COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.7.2006
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2006/0145 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on food additives

(presented by the Commission)

{SEC(2006) 1040}
{SEC(2006) 1041}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

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

The Commission announced in the White Paper on Food Safety (COM (1999) 719 final) that it would up-date and simplify existing Community legislation with regard to food additives (Action 11 in the White Paper).The objectives of this proposal are:

– To simplify food additive legislation by creating a single instrument for principles, procedures and approvals;

– To confer the implementing powers on the Commission to update the Community list of authorised food additives;

– To consult the European Food Safety Authority (EFSA) for the safety evaluation of food additives;

– To set up a re-evaluation programme for existing food additives;

– To require the authorisation of additives that consist of, contain or are produced from genetically modified organism under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

- **General context**

Authorisation and use of food additives in foodstuffs has been harmonised in the European Union since 1995 when the last of the specific directives on food additives (95/2/EC) was adopted. The current legislation consists of 4 co-decision directives (framework and 3 specific directives) and 3 Commission Directives (specifications).

Food additives legislation is the only technical area where the approval for use of a substance requires a co-decision procedure, which makes managing the approvals cumbersome and slow.

Two related proposals are proposed simultaneously:

1. Proposal on Regulation (EC) No […] establishing a common authorisation procedure for food additives, food enzymes and food flavourings

2. Proposal on Regulation for food enzymes.

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

  Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption lays down the general principles for authorisation of food additives in the European Union.

  This Directive is complemented with the European Parliament and the Council Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs and 95/2/EC on food additives other than colours and sweeteners. These 3 directives lay down the list of authorised food additives and their conditions of use to the exclusion of all others.

  In addition, the European Parliament and the Council have adopted a Decision No 292/97/EC on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs.

  The proposal brings together all the above mentioned provisions.

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

  Not applicable.

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. Among the stakeholders consulted were:

  BEUC (The European Consumers' Organisation)

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

  ISA (International Sweeteners Association)

  CEFIC (European Chemical Industry Council)

  AMFEP (Association of Manufacturers and Formulations of Enzyme products)

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

  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, the comments have been considered and the texts have been adapted. The following points were specifically raised and comments considered as follows:

1. Harmonisation and scope of legislation:

   During the development of this proposal it was considered whether the definition of processing aid could be revised to reduce interpretation difficulties. However the food industry considered that such a change would cause a considerable impact, it was therefore decided not to progress such a change at this stage but to consider other approaches such as development of agreed interpretive guidelines based upon the current definition.

2. Time limited authorisation:

   There was a strong indication from industry that a time limited authorisation could be a barrier to innovation and would introduce uncertainty in the food additives market. On the other hand Member States and Consumer organisations considered that additive approvals should be kept under some form of review to ensure that the Regulation remains current. A compromise solution has therefore been proposed where producers or users of additives should provide to the Commission on its request information on their actual uses.

3. Transitional periods:

   As part of the harmonisation and development of the scope of this Regulation it is proposed to additionally regulate the use of additives in additives and enzymes as is already the situation for additives used in flavourings. Although this will have some impact on the food industry this move has been generally welcomed by all stakeholders. The food industry did however suggest that an appropriate time period be included to allow for this change. This proposal therefore foresees a transitional period of 5 years to reduce the impact of this measure.

- **Collection and use of expertise**

  There was no need for external expertise.

- **Impact assessment**

  Environmental impact

  There would be no environmental impacts from any of the policy options considered, since the industry concerned is involved in secondary or tertiary processing of food products. Additives are already widely available and widely used.

  No action

  Economic impact

  The process of amending additive authorisations would still require the lengthy co-decision procedure including the time spent by the Member States on implementing the authorisation. This would continue to act as a barrier to innovation by industry, and as a consequence technological developments would not be encouraged.

  Social impact

  EFSA would not be required to carry out a review reassessing all currently approved additives and consumers would not benefit from the additional controls on the use of additives used in food additives and enzymes.

  Non legislative action

  Economic impact

  The process of amending additive authorisations would still require the lengthy codecision procedure including the time spent by the Member States on implementing the authorisation. This would continue to act as a barrier to innovation by industry, whereby technological developments would not be encouraged. Member States and stakeholders would have to elaborate and agree a code of practice on the use of additives in additives and in enzymes.

  Social impact

  Consumers would not benefit from increased assurance on the safety of food.

  Legislative option

  Additive legislation is already harmonised across the European Community, and therefore many aspects of the proposed legislative action will have a limited impact. This action will however affect all food additive manufacturers and will have some consequential impacts on the food industry.

Economic impact

The introduction of comitology for additive approvals will have a positive impact on industry as the procedures for permitting new additives will be faster. This has the potential to stimulate investment in developing new additives by removing many of the delays currently associated with realising the benefits of new developments. There will be an economic impact of the extension of the scope to cover additives in additives and enzymes, where some new substances may require authorisation, however the number of such substances is thought to be low. There will also be a small impact as a result of updating technical data sheets and also from minor changes in labelling as a result of enzymes being removed from the scope. However, these will be one off costs and the effect should be dissipated by the use of suitable transition periods included to allow time to adapt to these changes. Such changes are unlikely to affect the cost of goods sold to consumers.

