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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.10.2007
COM(2007) 673 final

2006/0145 (COD)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on food additives

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

EXPLANATORY MEMORANDUM

I. PROCEDURE

1. On 28th July 2006, the Commission adopted the proposal for a European Parliament and Council Regulation on food additives [Document (COM (2006)0428 final)] as part of a package of four proposals on food improvement agents. The proposal was submitted to the Council and the European Parliament on 28th July 2006.
2. The Economic and Social Committee adopted its opinion on 25th April 2007.
3. The Council has agreed a 'general approach' on the proposal at the EPSCO meeting on 31st May 2007.
4. The European Parliament has given in first reading a favourable opinion on the proposal on 10th July 2007
5. The present proposal amends the original proposal [COM (2006)0428 – 2006/0145(COD)] so as to take into account the amendments of the European Parliament that were accepted by the Commission.
6. With regard to the original proposal, the European Parliament adopted 59 amendments. Commissioner Kyprianou had indicated to the plenary meeting on 9 July 2007 that the Commission could accept many of the amendments, wholly or in part, and subject to rewording. The amendments that cannot be accepted by the Commission are: 10, 11, 12, 20, 24, 25, 29, 30, 34, 38, 40, 45, 47, 52, 54, 5, 6, 69rev, 73 and 78.
7. The amendments in the revised proposal are in **bold and underlined**. A number of amendments have been reformulated so as to ensure consistency of the terminology used throughout the proposal and the other proposals of the package, or to bring the text in line with the approach of the Council where similar amendments have been proposed.
8. The numbering of the Articles has been adapted to take into account a number of amendments.

II. 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.

III. OVERVIEW OF THE AMENDMENTS OF THE EUROPEAN PARLIAMENT

9. Technical/editorial amendments

A number of the proposed amendments aim to improve the proposal from a technical and editorial point of view. These amendments have largely been taken over by the Commission although some have been subject to editorial amendment (Amendments concerned: 3, 8, 13, 14, 15, 16, 18, 19, 21, 22, 33 (in part), 36, 37, 39, 42, 43, 44, 46, 48,67rev, 79, 68rev, 80, 51, 55, 56, 57, 58, 59 , 60 and 64rev.)

10. Scope (Article 2)

Amendment **10** cannot be accepted as plant protection products used for post harvest treatment are already subject to separate Community legislation. However if the substance(s) used for post harvest treatment does not fall under the plant protection product definition it would be considered as a food additive if exerting a preservative effect.

In the amended proposal, the Commission has not taken on board amendment **11** which would exclude microbial cultures from the scope of the legislation. Some cultures are added to foods near the end of their manufacture for an intended preservation effect and therefore could be considered to be food additives. It is therefore not appropriate to exclude such substances from food additives legislation.

11. Comitology

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

However amendment **12** introduces the regulatory procedure with scrutiny for deciding whether or not a given substance falls within the scope of the Regulation. The application of this provision is an implementation of the rules contained in the basic act ('food additive' definition) and therefore does not fall within the new regulatory procedure with scrutiny. The normal regulatory procedure should therefore apply. Similarly amendments **40** and **47** cannot be accepted as they also relate to provisions the application of which are an implementation of the rules contained in the basic act and therefore do not fall within the new regulatory procedure with scrutiny.

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

Amendments **9** and **22** aim to clarify that a food additive or a food in which a food additive is used should not be placed on the market, if the food additive or its use does not comply with the proposed Regulation. This clarification is endorsed in the amended proposal with the inclusion of Article 5.

13. Criteria for authorisation (Article 6)

The Commission proposal sets criteria for the authorisation of food additives. Food additives must be safe; there must be a technological need for their use; and their use must not mislead the consumer. The Commission introduced into the amended proposal in recital 7 the clarification of what is meant by misleading the consumer (amendments **3** and **26**). The principle of amendment **28** has also been included in recital 8 of the amended proposal which will reiterate that the authorisations of food additives will refer to the consideration of the criteria in the Regulation.

However, amendment **78** requires the authorisation of food additives to be based on the precautionary principle. The precautionary principle and the conditions for its application are already laid down in the General Food Law (Regulation (EC) No 178/2002) and it should not be repeated in the proposed Regulation on food additives.

