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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC)
No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC**

(presented by the Commission)

{SEC(2006) 1044}

{SEC(2006) 1045}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

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.

Currently the scope of Directive 89/107/EEC only covers enzymes used as food additives and only two enzymes are authorised under this Directive. The remaining enzymes are not regulated at all or are regulated as processing aids under the legislation of the Member States, which is diverse. Thus, there is a need for harmonised rules at Community level, in order to promote fair trading and effective functioning of the internal market in food enzymes and ensure protection of human health and consumers' interest. A proposal for a new Regulation on food enzymes, as part of the package on food improvement agents, is included in the Commission Legislative Working Programme of 2005.

- **General context**

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

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

- **Existing provisions in the area of the proposal**

Directive 95/2/EC on food additives other than colours and sweeteners allows for the use of two enzymes as food additives: E 1103 Invertase and E1105 Lysozyme.

In addition, Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, Council Directive 83/417/EEC relating to certain lactoproteins (caseins and caseinates) intended for human consumption and Council Regulation (EC) No 1493/1999 on the common organisation of the market in wine, regulate the use of certain food enzymes in these specific foods.

- **Consistency with other policies and objectives of the Union**

The policy objectives to be met are:

- the promotion of fair trading in food enzymes in order to ensure an efficient and internationally competitive food industry;
- the protection of human health and consumers' interest.

These objectives will contribute to the strategic objectives of the Commission as set out in the Lisbon Strategy, the Commission five year plan and the Commission's White paper of Food Safety published in 2000.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

The opinion of Member States and stakeholders has been sought through consultations at several working groups and during bilateral contacts with stakeholders since 2000. Some of the stakeholders consulted were:

BEUC (The European Consumers' Organisation)

CIAA (Confederation of the food and drink industries of the EU)

CEFIC (European Chemical Industry Council)

AMFEP (Association of Manufacturers and Formulators of Enzyme products)

ELC (Federation of European Food Additives and Food Enzymes Industries)

ISA (International Sweeteners Association)

FEDIMA (Federation of the Intermediate products Industries for the Bakery and Confectionery trades in the EEA)

CAOBISCO (Association of the Chocolate, Biscuit and Confectionery Industries of the EU)

Moreover, a questionnaire on the impacts of the proposal was circulated to the different stakeholders on 22.2.2005 to which 70 replies were received by the end of the consultation.

Summary of responses and how they have been taken into account

After each consultation, comments have been considered and texts have been adapted. General consensus exists on the proposal. The following points were specifically raised and comments considered as follows:

1. Harmonisation and scope of legislation:

The introduction of specific harmonising legislation on food enzymes was generally welcomed.

2. Harmonisation of safety evaluation and authorisation:

All stakeholders were generally positive to the introduction of a European wide safety evaluation and authorisation of food enzymes.

3. Labelling of enzymes on food:

Initially proposed labelling of enzymes which have no function in food raised concerns among the food industry. On the other hand some Member States and consumer's association supported more specific labelling for enzymes present in food. Revised labelling rules require specific and informative labelling for enzymes which have a technological function in the final food, but exclude from labelling enzymes which are used as processing aids.

4. Time limited authorisation:

There was a strong indication from industry that a time limited authorisation could be a barrier to innovation. On the other hand Member States and consumer organisations considered that enzyme approvals should be kept under review to ensure that they remain current. An intermediate solution is proposed where producers or users of enzymes should provide to the Commission on its request information on actual uses.

5. Transitional periods:

The proposal sets out a procedure for a smooth transition to a Community positive list. The consultation pointed out that during this transition period, industry should continue to be able to develop and market new enzymes. In order to avoid hindering innovation in this sector, the proposal now provides for additional transitional measures.

- **Collection and use of expertise**

Scientific/expertise domains concerned

A "study of the enzymes used in foodstuffs and collation of data on their safety", was generated under the scientific co-operation procedure within the legal frame of Council Directive 93/5/EEC 'on the assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food (SCOOP)'.

Methodology used

Data was collected from 9 Member States on the approval systems, safety evaluation procedures and uses of enzymes in the EU.

Main organisations/experts consulted

Experts from 9 Member States and AMFEP.

Summary of advice received and used

The existence of potentially serious risks with irreversible consequences has not been mentioned.

The SCOOP Task Force concluded that "A consensus was obtained to assert that, in all cases, whatever the status or the categorisation of the enzyme, a rationale for safety evaluation is necessary".