Social impact

Consumers will benefit from increased assurances on the composition and safety of the food which they purchase. Consumer organisations, however, have voiced some concern that the introduction of comitology may reduce the overall transparency of the process, where authorisations will no longer be scrutinised and debated to the same extent by the European Parliament. The use of comitology is however appropriate as food additive legislation is one of the few areas in food law where co-decision is still required for largely technical amendments. Consumer need and technological benefit will remain as important parameters to be considered by Member States representatives when authorisations are debated under the comitology procedure. In addition to formal comitology procedures and the routine publishing of agendas for standing committee meetings on the internet, other methods of consultation will continue. These will include discussing amendments to legislation in expert working groups or other fora to which consumer groups and other stakeholders are routinely invited.

Deregulation of additive legislation

Economic impact

Deregulation could result in different risk assessments being undertaken for additives between Member States. Member States could also stipulate different procedures for authorisation. Such a move would therefore have an impact on the administrative burden for the competent authorities of Member States in undertaking this additional work. As a consequence this would also present a considerable administrative burden on food additive manufacturers whereby it would be necessary to apply for authorisation individually in all the Member States in which they wish to use the additive. This would also have an effect on the food industry and international trade.

Social impact

Although the general principles of food law apply, the deregulation of additives legislation could still lead to a deterioration of consumer protection relating to food additives. This could arise due to different degrees of risk assessment being carried out in Member States combined with potential differences in interpretation of such assessments. The resulting divergence in additive authorisations would also complicate procedures for estimating and comparing the intake of authorised food additives across the European Union and within individual Member States where imported foods would be subject to different additive authorisations.

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**

Creation of a Regulation of the European Parliament and of the Council on food additives that lays down the principles for the use of food additives and lays down the positive list of substances that may be used as food additives.

Repeal of Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption, European Parliament and Council Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs and 95/2/EC on food additives other than colours and sweeteners and the European Parliament and the Council Decision No. 292/97/EC on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs.

- **Legal basis**

Article 95

- **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).

Action by Member States only could lead to a confusing situation for the consumers, with different levels of protection, and a loss of confidence in certain Member States and in the internal market.

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

A positive list with about 300 food additives needs to be managed. This requires a harmonised and centralised approach.

Efficiency of the authorisation procedure and effective functioning of the internal market will indicate that the objectives are best met by the European Union.

Effective functioning of the internal market in relation to food additives used in and on food while protecting the health and the interest of the European consumers can best be met via a centralised procedure for authorisation.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

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

The proposed measure simplifies current provisions by combining four co-decision Directives and one Decision and confers the implementing powers to the Commission to create and update the Community list of food additives. The proposed measure is a Regulation to accelerate the entry into force of approvals and to avoid misinterpretation of provisions.

Administrative burden will be minimised as the Regulation will be directly applicable. Financial burden is minimised as the current provisions exist already, they are only simplified.

- **Choice of instruments**

Proposed instruments: regulation.

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

The area of food additives is fully harmonised in the EU. The safe use of food additives depends on the safety evaluations and permitted conditions of use of these substances, therefore recommendations or self-regulations would not guarantee the protection of consumer's health. This proposal combines current framework Directive and specific Directives to a single instrument to facilitate the use of food additives in the EU.

4. BUDGETARY IMPLICATION

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

– development of an appropriate database for gathering and storing all information relating to Community legislation on food additives,

– undertaking studies necessary for the preparation and development of legislation on food additives,

– undertaking 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. 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 legislation.

  There will be only one co-decision Regulation to manage instead of the current four. The positive list can be created and updated by comitology procedure. In addition as the measure is a Regulation this will accelerate considerably the approval procedure for food additives.

  The proposal is included in the Commission's Work and Legislative Programme under the reference 2005/SANCO/034.

- **Repeal of existing legislation**

  The adoption of the proposal will lead to the repeal of existing legislation.

- **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

  Food additives used in foods, in food additives and in food enzymes shall be subject to safety evaluation and approval via community positive lists.

Chapter II - Community lists of approved food additives

All food additives and their use in food will be evaluated for the following criteria: 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, all applications for the approval of new food additives will be directed to EFSA which will carry out the safety evaluations. The inclusion of a food additive in the Community positive list will be considered by the Commission on the basis of the opinion from EFSA. In addition to the safety of the substance, the other general criteria (technological need, consumer aspects) have to be examined before a food additive may be included in the Community positive list. This will be done by the Standing Committee on the Food Chain and Animal Health (SCFCAH).

The final inclusion in the positive list will be done by the Commission by entering the food additive and its conditions of use in Annexes II and III of this Regulation.

A food additive which consists, contains or is produced from a genetically modified organism, should be authorised in respect of the genetic modification according to Regulation (EC) No 1829/2003 on genetically modified food and feed, prior to its inclusion in the positive list under this Regulation.