Amendment **24** proposes to link the technological need of a food additive with the benefit to the consumer. The technological function of a food additive can, in many cases, be beneficial for manufacturers without having a detrimental effect nor a direct benefit for the consumer. An example of this could be when the use of a food additive reduces wastage in a production process.

The environmental impact is not among the general conditions for authorising food additives but it is of course a legitimate factor to be considered. For instance when adverse environmental effects are identified, these can be taken into account during the authorisation or revision of the conditions of use for a food additive. Therefore, although amendment **25** cannot be accepted, other changes can be made to the text to reinforce the environmental aspects. Similarly amendment 7 can be accepted subject to modification to reflect the other principles contained within the General Food Law, i.e. that the rules on food additives used in foods will ensure the effective functioning of the internal market and a high level of protection of human health and protection of consumers' interests, including fair practices in food trade, taking account of the environment.

In relation to amendment **1**, the allergenicity of food (including food additives) is covered by labelling under Directive 2000/13/EC. Although the Commission cannot accept an outright restriction on the use of food additives which may be allergenic, the allergenicity can of course be considered as a legitimate factor during the authorisation of a food additive. This principle has therefore been emphasised in recital 7.

14. Criteria for authorisation (sweeteners) (Article 7)

Amendments **20** and **29** cannot be accepted. The current criteria of the use of sweeteners restrict their use to foods which are energy reduced or which contain no added sugar. This ensures that consumers have a benefit from the use of such sweeteners in that there is either an appreciable energy reduction (of 30%) or the product contains no added sugars. The new criterion proposed here has the potential to increase the range of foods to which sweeteners can be used and therefore may have an impact on the consumption of such additives. In addition in some instances there may only be a marginal benefit to the consumer from the replacement of 30% sugar.

Sweeteners are not used for the purpose of increasing the shelf life of foods by preservation. However, a consequence of the use of sweeteners can be that the shelf life is increased because of the lack of fermentable sugar which the sweetener has replaced; therefore the Commission is unable to accept amendment **73**.

15. Criteria for authorisation (colours) (Article 8)

The general criteria for the use of additives in Article 6 already stipulate that the use of additives should not mislead the consumer. General labelling information also exists to ensure that consumers are aware of the composition of foods in particular with regard to the ingredients present. With regard to the use of colours, these are traditionally used in some foods to identify particular flavours for instance in soft drinks or confectionery. In these instances there is no evidence that consumers are misled as to the content of the foods. Therefore bearing in mind the principle already contained in Article 6, amendment **30** has not been taken on board in this amended proposal.

16. Community lists of food additives (Articles 4 and 10, Annexes II and III)

Amendment **34** is proposed to include in the Community list a reference to the other food additives which may not be used in combination with the food additive. The Commission has not accepted this amendment as it is considered that such a reference would already be covered under point 'c' which requires the conditions of use to be specified. In such cases, where concerns relating to the use of additives in combination are highlighted in the EFSA evaluation, suitable conditions of use would be stipulated when the additive is authorised.

17. Relation with Regulation 1829/2003 on GM food and feed (Article 13)

The Commission proposal aims to cover all food additives including those produced from genetically modified organisms (GMOs) or by (fermentation using) genetically modified micro-organisms (GMMs). Food additives produced using GMMs do not fall under Regulation 1829/2003 on GM food and feed and they will be entirely covered for their assessment and authorisation by the Regulation on food additives. Food additives which fall within the scope of Regulation (EC) No 1829/2003 will be subject to that Regulation with regard to the safety assessment of the genetic modification, while the other aspects of safety, the consideration of the other criteria and the final authorisation will be dealt with under the food additives Regulation. The two evaluations and authorisations can run in parallel.

Amendments **4** and **63** clarify that the two procedures may run simultaneously in accordance with good administrative practice. The proposed clarification is endorsed by the Commission subject to some drafting changes in order to make the provision more compatible with Regulation 1829/2003. Amendment **38** however proposes to introduce additional labelling requirements. The labelling of GMOs is subject to horizontal rules under Regulation 1829/2003, therefore it is not appropriate to introduce specific measures under this vertical legislation on food additives.