Means used to make the expert advice publicly available

The report was published on:
http://europa.eu.int/comm/food/fs/scoop/7.4.1_en.pdf

- **Impact assessment**

The impacts expected on the different options concern economic and social aspects. Environmental impacts are not expected from the different options considered, since the industry concerned - the food industry - is involved in secondary or tertiary processing of food products. Enzymes are already widely used.

1. No action

- 1.1 Economic impact

The current legal uncertainty due to the differing regulatory approaches among Member States would remain, along with the current market distortions in the trade of food enzymes. Enzyme producers would continue to seek authorisation for the same enzyme in more than one Member States which is an administrative and financial burden for industry.

1.2 Social impact

Differences in risk perception, safety assessment and regulation of food enzymes among Member States would lead to different levels of consumer protection. GMO produced enzymes not covered by Regulation 1829/2003, such as microbial enzymes, would not be assessed for their safety.

2. Non-Regulatory instrument

2.1 Economic impact

Self-regulation would provide flexibility; on the other hand, food enzymes are already regulated when used as food additives by Community law and as processing aids by national legislation. This could lead to contradictory and confusing situation for the industry and negative economic impact.

2.2 Social impact

A safety assessment, which is not carried out by an independent body, would not get the same level of acceptance from the public. The transparency of the procedures built in a self-regulatory system would be limited. An unclear legal situation would result in loss of consumer confidence, especially with regard to enzymes obtained from GMOs.

3. Regulatory approach

3.1 Economic impacts

The harmonisation of the safety evaluation and authorisation of food enzymes, may result in higher upfront investments before market introduction of food enzymes due to the authorisation cost, estimated to be in the range of 150-250k € per enzyme. However, some Member States already have authorisation procedures in place entailing similar costs for companies that market their products in those Member States. With this proposal industry will benefit from a harmonised Community procedure with defined deadlines, instead of multiple national ones.

The proposal exempts from labelling those food enzymes used as processing aids. Food enzymes used in the same way as food additives, to exert a technological function in the final food should be labelled with their function (e.g. stabiliser etc) and specific name. This provision is unlikely to have an economic impact on businesses as only a limited number of enzymes (currently only 2 and in the future not more than a dozen) would need to be labelled. This implies no major change to the current situation.

This proposal will have a very limited impact on households. Although the costs of evaluation seem high it is unlikely that these costs will result in any significant increases in the cost which consumers pay for food.

3.2 Social impact

It can be expected that the proposed comprehensive system of safety evaluation of food enzymes will have positive impacts on public health and consumer confidence.

The Commission carried out an impact assessment listed in the Work Programme, whose report is accessible on http://ec.europa.eu/food/food/chemicalsafety/additives/index_en.htm.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

The proposed Regulation sets the conditions of use of food enzymes, provides for the establishment of a Community list of approved food enzymes and lays down labelling rules for those enzymes. The proposal will complete the framework of GM food and feed legislation.

- **Legal basis**

Article 95 of the EC Treaty

- **Subsidiarity principle**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reason(s).

In the absence of harmonisation and to the extent that there is still uncertainty in the current state of scientific research, which is particularly the case in new technology sectors such as food enzymes, it is for the Member States to decide on the level of protection of human health they wish to ensure and whether to require prior authorisation for the marketing of foodstuffs, taking into account the requirements of the free movement of goods within the Community. In terms of risk assessment, Member States often start with different scientific assumptions and may require different scientific data. Therefore, if Member States were to introduce their own legislation, that would risk creating barriers to trade and possible burdens to industry from different requirements which might arise, as well as different levels of consumer protection among Member States.

Community action will better achieve the objectives of the proposal for the following reason(s).

As food enzymes and food containing those enzymes are traded across borders, Member States cannot by themselves achieve the objectives of the proposal sufficiently. 300 food enzymes need to be managed. This requires a harmonised and centralised approach.

Efficiency of the authorisation procedure and effective functioning of the internal market with a level playing field for all economic operators will indicate that the objectives are best met by the Community action.

The proposal achieves its objectives by limiting its scope to general conditions for the safe use of food enzymes, provisions for the establishment of a Community list of food enzymes and common labelling provisions.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

The proposal is a framework Regulation that sets the general rules for the safe use and authorisation of food enzymes via a Community list. In terms of consumer information, the proposal provides for a proportionate labelling of food enzymes with a limited cost for industry while at the same time offers, where necessary, sufficient information to the consumer.