For every authorised food additive included in the positive list a specification must be laid down. This contains the criteria on purity and defines the origin of a food additive.

Chapter III - Use of food additives in foods

General rules on placing on the market of foods containing food additives are laid down.

Chapter IV - Labelling

Labelling of food additives sold to the manufacturer or directly to the consumer is regulated by Directive 89/107/EC. This proposal up-dates these rules.

Chapter V - Procedural provisions and implementation

To ensure that food additives once permitted are kept under continuous observation and re-evaluated wherever necessary producers or users of food additives will be obliged to inform the Commission of any new information which may affect the safety assessment of the food additive. They shall also provide data on the usage of food additives to enable assessments of dietary intake to be undertaken.

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. This consists of including the use of a food additive and laying down the conditions of use in the positive list as well as laying down specifications, including criteria on origin and purity criteria and the verification of such criteria. As these are matters of high technicality that are adopted on the basis of commonly agreed principles, they should be trusted to the Commission for the sake of efficiency and simplification.

Chapter VI - Transitional and final provisions

Food additives currently included in Directives 94/35/EC, 94/36/EC and 95/2/EC shall be entered in Annex II of this proposal after a review carried out by the SCFCAH. The Standing Committee will evaluate the compliance of existing authorisations for food additives and their conditions of use with the general criteria laid down in the Regulation taking into account the latest scientific opinion on the safety of the food additive. Until the Committee has completed the review of existing authorisations, the above-mentioned Directives shall remain applicable.

The Authority shall carry out a risk assessment on all currently approved food additives. In consultation with the Authority, the Commission should set up an evaluation programme in order to define the need and the order of priorities for the risk assessment. Time limits for the evaluation should be laid down in the programme.

Provisions on additives in food additives (other than carriers) and in food enzymes will apply after an appropriate interval to provide time for safety assessments to be undertaken.

2006/0145 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on food additives

(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 Commission[1],

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

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

Whereas:

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

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

(3) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market and a high level of protection of human health and the interests of consumers via comprehensive and streamlined procedures.

(4) This Regulation harmonises the use of food additives in foods in the Community. This includes the use of food additives in foods covered by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[3] and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs. It also harmonises the use of food additives in food additives and food enzymes thus ensuring their safety and quality and facilitating their storage and use. The last category has not previously been regulated at Community level.

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1 OJ C […], […], p. […].
2 OJ C […], […], p. […].
3 OJ L 186, 30.6.1989. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(5) Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose, such as the preservation of food. However, substances should not be considered as food additives when they are used for the purpose of imparting flavour and/or taste. Moreover, substances considered as foods which may be used for a technological function, such as sodium chloride or saffron for colouring and food enzymes should also not fall within the scope of this Regulation. Finally, as regard food enzymes, they are covered by Regulation (No) …[on food enzymes][4], which excludes the application of this Regulation.

(6) Substances not consumed as food itself but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

(7) Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological necessity for their use, their use must not mislead the consumer and their use must bring a benefit to the consumer.

(8) Food additives must at all times comply with the approved specifications. The specification should include information to adequately identify the food additive, including origin and to describe the acceptable criteria of purity. The specifications previously developed for food additives included in Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs[5], Commission Directive 95/45/EC of 26 July 1995 laying specific purity criteria concerning colours for use in foodstuffs[6] and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners[7] should be maintained until the corresponding additives are entered in the Annexes to this Regulation. At that time, the specifications related to such additives should be set out in a Regulation. Those specifications should relate directly to the additives included in the Community lists in the Annexes to this Regulation. However, considering the complex character and substance of such specifications for the sake of clarity, they should not be integrated as such in the those Community lists but should be set out in one or more separate Regulations.

(9) Some food additives are permitted for specific uses for certain authorised oenological practices and processes. The use of such food additives should comply with this Regulation and with the specific provisions laid down in the relevant Community legislation.

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4 OJ L […], dd/mm/yyyy, p. […].

5 OJ L 178, 28.7.1995, p. 1. Directive as last amended by Directive 2004/46/EC (OJ L 114, 21.4.2004, p. 15).

6 OJ L 226, 22.9.1995, p. 1. Directive as last amended by Directive 2004/47/EC (OJ L 113, 20.4.2004, p. 24).

7 OJ L 339, 30.12.1996, p. 1. Directive as last amended by Directive 2004/45/EC (OJ L 113, 20.4.2004, p. 19).

(10) In order to ensure uniformity, the risk assessment and approval of food additives should be carried out in accordance with the procedure laid down in Regulation (EC) No […] establishing a common authorisation procedure for food additives, food enzymes and food flavourings[8].

(11) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[9] the European Food Safety Authority ('the Authority'), is to be consulted on matters likely to affect public health.

(12) A food additive which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[10] should be authorised under that Regulation prior to its approval under this Regulation.

(13) A food additive already approved under this Regulation which is prepared by production methods or starting materials significantly different from those included in the risk assessment of the Authority, or different than those covered by the specifications laid down, should be submitted for evaluation by the Authority for an evaluation with emphasis on the specifications. Significantly different production methods or starting materials could mean a change of the production method from extraction from a plant to production by fermentation using a micro-organism or a genetic modification of the original micro-organism.