18. Labelling (Articles 21 to 24)

Amendment **45** would introduce a requirement for allergen warning where azo dyes are present. The labelling of allergens is addressed horizontally under Directive 2000/13/EC and therefore the issue of allergen labelling should continue to be addressed under that legislation based on scientific evaluations by EFSA.

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

Amendments **42**, **43** and **44** are acceptable as they introduce some useful aspects to the business to business labelling provisions. In particular amendment **44** provides a practical derogation so that certain information can be included on the accompanying documentation rather than the packaging in the case of bulk delivery of additives (e.g. in tankers).

In its original proposal the Commission aligned the labelling provisions of additives with those of enzymes. The European Parliament made a number of amendments to the enzymes proposal to ensure a new presentation and simplification of the labelling provisions for enzymes sold from business to business or to the final consumer. The Commission has therefore taken on board the spirit of these amendments also in this amended proposal on food additives.

In addition, since food additives intended for sale to the final consumer are considered food and must comply with the relevant labelling provisions of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs, the text has been further simplified so as not to repeat the provisions of Directive 2000/13/EC.

19. Changes in production process or starting materials of a food additive (Article 11)

Amendment **35** would introduce separate limit values for nanoscale food additives; the Commission does not feel that such an amendment is necessary as specific restrictions could already be allocated under the conditions of use if these are deemed necessary.

However as this is an important issue it is useful to amend the text to reiterate and clarify that nanoscale additives would need to be evaluated by EFSA before they could be used as they may behave in a different manner which could affect their safety.

The amended Commission proposal includes a new Article 11 introducing requirements for food additives already included in the Community list which are prepared by production methods or starting materials significantly different from those included in the risk assessment of the Authority. This Article reflects the principle in recital 14 of the Commission proposal.

20. Reviews and re-evaluation (Articles 29 and 30)

The Commission has proposed that the current authorisations for food additives will be transferred into the new annexes after a review of the criteria other than safety. This review will take approximately 2 years. At the same time the EFSA has been tasked with a re-evaluation of the safety of all currently permitted food additives, which will take a number of years. If during the EFSA re-evaluation particular concerns are raised, any necessary amendments can be made at any time. Because of the differences in timing, it is not appropriate to bind these two separate reviews together. Additionally for clarity it is appropriate that the annexes are completed at the earliest possible opportunity. Amendments **52**, **6** and **69rev** would link these 2 aspects and therefore, for the reasons highlighted above, cannot be accepted by the Commission. The principle of amendment **55** can however be accepted and article 29 has been amended to make clear that when the annex II is populated, food additive uses which are no longer necessary will not be included.

In amendment **57** it has been proposed to amend the definition of carriers to include also substances which are used to dissolve, dilute, disperse or otherwise physically modify nutrients and/or other substances added for nutritional or physiological purposes. Amendment **60** provides provision for such substances to be included in Annex III. The Commission can accept these amendments which widen the scope and further harmonise the area of food additives. The amended proposal has therefore been drafted to reflect these amendments and also some other consequential changes necessary to incorporate these provisions. As this change in scope will be new to the legislation on food additives the entry into force will be delayed as with the other new provisions on food additives in food additives and food enzymes.

Other amendments have also been proposed with a the consequence that the food additives permitted in flavourings will be listed in Annex III rather than Annex II as originally foreseen (amendments **58** and **59**). The Commission can accept this amendment which will treat food additives used in food additives, food enzymes and flavourings in the same way and has amended the proposal to reflect this change; some consequential amendments to other aspects of the proposal have also been made. The listing of tables in the annex however has been adapted to take into account the different requirements and also in particular the differences in their date of entry into force or completion.

21. Re-evaluation programme

Amendments **5** and **54** would introduce a requirement for a rolling re-evaluation programme. Food additives are subject of continuous observation once they have been authorised and are re-evaluated whenever new scientific data becomes available which may affect the outcome of the previous evaluation. A regular review is therefore not necessary and it would increase the administrative burden for the Commission and EFSA.