The Community procedure for the safety assessment of food enzymes will have a financial and administrative impact upon the European Food Safety Authority. However, it will move the burden of safety assessment from those Member States that have currently legislation on food enzymes, and will allow them to direct their resources more towards the implementation of legislation and control activities. The financial and in particular administrative impact on economic operators will be decreased as they will have to apply for a single Community authorisation instead of multiple national ones.

- **Choice of instruments**

Proposed instruments: regulation.

Other means would not be adequate for the following reason(s).

The provisions of this proposal are of technical nature. The use of regulation as the legal instrument for the proposal will ensure uniform and direct application of the rules for the benefit both of the consumers and of the competitiveness of the industry.

4. BUDGETARY IMPLICATION

The Community may finance the establishment of a harmonised policy and system in the field of food enzymes including:

development of an appropriate database for gathering and storing all information relating to Community legislation on enzymes, undertaking of studies necessary for the preparation of legislation, for the harmonisation of procedures, for decision-making criteria and data requirements to facilitate work sharing between Member States and to develop guidance in these areas.

5. ADDITIONAL INFORMATION

- **Simulation, pilot phase and transitory period**

There was or there will be a transitory period for the proposal.

- **Simplification**

The proposal provides for simplification of administrative procedures for public authorities (EU or national), simplification of administrative procedures for private parties.

The evaluation and authorisation of food enzymes by national authorities will be replaced by a Community procedure.

Administrative burden will be decreased for private parties as they will have to apply for a single Community authorisation instead of multiple national ones.

The proposal is included in the Commission's rolling programme for up-date and simplification of the *acquis communautaire* and its Work and Legislative Programme under the reference 2005/SANCO/034.

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- **Detailed explanation of the proposal**

Chapter I - Subject matter, scope and definitions.

The proposed Regulation will apply to enzymes used for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including those used as processing aids ('food enzymes'). Food enzymes shall be subject to safety evaluation and approval via a community list.

Chapter II - Community list of approved food enzymes

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

Chapter III - Labelling

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

Chapter IV - Procedural provisions and implementation

Wherever necessary, producers or users of food enzymes will be obliged to inform the Commission of any new information which may affect the safety assessment of the food enzyme.

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

Chapter V -Transitional and final provisions

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

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(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 95 thereof,

Having regard to the proposal from the Commission¹,

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

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.
- (4) This Regulation should only cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids ('food enzymes'). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function but are intended for human consumption, such as enzymes for nutritional purposes. Microbial

¹ OJ C [...],[...], p. [...].

² OJ C [...],[...], p. [...].

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 ingredients³ 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.
- (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 consumption⁴, 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 consumption⁵ and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine⁶ should therefore be amended accordingly.
- (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/EC⁷, the unique identifier assigned to the GMO under 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

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 268, 18.10.2003, p. 24.

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 flavourings⁸.

- (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 safety⁹, 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 feed¹⁰ should be authorised in accordance with that Regulation, prior to its approval 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.
- (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 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.
- (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.
- (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

⁸ OJ L [...], [...], p. [...].

⁹ 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).

¹⁰ OJ L 268, 18.10.2003, p. 1.

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 sweeteners¹¹, 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 processes¹². 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.
- (17) Food enzymes remain subject to the general labelling obligations provided for 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 foodstuffs¹³. 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 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.

¹¹ OJ L 61, 18.3.1995 p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

¹² 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).

¹³ 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).

- (20) The measures necessary for the implementation of this Regulation should be in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁴.
- (21) 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 rules¹⁵ and consequently the legal basis for the financing of the above measures will be Regulation (EC) No 882/2004.
- (22) Member States are to carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.
- (23) 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.

¹⁴ OJ L 184, 17.7.1999, p. 23.

¹⁵ OJ L 165, 30.4.2004, p. 1. Corrected version (OJ L 191, 28.5.2004, p. 1).

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

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 shall also apply:

‘food enzyme’ means a product obtained by extraction from plants or animals or 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.

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(2).

Article 5 *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 *The content of the Community list of food enzymes*

1. A food enzyme which complies with the conditions set out in Article 5 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 of the food enzyme;
 - (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;
 - (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;
 - (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 7

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 only 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

Labelling of food enzymes not intended for sale to the final consumer

Food enzymes not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with other ingredients as defined in Article 6(4) of Directive 2000/13/EC, may be marketed only where the packaging or containers bear the information provided for in Articles 9 to 12 of this Regulation, which must be easily visible, clearly legible and indelible.