(14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

(15) Member States which have maintained prohibitions on the use of certain additives in certain specific foods which are considered traditional and are produced on their territory should be permitted to continue to apply those prohibitions. Moreover, as regard products such as 'Feta' or 'Salame cacciatore', the present Regulation is without prejudice to more restrictive rules linked to the use of certain denominations under Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs[11] and Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates for specific character for agricultural products and foodstuffs[12].

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8 OJ L […], […], p. […].

9 OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) 1642/2003 (OJ L 245, 29.9.2003, p. 4).

10 OJ L 268, 18.10.2003, p. 1.

11 OJ L 208, 24.7.1992, p. 1. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

12 OJ L 208, 24.7.1992, p. 9. Regulation as last amended by Regulation (EC) No 806/2003.

(16) Food additives remain subject to the general labelling obligations as provided for in Directive 2000/13/EC and, as the case may be, in Regulations (EC) Nos 1829/2003 and 1830/2003. In addition, specific provisions on labelling of food additives sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

(17) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[13].

(18) In order to develop and update Community legislation on food additives 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 the view to facilitating the decision-making process. It is appropriate that the Community may finance such studies as part of its budgetary procedure. The financing of such measures is covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[14] and consequently the legal basis for the financing of the above measures will be Regulation (EC) No 882/2004.

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

(20) Since the objective of the action to be taken, namely to lay down Community rules on food additives 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.

(21) Following the adoption of this Regulation the Commission assisted by the Standing Committee on Food Chain and Animal Health should review all the existing authorisations for criteria, other than safety, such as intake, technological need and the potential to mislead the consumer. All food additives that are to continue to be authorised in the Community should be transferred to the Community lists in Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and enzymes and their conditions of use in accordance with Regulation (EC) No […] establishing a common authorisation procedure for food additives, food enzymes and food flavourings. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives, should not apply until [1.1.2011].

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13 OJ L 184, 17.7.1999, p. 23.

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

(22) Without prejudice to the outcome of that review, within one year following the adoption of this Regulation, the Commission should set up an evaluation programme for the Authority to re-evaluate the safety of the food additives that were already approved in the Community. That programme should define the needs and the order of priorities according to which the approved food additives are to be examined.

(23) This Regulation repeals and replaces the following acts: Council Directive 62/2645/EEC on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption[15], Council Directive 65/66/EEC of 26 January 1965 laying specific criteria on purity for preservatives authorised for use in foodstuffs intended for human consumption[16], Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs[17], Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption[18], First Commission Directive 81/712/EEC of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity[19], Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[20], Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs[21], Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs[22], Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners[23] and Decisions 292/97/EC of the European Parliament and of the Council of 19 December 1996 on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs[24] and Commission Decision 2002/247/EC of 27 March 2002 suspending the placing on the market and import of jelly confectionary containing the food additive E 425 konjac[25]. However, it is appropriate that certain provisions of those acts remain in force during a transitional period to allow time for the preparation of the Community lists in the Annexes to the present Regulation,

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15 OJ L 115, 11.11.1962, p. 2645/62. Directive as last amended by Directive 95/45/EC (OJ L 226, 22.9.1995, p. 1).

16 OJ 22, 9.2.1965, p. 373. Directive as last amended by Commission Directive 96/77/EC (OJ L 339, 30.12.1996, p. 1).

17 OJ L 223, 14.8.1978, p. 7. Directive as amended by Commission Directive 92/4/EC (OJ L 55, 29.2.1992, p. 96).

18 OJ L 223, 14.8.1978, p. 30. Directive as last amended by Commission Directive 96/77/EC.

19 OJ L 257, 10.9.1981. p. 1.

20 OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council.

21 OJ L 237, 10.9.1994, p. 3. Directive as last amended by Regulation (EC) 1882/2003.

22 OJ L 237, 10.9.1994, p. 13. Directive as amended by Regulation (EC) 1882/2003.

23 OJ L 61, 18.3.1995, p. 3. Directive as last amended by Regulation (EC) 1882/2003.

24 OJ L 48, 19.2.1997, p. 13.

25 OJ L 84, 28.3.2002, p. 69.

HAVE ADOPTED THIS REGULATION:

CHAPTER I
SUBJECT-MATTER, SCOPE AND DEFINITIONS

Article 1
Subject matter

This Regulation lays down rules on food additives used in foods 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) Community lists of approved food additives;

(b) conditions of use of food additives in foods, in food additives and in food enzymes;

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

Article 2
Scope

1. This Regulation shall apply to food additives.

2. This Regulation shall not apply to the following substances unless they are used as food additives:

   (a) processing aids;

   (b) substances used for the protection of plants and plant products in conformity with Community rules relating to plant health;

   (c) substances added to foods as nutrients;

   (d) substances used for the treatment of water for human consumption falling within the scope of Council Directive 98/83/EC[26].

3. This Regulation shall not apply to food enzymes falling within the scope of Regulation (EC) No […/..] [on food enzymes].

