), second indent, points (d) to (g), 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 foodstuffs and not for retail sale” appears on a conspicuous part of the packaging or container of the product in question.

Article 13

1. For the purposes of food labelling, enzymes used in food shall be considered as additives, and shall be labelled in compliance with the provisions applicable to that category of ingredients in Directive 2000/13/EC, in particular Article 6 paragraph 4.
2. However, they shall be designated in accordance with the rules laid down in Article 6 paragraph 6 subparagraph 2 first indent of that Directive.

Article 14 *Public access*

1. The application for authorisation, supplementary information from the applicant and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Article 38, 39 and 41 in Regulation (EC) No 178/2002.
2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents when handling applications for access to documents held by the Authority.
3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 15 *Confidentiality*

1. The applicant may indicate which information submitted under Article 6 should be treated as confidential because disclosure may significantly harm its competitive position. Verifiable justification must be given in such cases.
2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.

3. Without prejudice to Article 39 (3) of Regulation (EC) No 178/2002, information relating to the following shall not be considered confidential:
 - (a) the name and address of the applicant and the name of the product;
 - (b) in the case of an opinion in favour of authorising the evaluated enzyme, the particulars mentioned in Article 5 (2);
 - (c) information of direct relevance to the assessment of the safety of the product.
4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and the Member States with all information in its possession.
5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under the present Regulation except for information which must be made public if circumstances so require in order to protect human health.
6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of the commercial and industrial information provided, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.

*Article 16
Amendments*

Amendments to the Annexes to this Regulation and to the list referred to in Article 5 (1) shall be adopted in accordance with the procedure referred to in Article 18 (2), after having consulted the Authority for scientific and/or technical assistance.

*Article 17
Amendments to existing legislation*

1. In Annex I to Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs the following shall be added:

Definition	Designation
Food enzymes as defined in [the proposal for a] Regulation enzymes used or intended for use in foods	“Enzymes”

2. In the Annexes to Directive 95/2/EC on food additives other than colours and sweeteners, the following shall be deleted:

(a) In Annex I, “E 1103 Invertase”

(b) In Annex III, part C

“E 1105”	Lysozyme	Ripened Cheese	<i>quantum satis</i> ”
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*Article 18
Implementing powers of the Commission*

1. The Commission shall be assisted by the Committee referred to in Article 58 (1) of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.

*Article 19
Transitional measures*

Without prejudice to Article 4 (2), trade in and use of the following food enzymes, as well as foods containing any of these products, already on the market on the date of entry into force of this Regulation, shall be permitted for the following periods:

- (a) food enzymes for which a valid application is submitted in accordance with Article 6 and Article 7 (3) before [18 months after the date of entry into force of this Regulation]; until the establishment of the list referred to in Article 9 (1);
- (b) food produced with enzymes for which a valid application is submitted in accordance with Article 6 and Article 7 (3) before [18 months after the date of entry into force of this Regulation] : until 12 months after the establishment of the list referred to in Article 9 (1);
- (c) food produced with enzymes for which a valid application is not submitted in accordance with Article 6 and Article 7 (3) before [18 months from the date of entry into force of this Regulation] : until [30 months after the date of entry into force of this Regulation];

Foods that have been lawfully placed on the market before the end of the periods referred to in (b) and (c) may be marketed until stocks are exhausted.

Article 20
Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4 (2) shall apply from [~~18 months from the date of entry into force of this Regulation~~].
Until this date, national provisions in force concerning enzymes used or intended for use in food and food produced with enzymes continue to apply in the Member States.

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

Working document

ANNEX

Working document