22. Transitional provisions (Article 32)

As some amendments, in particular to labelling, introduce changes from the current legislation it is appropriate to introduce a transitional provision as proposed in amendment **56**. A suitable provision has therefore been included in Article 32 which will permit food additives which were legally labelled to continue to be marketed until their date of minimum durability.

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

Amended 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 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) 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 uses³ 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.

¹ OJ C [...], [...], p. [...].

² OJ C **168, 20.7.2007, p. 34.**

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. **Misleading the consumer includes, but is not limited to, issues related to the quality of the ingredients used, the naturalness of a product or of the production process, its nutritional quality and its fruit and vegetable content. The approval of food additives should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors and the feasibility of controls. The use and maximum levels of a food additive should take into account the intake of the food additive from other sources and the exposure to the food additive by special groups of consumers (e.g. allergic consumers).**
- (8) **The inclusion of a food additive in the annexes shall refer to the consideration given to the criteria laid down in this Regulation.**

⁴ OJ L [...], dd/mm/yyyy, p. [...].

- (9) 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 foodstuffs⁵, Commission Directive 95/45/EC of 26 July 1995 laying specific purity criteria concerning colours for use in foodstuffs⁶ and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners⁷ 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.
- (10) 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.
- (11) 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 flavourings⁸.
- (12) 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.
- (13) 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 feed¹⁰ should be **subject to the authorisation procedure under that Regulation with regard to the safety assessment of the genetic modification while the final authorisation of the food additives should be granted** authorised under that Regulation prior to its approval under this Regulation.

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).

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.

- (14) 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.
- (15) 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.
- (16) 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 foodstuffs¹¹ and Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates for specific character for agricultural products and foodstuffs¹².
- (17) 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.
- (18) 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 Commission¹³.
- (19) **In particular power should be conferred on the Commission to amend the Annexes of this Regulation and to adopt appropriate transitional measures. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, and/or to supplement it by addition of new non essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.**

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.

¹³ OJ L 184, 17.7.1999, p. 23.

- (20) 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 rules¹⁴ and consequently the legal basis for the financing of the above measures will be Regulation (EC) No 882/2004.
- (21) Member States are to carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.
- (22) 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.
- (23) 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 **food enzymes as well as carriers for nutrients** 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 **and food additives in flavourings**, should not apply until [1.1.2011].
- (24) 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.

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

(25) 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 consumption¹⁵, Council Directive 65/66/EEC of 26 January 1965 laying specific criteria on purity for preservatives authorised for use in foodstuffs intended for human consumption¹⁶, 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 foodstuffs¹⁷, 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 consumption¹⁸, 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 purity¹⁹, 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 consumption²⁰, Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs²¹, Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs²², Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners²³ 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 foodstuffs²⁴ 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 konjac²⁵. 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,

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 **protection of human health and protection and of consumers' interest, including fair practices in food trade, taking account of the environment**~~protection~~.

For those purposes, this Regulation provides for:

- (a) Community lists of approved food additives;
- (b) conditions of use of food additives in foods, **including food additives, and in food enzymes as referred to in Regulation (EC) No .../...[on food enzymes] and flavourings as referred to in Regulation (EC) No .../... [on food ingredients with flavouring properties]**;
- (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/EC²⁶.

²⁶ OJ L 330, 5.12.1998, p. 32.

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;
 - (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 ~~2827~~(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, **and foods containing them**, 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 **or other technological** 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 amylolytic enzymes;
 - (vii) ammonium chloride;
 - (viii) blood plasma, **blood proteins**, 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, **or** disaccharides ~~or oligosaccharides~~; or
 - (ii) food containing monosaccharides **or**, 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 sugars.
- (h) 'quantum satis' shall mean that no maximum level is specified and that substances have to 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.**

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 **and in food flavourings under the conditions of use specified therein.**
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, **food flavourings and nutrients** 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~~**14**.

Article 5

Prohibition of non-compliant food additives and/or non-compliant foodstuffs

No food additive and/or food containing such a food additive may be placed on the market if the food additives or its use does not comply with the requirements of this Regulation.