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

   (a) in specific foods;

[26] OJ L 330, 5.12.1998, p. 32.

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

5. Where necessary, it may be decided in accordance with the procedure referred to in Article 28(2) as to whether or not a given substance falls within the scope of this Regulation.

Article 3
Definitions

1. For the purposes of this Regulation, the definitions laid down in Regulations (EC) Nos 178/2002 and 1829/2003 shall apply.

2. The following definitions shall also apply:

(a) 'food additive' shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods;

however, the following are not considered to be food additives:

(i) foods containing monosaccharides, disaccharides or oligosaccharides used for their sweetening properties;

(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect;

(iii) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods;

(iv) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts ('liquid pectin');

(v) chewing gum bases;

(vi) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;

(vii) ammonium chloride;

(viii) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

(ix) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function;

(x) caseinates and casein;

(xi) inulin;

(b) ‘processing aid’ shall mean any substance which:

(i) is not consumed as a food by itself;

(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;

(c) ‘functional class’ shall mean one of the categories set out in Annex I based on the technological function a food additive exerts in the foodstuff;

(d) ‘unprocessed food’ shall mean a food which has not undergone any treatment resulting in a substantial change in the original state of the food, for which purpose the following in particular are not regarded as resulting in substantial change: dividing, parting, severing, boning, mincing, skinning, paring, peeling, grinding, cutting, cleaning, trimming, deep-freezing, freezing, chilling, milling, husking, packing or unpacking;

(e) ‘food with no added sugars’ shall mean a food without the following:

(i) any added monosaccharides, disaccharides or oligosaccharides; or

(ii) food containing monosaccharides, disaccharides or oligosaccharides which is used for its sweetening properties;

(f) ‘energy-reduced food’ shall mean a food with an energy value reduced by at least 30% compared with the original food or a similar product;

(g) ‘table-top sweeteners’ shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugar.

CHAPTER II
COMMUNITY LISTS OF APPROVED FOOD ADDITIVES

Article 4
Community lists of food additives

1. Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods, including foodstuffs for particular nutritional uses falling within the scope of Directive 89/398/EEC.

2. Only food additives included in the Community list in Annex III may be used in food additives and in food enzymes.

3. The listing of food additives in Annex II shall be made on the basis of the categories of food to which they may be added.

4. The listing of food additives in Annex III shall be made on the basis of the food additives or food enzymes or categories thereof to which they may be added.

5. Food additives shall at all times comply with the specifications as referred to in Article 12.

Article 5
General conditions for inclusion and use of food additives in Community lists

1. A food additive may be included in the Community lists in Annexes II and III 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 that cannot be achieved by other economically and technologically practicable means;

   (c) its use does not mislead the consumer.

2. To be included in the Community lists in Annexes II and III a food additive must have advantages and benefits for the consumer and therefore serve one or more of the following purposes:

   (a) preserving the nutritional quality of the food;

   (b) providing necessary ingredients or constituents for foods manufactured for groups of consumers with special dietary needs;

   (c) enhancing the keeping quality or stability of a food or improving its organoleptic properties, provided that the nature, substance or quality of the food is not changed in such a way as to mislead the consumer;

(d) aiding in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the food additive is not used to disguise the effects of the use of faulty raw materials or of any undesirable practices or techniques, including unhygienic practices or techniques, during the course of any such activities.

3. By way of derogation from point (a) of paragraph 2, a food additive which reduces the nutritional quality of a food may be included in the Community list in Annex II provided that:

(a) the food does not constitute a significant component of a normal diet; or

(b) the food additive is necessary for the production of foods for groups of consumers with special dietary needs.

Article 6
Specific conditions for sweeteners

A food additive may be included in the Community list in Annex II for the functional class of sweetener only if, in addition to serving one or more of the purposes set out in Article 5(2), it also serves one or more of the following purposes:

(a) replacing sugars for the production of energy-reduced food, non-cariogenic food or food with no added sugars;

(b) extending shelf life through the replacement of sugars;

(c) producing food intended for particular nutritional uses as defined in Article 1 (2)(a) of Directive 89/398/EEC.

Article 7
Specific conditions for colours

A food additive may be included in the Community list in Annex II for the functional class of colour only if, in addition to serving one or more of the purposes set out in Article 5(2), it also serves one of the following purposes:

(a) restoring the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;

(b) making food more visually appealing;

(c) giving colour to food otherwise colourless.

Article 8
Functional classes of food additives

1. Food additives may be assigned to one of the functional classes in Annex I on the basis of the principal technological function of the food additive.

   Allocating a food additive to a functional class shall not preclude it from being used for several functions.

2. Where necessary, as a result of scientific progress or technological development, additional functional classes may be added to Annex I in accordance with the procedure referred to in Article 28(2).

Article 9
The content of the Community lists of food additives

1. A food additive which complies with the conditions set out in Articles 5, 6 and 7 may, in accordance with the procedure laid down in Regulation (EC) No [common procedures], be included in:

   (a) the Community list in Annex II to the present Regulation; and/or

   (b) the Community list in Annex III to the present Regulation.