Article 9

Information requirements concerning the identification of food enzymes

1. Where food enzymes not intended for sale to the final consumer are sold singly or mixed with each other, their packaging or containers shall bear the following information in respect of each food enzyme:
- (a) the name laid down in this Regulation; or
 - (b) in the absence of a name, as referred to in point (a), a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused.

2. Where food enzymes are sold mixed with each other, the information provided for in paragraph 1 shall be given in respect of each food enzyme in descending order of its percentage by weight of the total.

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

Labelling of food enzymes intended for sale to the final consumer

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:

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

SECTION 3

OTHER LABELLING REQUIREMENTS

Article 14

Other labelling requirements

1. Articles 8 to 13 shall be without prejudice to more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or applying to the transport of such substances.
2. The information provided for in Articles 8 to 13 shall be in a language easily understandable to purchasers.

Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that this information shall be given in one or more of the official languages of the Community, to be determined by that Member State.

The first and second subparagraph of this paragraph shall not preclude such information from being indicated in several languages.

Chapter IV

Procedural provisions and implementation

Article 15 *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 *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. The Committee shall adopt its Rules of Procedure.

Article 17 *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 *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.

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 may be adopted in accordance with the procedure referred to in Article 16(2).

Article 19

Transitional measures for certain food enzymes already covered by Community legislation

Notwithstanding Articles 6 and 18 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.

Article 20
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 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 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

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

Proposal for a Regulation of the European Parliament and of the Council on food enzymes.

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned: Health and Consumer Protection

Activity/Activities: Food Safety, Animal Health, Animal Welfare and Plant Health

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings:

17.01.04.05: Feed and food safety and related activities — Expenditure on administrative management.

3.2. Duration of the action and of the financial impact:

Open ended

3.3. Budgetary characteristics :

| Budget line | Type of expenditure | | New | EFTA contribution | Contributions from applicant countries | Heading in financial perspective |
|-------------|---------------------|--------------------|-----|-------------------|--|----------------------------------|
| 17.01.04.05 | Comp/ | Diff ¹⁶ | NO | NO | NO | No 1a |

In order to develop and update Community legislation on food enzymes in a proportionate and effective way, it may be useful to undertake studies to collect data, share information and coordinate work between Member States. This kind of support expenditure, indicated under points 4.1 and 8.1, is covered by Regulation (EC) no 882/2004 on official feed and food controls within the amounts foreseen for its implementation during 2007/2013.

¹⁶ Differentiated appropriations.

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

| Expenditure type | Section no. | | Year n | n + 1 | n + 2 | n + 3 | n + 4 | n + 5 and later | Total |
|------------------|-------------|--|--------|-------|-------|-------|-------|-----------------|-------|
|------------------|-------------|--|--------|-------|-------|-------|-------|-----------------|-------|

Operational expenditure¹⁷

| | | | | | | | | | |
|--------------------------------|------|---|-----|------|------|------|------|------|------|
| Commitment Appropriations (CA) | 8.1. | a | 0.1 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.35 |
| Payment Appropriations (PA) | | b | 0.1 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.35 |

Administrative expenditure within reference amount¹⁸

| | | | | | | | | | |
|---|--------|---|-----|-----|-----|-----|-----|-----|-----|
| Technical & administrative assistance (NDA) | 8.2.4. | c | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
|---|--------|---|-----|-----|-----|-----|-----|-----|-----|

TOTAL REFERENCE AMOUNT

| | | | | | | | | | |
|----------------------------------|--|-----|-----|------|------|------|------|------|------|
| Commitment Appropriations | | a+c | 0.1 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.35 |
| Payment Appropriations | | b+c | 0.1 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.35 |

Administrative expenditure not included in reference amount¹⁹

| | | | | | | | | | |
|---|--------|---|--|--|--|--|--|--|--|
| Human resources and associated expenditure (NDA) | 8.2.5. | d | | | | | | | |
| Administrative costs, other than human resources and associated costs, not included in reference amount (NDA) | 8.2.6. | e | | | | | | | |

¹⁷ Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

¹⁸ Expenditure within article xx 01 04 of Title xx.