Article 56

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 **and where relevant other legitimate factors:**
 - (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 67
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 56(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 78
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 56(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 89
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, **the measures, designed to amend non-essential elements of this Regulation, relating to additional functional classes may be added to Annex I shall be adopted** in accordance with the **regulatory procedure with scrutiny** referred to in Article ~~28~~**27(23)**.

*Article ~~9~~**10***

The content of the Community lists of food additives

1. A food additive which complies with the conditions set out in Articles ~~56~~, ~~67~~ and ~~78~~ 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 **and/or food additives and/or food enzymes and/or food flavourings** 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 11

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

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

Article ~~10~~12
Levels of use of food additives

1. When establishing the conditions of use referred to in Article ~~9~~10(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 **the principle of *quantum satis*** ~~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. **For dried and/or concentrated foods which need to be reconstituted, the maximum levels apply to the food as reconstituted taking into account the minimum dilution factor.**
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~~13
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 **in accordance with the** ~~to the present Regulation~~ only **when it is covered by an authorisation** ~~after it has been authorised in accordance with Article 7 of Regulation (EC) No 1829/2003.~~

Article ~~12~~14
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~~15
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~~16
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~~17
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/EEC²⁷ 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 1274/91²⁸.

²⁷ OJ L 268, 24.9.1991, p. 69.

²⁸ OJ L 121, 16.5.1991, p. 11.

Article ~~16~~18
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 **food additive, food enzyme or** flavouring has been added, where the food additive:
 - (i) is permitted in the **food additive, food enzyme or** flavouring in compliance with this Regulation;
 - (ii) has been carried over to the food via the **food additive, food enzyme or** 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.
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~~19
Interpretation decisions

Where necessary, a it may be decided in accordance with the procedure referred to in Article ~~28~~27(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~~12(2).

Article ~~18~~20
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~~21
Labelling of food additives not intended for sale to the final consumer

- 1.** 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 **they comply with the labelling** ~~their packaging or containers bear the information provided for in Articles ~~20~~22 to ~~23~~~~ of this Regulation, which must be easily visible, clearly legible and indelible. **The information provided for in Article 22 shall be in a language easily understandable to purchasers.**
- 2.** **Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that this information shall be given in one or more official languages of the Community, to be determined by that Member State. This shall not preclude such information from being indicated in several languages.**

Article ~~20~~22
General labelling requirements for food additives not intended for sale to the final consumer
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 **and/or other food ingredients, and/or to which other substances are added,** 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 **in respect of each food additive** or **a sales description which includes the name and/or E-number of each food additive**;
- ~~(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.~~
- (b) the statement either 'for food' or the statement 'restricted use in food' or a more specific reference to its intended use;**
- (c) if necessary, the special conditions of storage and/or use;**
- (d) a mark identifying the batch or lot;**
- (e) instructions for use, if the omission thereof would preclude appropriate use of the food additive;**
- (f) the name or business name and address of the manufacturer, packager or seller;**
- (g) where applicable, an indication of the maximum quantity of each component or group of components subject to a quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community legislation; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the *quantum satis* principle;**
- (h) the net quantity;**
- (i) the date of minimum durability;**
- (j) where relevant, information on a food additive or other substances as referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC to enable the purchaser to ensure compliance with that Directive.**

2. Where food additives are sold mixed with each other and/or with other food ingredients, the packaging or containers of the resulting product shall bear a list of all ingredients, 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.

- 3. Where substances (including food additives or other food ingredients) are added to food additives to facilitate their storage, sale, standardisation, dilution or dissolution, their packaging or containers shall bear a list of all such substances in descending order of their percentage by weight of the total.**
- 4. By way of derogation from paragraphs 1, 2 and 3, the information required in paragraph 1 points (e) to (g), (j) and in paragraphs 2 and 3 may appear merely on the documents relating to the consignment which are to be supplied with or prior to delivery, provided that the indication "intended for the manufacture of food and not for retail sale" is easily visible on the packaging or container of the product in question.**
- 5. By way of derogation from paragraph 1, 2 and 3, where food additives are supplied in tankers all of the information may appear merely on the accompanying documents relating to the consignment which are to be supplied with the delivery.**