2. The entry for a food additive in the Community lists in Annexes II and III shall specify:

   (a) the name of the food additive and its E number if one has been assigned;

   (b) the foods to which the food additive may be added;

   (c) the conditions under which the food additive may be used;

   (d) if appropriate, whether there are any restrictions on the sale of the food additive directly to consumers.

3. The Community lists in Annexes II and III 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 10
Levels of use of food additives

1. When establishing the conditions of use referred to in Article 9(2)(c):

   (a) the level of use shall be set at the lowest level necessary to achieve the desired effect;

(b) the level shall take into account:

(i) any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources;

(ii) where the food additive is to be used in foods eaten by special groups of consumers, the possible daily intake of the food additive by consumers in those groups.

2. Where appropriate, no maximum level shall be fixed for a food additive (*quantum satis*). In that case, the food additive shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that the consumer is not misled.

3. The maximum levels of use of food additives set out in Annex II apply to ready-to-eat foods prepared in accordance with the instructions for use unless otherwise stated.

4. The maximum levels for colours set out in Annex II apply to the quantities of colouring principle contained in the colouring preparation unless otherwise stated.

Article 11
Food additives falling within the scope of Regulation (EC) No 1829/2003

A food additive falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community lists in Annexes II and III to the present Regulation only after it has been authorised in accordance with Article 7 of Regulation (EC) No 1829/2003.

Article 12
Specifications of food additives

The specifications of food additives relating, in particular, to origin, purity criteria and any other necessary information, shall be adopted when the food additive is included in the Community lists in Annexes II and III for the first time, in accordance with the procedure referred to in Regulation EC […establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

CHAPTER III
USE OF FOOD ADDITIVES IN FOODS

Article 13
Use of food additives in unprocessed foods

Food additives shall not be used in unprocessed foods, except where such use is specifically provided for in Annex II.

Article 14
Use of colours and sweeteners in foods for infants and young children

Colours and sweeteners shall not be used in foods for infants and young children as referred to in Directive 89/398/EEC, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to the present Regulation.

Article 15
Use of colours for markings

Only food colours listed in Annex II to the present Regulation may be used for the purpose of health marking as provided for in Council Directive 91/497/EEC[27] and other markings required on meat products, for the decorative colouring of eggshells and for the stamping of eggshells as provided for in Commission Regulation (EEC) No 1274/91[28].

Article 16
Carry-over principle

1. The presence of a food additive shall be permitted:

   (a) in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food;

   (b) in a food to which a flavouring has been added, where the food additive:

      (i) is permitted in the flavouring in compliance with this Regulation;

      (ii) has been carried over to the food via the flavouring;

      (iii) has no technological function in the final food;

   (c) in a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with this Regulation.

2. Paragraph 1 of this Article shall not apply to infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children as referred to in Directive 89/398/EEC, except where specifically provided for.

3. Where a food additive in a flavouring, food additive or food enzyme is added to a food and has a technological function in that food, then it shall be considered a food additive of that food and not a food additive of the added flavouring, food additive or food enzyme.

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27 OJ L 268. 24.9.1991, p. 69.
28 OJ L 121, 16.5.1991, p. 11.

4. Without prejudice to paragraph 1, the presence of an intense sweetener shall be permitted in a compound food with no added sugar, in an energy-reduced compound food, in compound dietary foods intended for low-calorie diets, and in a compound food with a long shelf-life, provided that the intense sweetener is permitted in one of the ingredients of the compound food.

Article 17
Interpretation decisions

Where necessary, a it may be decided in accordance with the procedure referred to in Article 28(2) as to whether or not:

(a) a particular food belongs to a category of food referred to in Annex II; or

(b) a food additive listed in Annexes II and III and permitted at "*quantum satis*" is used in accordance with the criteria referred to in Article 10(2).

Article 18
Traditional foods

The Member States listed in Annex IV may continue to prohibit the use of certain categories of food additives in the traditional foods produced on their territory as listed in that Annex.

CHAPTER IV
LABELLING

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

Article 19
Labelling of food additives not intended for sale to the final consumer

Food additives not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with ingredients as defined in Article 6(4) of Directive 2000/13/EC may be marketed only if their packaging or containers bear the information provided for in Articles 20 to 23 of this Regulation, which must be easily visible, clearly legible and indelible.

Article 20
Information requirements concerning the identification of food additives

1. Where food additives 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 additive:

   (a) the name and/or its E-number laid down in this Regulation; or

   (b) in the absence of a name and/or E-number, as referred to in point (a), a description of the food additive that is sufficiently precise to distinguish it from products with which it could be confused.

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

Article 21
Information requirements where other substances, materials or food ingredients are incorporated in food additives

Where substances, materials or food ingredients other than food additives are incorporated in food additives 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 additives shall bear the information provided for in Article 20 and an indication of each component in descending order of its percentage by weight of the total.