¹⁹ Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

Total indicative financial cost of intervention

| | | | | | | | | | |
|---|-----------------|-----|------|------|------|------|------|------|------|
| TOTAL CA including cost of Human Resources | a+c +d +e | 0.1 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.35 |
| TOTAL PA including cost of Human Resources | b+c +d +e | 0.1 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.35 |

Co-financing details

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

EUR million (to 3 decimal places)

| Co-financing body | | Year n | n + 1 | n + 2 | n + 3 | n + 4 | n + 5 and later | Total |
|---------------------------------|-----------------------|-----------|-------|-------|-------|-------|-----------------------|-------|
| | f | | | | | | | |
| TOTAL CA including co-financing | a+c +d +e +f | | | | | | | |

4.1.2. Compatibility with Financial Programming

- Proposal is compatible with existing financial programming.
- Proposal will entail reprogramming of the relevant heading in the financial perspective.
- Proposal may require application of the provisions of the Interinstitutional Agreement²⁰ (i.e. flexibility instrument or revision of the financial perspective).

4.1.3. Financial impact on Revenue

- Proposal has no financial implications on revenue
- Proposal has financial impact – the effect on revenue is as follows:

EUR million (to one decimal place)

²⁰ See points 19 and 24 of the Interinstitutional agreement.

| | | Prior to action [Year n-1] | Situation following action | | | | | |
|-------------|-------------------------------|-------------------------------|----------------------------|-------|-------|-------|-------|---------------------|
| Budget line | Revenue | | [Year n] | [n+1] | [n+2] | [n+3] | [n+4] | [n+5] ²¹ |
| | (a) Revenue in absolute terms | | | | | | | |
| | (b) Change in revenue | Δ | | | | | | |

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

| Annual requirements | Year n | n + 1 | n + 2 | n + 3 | n + 4 | n + 5 and later |
|---------------------------------|--------|-------|-------|-------|-------|-----------------|
| Total number of human resources | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |

5. CHARACTERISTICS AND OBJECTIVES

5.1. Need to be met in the short or long term

The proposed Regulation on Food enzymes aims at harmonising the use of food enzymes within the EU. The Regulation provides, among other, for the establishment of a Community list of authorised food enzymes after the European Food Safety Authority (EFSA) has evaluated them for their safety. About 200 food enzymes are already on the market in the Community subject to national laws of the Member States. Their safety assessment and transfer to the Community list should be smooth and fair for all producers. Therefore transition periods are provided for, until the initial establishment of the Community list. During this period the Commission should maintain and make available to the public a database of food enzymes for which a valid application has been submitted with information about the status of their assessment.

Moreover in the future, data on usage of food enzymes may be needed in some cases for risk management decisions.

In order to assure proportionality of the implementing measures that will be taken in the framework of the proposed regulation and to meet the objectives of Regulation (EC) 882/2004 on official feed and food control, the following instruments are therefore needed:

- An appropriate database for gathering and storing all information relating to Community legislation on food enzymes,

²¹ Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.

- undertaking of studies necessary for the preparation and development of legislation on food enzymes,
- undertaking of studies necessary to harmonise procedures, decision-making criteria and data requirements, to facilitate work sharing between Member States and to develop guidance in these areas.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

The data and information obtained will help in assuring the best protection of the health of the consumer while allowing industry to continue to develop and use food enzymes.

In the harmonised market this can only be achieved via a coordinated approach allowing exchange of comparable information between Member States.

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

Objective 1: Create and maintain a database and undertake related studies in collaboration with external organisations to be selected via the appropriate procedures.

Objective 2: Assure that the use of food enzymes does not lead to unacceptable risks for the consumer and at the same time does not impose unnecessary burden to the industry.

Objective 3: Effective and transparent handling of the food enzymes applications before the establishment of the Community positive list, via a centralised database containing updated information about the status of the applications and safety assessments.

5.4. Method of Implementation (indicative)

X *Centralised Management*

X directly by the Commission

indirectly by delegation to:

executive Agencies

bodies set up by the Communities as referred to in art. 185 of the Financial Regulation

national public-sector bodies/bodies with public-service mission

- Shared or decentralised management***
 - with Member states
 - with Third countries
- Joint management with international organisations (please specify)***

Relevant comments:

6. MONITORING AND EVALUATION

6.1. Monitoring system

The content of the database and the conclusions of the results of the studies can be monitored via their usability for proposing good implementing measures. A basic tool will be the Standing Committee for the Food Chain and Animal Health.

6.2. Evaluation

6.2.1. Ex-ante evaluation

The anticipated expenditure is not significant and therefore data for an ex ante evaluation are not currently available.

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

6.2.3. Terms and frequency of future evaluation

Ongoing in relation to the need to propose implementing measures.