Article 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 2423

Labelling of food additives intended for sale to the final consumer

1. Without prejudice to Directive 2000/13/EC, **Directive 89/396/EEC and to Regulation (EC) 1829/2003**, food additives **sold singly or mixed with each other and/or other food ingredients** intended for sale to the final consumer may be marketed only if their packaging contains the following information, ~~which must be easily visible, clearly legible and indelible:~~
- (a) the name **and E-number** under which the food additive is sold; that name shall be constituted by the name laid down **in this Regulation in respect of each food additive or a sales description which includes the name and E-number of each food additive** by any Community provisions applying to the food additive in question and its E-number;

- (b) the statement either 'for food' or the statement 'restricted used in food' or a more specific reference to its intended use ~~information required in accordance with Articles 20, 21 and 22 and points (a) to (e), (g) and (h) of Article 23(1).~~
2. By derogation from paragraph 1 (a), ~~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'.
4. For the information provided for in paragraphs (1) to (3), Article 13(2) of Directive 2000/13/EC shall apply accordingly.

SECTION 3

OTHER LABELLING REQUIREMENTS

Article 25~~24~~

Other labelling requirements

1. ~~Articles 19~~21~~ to 24~~23~~ 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~~25 *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~~26 *Monitoring of food additive intake*

1. Member States shall maintain systems to monitor the consumption and use of food additives **on a risk based approach** 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~~27(2).

Article ~~28~~27 *Committee*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health (hereinafter referred to as 'the Committee').
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

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

Article 2928
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 3029
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 ~~56~~, ~~67~~ and ~~78~~ of the present Regulation. **The measures relating to the entry of such additives in Annex II, which are designed to amend non-essential elements of this Regulation, shall be adopted** in accordance with the **regulatory procedure with scrutiny** referred to in Article ~~2827(23)~~. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by ~~{...}~~ **2 years after the date of publication of this Regulation. Food additives and uses which are no longer current shall not be entered in the Annex.**
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 ~~56~~ of this Regulation. **The measures relating to the entry of such additives in Annex III, which are designed to amend non essential elements of this Regulation, shall be adopted** in accordance with the **regulatory procedure with scrutiny** ~~laid down referred to~~ in Article ~~2827(23)~~. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by ~~{.....}~~ **2 years after the date of publication of this Regulation. Food additives and uses which are no longer current shall not be entered in the Annex.**
3. **Food additives authorised for use in food flavourings in Directive 95/2/EC and their conditions of use shall be entered in Annex III, part 4 to this Regulation after a review of their compliance with Article 6 of this Regulation. The measure relating to the entry of such additives in Annex III, which are designed to amend non-essential elements of this regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3). This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by 2 years after the date of publication of this Regulation. Food additives and uses which are no longer current shall not be entered in the Annex.**

- 34.** Specifications of the food additives covered under paragraphs 1, ~~and 2~~ **and 3** 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.
- 45.** **The measures relating to a**Any appropriate transitional measures, **which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it shall** ~~may~~ be adopted in accordance with the **regulatory** procedure **with scrutiny** ~~laid down~~ **referred to** in Article ~~2827~~(~~23~~).

*Article ~~31~~**30***

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 ~~2827~~(2). The evaluation programme shall be published in the *Official Journal of the European Union*.

*Article ~~32~~**31***

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~~32
Transitional provisions

By way of derogation from Article ~~32~~31, 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 ~~48~~17 of the [Regulation on food enzymes].

Food additives which do not comply with the provisions of the Regulation and were legally placed on the market or labelled prior to [12 months after the publication of this Regulation] may continue to be marketed until their date of minimum durability.

Article ~~34~~33
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 ~~45~~(2) shall apply to Parts 2, ~~and~~ 3 **and 5** 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
The President

For the Council
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, **nutrient and/or other substance added for nutritional or physiological purposes to a foodstuff (or food and/or food supplement)** 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, **food flavourings** and **their** conditions of use. **Community list of carriers in nutrients and their conditions of use.**

Part 1 Carriers in food additives

Part 2 Additives other than carriers in food additives

Part 3 Additives **including carriers** in food enzymes

Part 4 Additives including carriers in food flavourings

Part 5 Carriers in nutrients

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