Article 22
Information requirements where food additives are mixed with other food ingredients

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

Article 23
General information requirements for food additives

1. The packaging or containers of food additives 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 additive;

(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 additive is subject to a limit on quantity in food, an indication of that component's percentage of the food additive or sufficient information on the composition of the food additive 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 additive or other substances referred to in Articles 20, 21 and 22, of the present Regulation and listed in Annex IIIa to Directive 2000/13/EC as regards the indication of the ingredients present in foodstuffs.

2. By way of derogation from paragraph 1, the information required in points (c) to (f) and point (h) of that paragraph may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication "intended for the manufacture of food and not for retail sale" appears on an easily visible part of the packaging or container of the product in question.

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

Article 24
Labelling of food additives intended for sale to the final consumer

1. Without prejudice to Directive 2000/13/EC, food additives 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 additive is sold; that name shall be constituted by the name laid down by any Community provisions applying to the food additive in question and its E-number;

(b) the information required in accordance with Articles 20, 21 and 22 and points(a) to (e), (g) and (h) of Article 23(1).

2. The sales description of a table-top sweetener shall include the term '. . . -based table-top sweetener', using the name(s) of the sweetener(s) used in its composition.

3. The labelling of a table-top sweetener containing polyols and/or aspartame and or aspartame-acesulfame salt shall bear the following warnings:

(a) polyols: 'excessive consumption may induce laxative effects';

(b) aspartame/aspartame-acesulfame salt: 'contains a source of phenylalanine'.

SECTION 3
OTHER LABELLING REQUIREMENTS

Article 25
Other labelling requirements

1. Articles 19 to 24 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 19 to 24 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 V
PROCEDURAL PROVISIONS AND IMPLEMENTATION

Article 26
Information obligation

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

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

Article 27
Monitoring of food additive intake

1. Member States shall maintain systems to monitor the consumption and use of food additives and report their findings each year to the Commission and the European Food Safety Authority (hereinafter referred to as the 'Authority').

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community may be adopted in accordance with the procedure referred to in Article 28(2).

Article 28
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 29
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 VI
TRANSITIONAL AND FINAL PROVISIONS

Article 30
Establishment of Community lists of food additives

1. Food additives which were permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with Articles 5, 6 and 7 of the present Regulation in accordance with the procedure referred to in Article 28(2). This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by […]

2. Food additives authorised for use in food additives as permitted carriers in Annex V to Directive 95/2/EC and their conditions of use shall be entered in Annex III, Part 1 to this Regulation after a review of their compliance with Article 5 of this Regulation in accordance with the procedure laid down in Article 28(2). This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by […..].

3. Specifications of the food additives covered under paragraphs 1 and 2 of this Article shall be adopted, in accordance with Regulation EC […establishing a common authorisation procedure for food additives, food enzymes and food flavourings], at the moment those food additives are entered in the Annexes in accordance with those paragraphs.

4. Any appropriate transitional measures may be adopted in accordance with the procedure laid down in Article 28(2).

Article 31
Re-evaluation of approved food additives

1. Food additives which were permitted before the date of entry into force of this Regulation shall be subject to a new risk assessment carried out by the Authority.

2. After consultation of the Authority, an evaluation programme for those additives shall be adopted within one year after the date of entry into force of this Regulation, in accordance with the procedure laid down in Article 28(2). The evaluation programme shall be published in the *Official Journal of the European Union.*

Article 32
Repeals

1. The following acts are repealed:

   (a) Directive 62/2645/EEC;

   (b) Directive 65/66/EEC;

   (c) Directive 78/663/EEC;

   (d) Directive 78/664/EEC;

   (e) Directive 81/712/EEC;

   (f) Directive 89/107/EEC;

   (g) Directive 94/35/EC;

   (h) Directive 94/36/EC;

   (i) Directive 95/2/EC;

   (j) Decision 292/97/EC;

   (k) Decision 2002/247/EC.

2. References to the repealed acts shall be construed as references to this Regulation.

Article 33
Transitional provisions

By way of derogation from Article 32, the following provisions shall continue to apply until […]:

(a) Article 2 (1), (2) and (4) of Directive 94/35/EC and the Annex thereto;

(b) Article 2(1) to (6), (8), (9) and (10) of Directive 94/36/EC and Annexes I to V thereto;

(c) Articles 2 and 4 of Directive 95/2/EC and Annexes I to VI thereto.

Notwithstanding point (c), the authorisations for E 1103 Invertase and E 1105 Lysozyme laid down in Directive 95/2/EC are repealed with effect from the date of application of the Community list on food enzymes in accordance with Article 18 of the [Regulation on food enzymes].

Article 34
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*.

It shall apply from [one year after the date of publication of this Regulation].

However, Article 4(2) shall apply to Parts 2 and 3 of Annex III from [1 January 2011]

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

Functional classes of food additives in foods and of food additives in food additives and food enzymes

1. "sweeteners" are substances (bulk sweeteners and intense sweeteners) used to impart a sweet taste to foods or in table top sweeteners.

2. "colours" are substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Regulation.