7. ANTI-FRAUD MEASURES

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

| (Headings of Objectives, actions and outputs should be provided) | Type of output | Av. cost | Year n | | Year n+1 | | Year n+2 | | Year n+3 | | Year n+4 | | Year n+5 and later | | TOTAL | |
|--|----------------|----------|-------------|-------------------|-------------|--------------------|-------------|------------|-------------|------------|-------------|------------|--------------------|------------|-------------|------------|
| | | | No. outputs | Total cost | No. outputs | Total cost | No. outputs | Total cost | No. outputs | Total cost | No. outputs | Total cost | No. outputs | Total cost | No. outputs | Total cost |
| OPERATIONAL OBJECTIVE No.1 ²² | | | 1 | 0.1 ²³ | 1 | 0.05 ²⁴ | 1 | 0.05 | 1 | 0.05 | 1 | 0.05 | 1 | 0.05 | 6 | 0.35 |
| TOTAL COST | | | 1 | 0.1 | 1 | 0.05 | 1 | 0.05 | 1 | 0.05 | 1 | 0.05 | 1 | 0.05 | 6 | 0.35 |

²² As described under Section 5.3.

²³ Creation of the database.

²⁴ Updating and maintaining database, and organising related studies.

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

| Types of post | | Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs) | | | | | |
|--|------------|---|----------|----------|----------|----------|----------|
| | | Year n | Year n+1 | Year n+2 | Year n+3 | Year n+4 | Year n+5 |
| Officials or temporary staff ²⁵ (17 01 01) | A*/AD | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| | B*, C*/AST | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Staff financed ²⁶ by art. XX 01 02 | | | | | | | |
| Other staff ²⁷ financed by art. XX 01 04/05 | | | | | | | |
| TOTAL | | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |

8.2.2. Description of tasks deriving from the action

Examination of technical and financial reports, preparations of commitments and pass to payment

8.2.3. Sources of human resources (statutory)

- Posts currently allocated to the management of the programme to be replaced or extended
- Posts pre-allocated within the APS/PDB exercise for year n
- Posts to be requested in the next APS/PDB procedure
- Posts to be redeployed using existing resources within the managing service (internal redeployment)
- Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

²⁵ Cost of which is NOT covered by the reference amount.

²⁶ Cost of which is NOT covered by the reference amount.

²⁷ Cost of which is included within the reference amount.

~~8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)~~

EUR million (to 3 decimal places)

| Budget line (number and heading) | Year n | Year n+1 | Year n+2 | Year n+3 | Year n+4 | Year n+5 and later | TOTAL |
|---|-----------|-------------|-------------|-------------|-------------|-----------------------------|-------|
| 1. Technical and administrative assistance (including related staff costs) | | | | | | | |
| Executive agencies ²⁸ | | | | | | | |
| Other technical and administrative assistance | | | | | | | |
| intra muros | | | | | | | |
| <i>extra muros</i> | | | | | | | |
| Total Technical and administrative assistance | | | | | | | |

~~8.2.5. Financial cost of human resources and associated costs not included in the reference amount~~

EUR million (to 3 decimal places)

| Type of human resources | Year n | Year n+1 | Year n+2 | Year n+3 | Year n+4 | Year n+5 and later |
|--|--------|-------------|-------------|-------------|-------------|--------------------------|
| Officials and temporary staff (XX 01 01) | | | | | | |
| Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line) | | | | | | |
| Total cost of Human Resources and associated costs (NOT in reference amount) | | | | | | |

Calculation – *Officials and Temporary agents*

²⁸ Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

Calculation – *Staff financed under art. XX 01 02*

~~8.2.6. Other administrative expenditure not included in reference amount~~

EUR million (to 3 decimal places)

| | Year n | Year n+1 | Year n+2 | Year n+3 | Year n+4 | Year n+5 and later | TOTAL |
|---|-----------|-------------|-------------|-------------|-------------|-----------------------------|-------|
| XX 01 02 11 01 – Missions | | | | | | | |
| XX 01 02 11 02 – Meetings & Conferences | | | | | | | |
| XX 01 02 11 03 – Committees ²⁹ | | | | | | | |
| XX 01 02 11 04 – Studies & consultations | | | | | | | |
| XX 01 02 11 05 - Information systems | | | | | | | |
| 2. Total Other Management Expenditure (XX 01 02 11) | | | | | | | |
| 3. Other expenditure of an administrative nature (specify including reference to budget line) | | | | | | | |
| Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount) | | | | | | | |

Calculation – *Other administrative expenditure not included in reference amount*

²⁹ Specify the type of committee and the group to which it belongs.