3. "preservatives" are substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms;

4. 'antioxidants' are substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes;

5. 'carriers', are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring or food enzyme without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

6. 'acids' are substances which increase the acidity of a foodstuff and/or impart a sour taste to it;

7. 'acidity regulators' are substances which alter or control the acidity or alkalinity of a foodstuff;

8. 'anti-caking agents' are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another;

9. 'anti-foaming agents' are substances which prevent or reduce foaming;

10. 'bulking agents' are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value;

11. 'emulsifiers' are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff;

12. 'emulsifying salts' are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components;

13. 'firming agents' are substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel;

14. 'flavour enhancers' are substances which enhance the existing taste and/or odour of a foodstuff;

15. 'foaming agents' are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff;

16. 'gelling agents' are substances which give a foodstuff texture through formation of a gel;

17. 'glazing agents' (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating;

18. 'humectants' are substances which prevent foods from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium;

19. 'modified starches' are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

20. 'packaging gases' are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container;

21. 'propellants' are gases other than air which expel a foodstuff from a container;

22. 'raising agents' are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter;

23. 'sequestrants' are substances which form chemical complexes with metallic ions;

24. 'stabilisers' are substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food.

25. ‘thickeners’ are substances which increase the viscosity of a foodstuff;

26. ‘flour treatment agents’ are substances, other than emulsifiers, which are added to flour or dough to improve its baking quality.

ANNEX II

Community list of food additives approved for use in foods and conditions of use.

ANNEX III

Community list of food additives approved for use in food additives and food enzymes, and conditions of use.

Part 1 Carriers in food additives

Part 2 Additives other than carriers in food additives

Part 3 Additives in food enzymes

ANNEX IV

Traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives

Member State	Foods	Categories of additives which may continue to be banned
Germany	Traditional German beer ("Bier nach deutschem Reinheitsgebot gebraut")	All except propellant gases
France	Traditional French bread	All
France	Traditional French preserved truffles	All
France	Traditional French preserved snails	All
France	Traditional French goose and ducks preserves ("confit")	All
Austria	Traditional Austrian "Bergkäse"	All except preservatives
Finland	Traditional Finnish "Mämmi"	All except preservatives
Sweden Finland	Traditional Swedish and Finnish fruit syrups	Colours
Denmark	Traditional Danish "Kødboller"	Preservatives and colours
Denmark	Traditional Danish "Leverpostej"	Preservatives (other than sorbic acid) and colours
Spain	Traditional Spanish "Lomo embuchado"	All except preservatives and antioxidants
Italy	Traditional Italian "Mortadella"	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas
Italy	Traditional Italian "Cotechino e zampone"	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

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

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 (add rows if necessary):

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
17.01.04.05	Comp/	Diff[29]	NO	NO	NO	**No 1a**

In order to develop and update Community legislation on food additives 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.

[29] 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 expenditure[30]									
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 amount[31]									
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 amount**~~[32]									
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							

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

31 Expenditure within article xx 01 04 of Title xx.

32 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	0.35
TOTAL PA including cost of Human Resources		b+c +d+ e	0.1	0.05	0.05	0.05	0.05	0.05	0.35

~~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 Agreement[33] (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:

NB: All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.

[33] See points 19 and 24 of the Interinstitutional agreement.

EUR million (to one decimal place)

Budget line	Revenue	Prior to action [Year n-1]	Situation following action					
			[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5][34]
	(a) Revenue in absolute terms							
	(b) Change in revenue	*Δ*						

(Please specify each revenue budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)

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

Details of the context of the proposal are required in the Explanatory Memorandum. This section of the Legislative Financial Statement should include the following specific complementary information:

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

Legislation on Food additives is harmonised within the EU. Presently there are around 330 food additives permitted under the legislation and requests to allow additional additives or new uses of additives are continually being presented. When assessing new additives and additional uses of additives data on usage is needed 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 additives,

[34] 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 additives,

- 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 additives.

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 additives does not lead to unacceptable risks for the consumer and at the same time does not impose unnecessary burden to the industry.

Objective 3: To make risk management decisions based on appropriate estimations of intake via a centralised database containing updated information about composition and the use of food additives.

5.4. Method of Implementation (indicative)

Show below the method(s)[35] chosen for the implementation of the action.

X ***Centralised Management***

X directly by the Commission

[35] If more than one method is indicated please provide additional details in the "Relevant comments" section of this point.

- ☐ 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[36]			1	0.1[37]	1	0.05[38]	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

36 As described under Section 5.3.

37 Creation of the database.

38 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[39] (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[40] by art. XX 01 02							
Other staff[41] 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)

When more than one source is stated, please indicate the number of posts originating from each of the sources

X 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

[39] Cost of which is NOT covered by the reference amount.
[40] Cost of which is NOT covered by the reference amount.
[41] 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[42]							
Other technical and administrative assistance							
– intra muros							
– *extra muros*							
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***

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

Reference should be made to Point 8.2.1, if applicable

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

Reference should be made to Point 8.2.1, if applicable

~~*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[43]							
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***

[43] Specify the type of committee and the group to which it belongs.