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[1] Text with EEA relevance

III

*(Preparatory Acts)*

# COUNCIL

## COMMON POSITION (EC) No 6/2008

**adopted by the Council on 10 March 2008**

**with a view to adopting Regulation (EC) No …/2008 of the European Parliament and of the Council of … establishing a common authorisation procedure for food additives, food enzymes and food flavourings**

**(Text with EEA relevance)**

(2008/C 111 E/01)

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,

Having regard to the Opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

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) In order to protect human health, the safety of additives, enzymes and flavourings for use in foodstuffs for human consumption must be assessed before they are placed on the Community market.

(4) Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food additives [3], Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 [4] and Regulation (EC) No …/2008 of the European Parliament and of the Council of … on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC [5] lay down harmonised criteria and requirements concerning the assessment and authorisation of these substances.

(5) It is envisaged, in particular, that food additives, food enzymes and food flavourings, to the extent that the safety of food flavourings must be assessed in accordance with Regulation (EC) No …/2008 (*), must not be placed on the market or used in foodstuffs for human consumption, in accordance with the conditions laid down in each sectoral food law, unless they are included on a Community list of authorised substances.

(6) In this context, it appears appropriate to establish for these three categories of substances a common Community assessment and authorisation procedure that is effective, time-limited and transparent, so as to facilitate their free movement within the Community market.

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[1] OJ C 168, 20.7.2007, p. 34.

[2] Opinion of the European Parliament of 10 July 2007 (not yet published in the Official Journal), Council Common Position of 10 March 2008, Position of the European Parliament of … (not yet published in the Official Journal) and Council Decision of …

[3] See page 10 of this Official Journal.

[4] See page 32 of this Official Journal.

[5] See page 46 of this Official Journal.

(*) See footnote 5.

(7) This common procedure must be founded on the principles of good administration and legal certainty and must be implemented in compliance with those principles.

(8) This Regulation will thus complete the regulatory framework concerning the authorisation of the substances by laying down the various stages of the procedure, the deadlines for those stages, the role of the parties involved and the principles that apply. Nevertheless, for some aspects of the procedure, it is necessary to take the specific characteristics of each sectoral food law into consideration.

(9) The deadlines laid down in the procedure take into account the time needed to consider the different criteria set in each sectoral law, as well as allowing adequate time for consultation when preparing the draft measures. In particular, the nine-months deadline for the Commission to present a draft regulation updating the Community list should not preclude the possibility of this being done within a shorter period.

(10) Upon receipt of an application the Commission should initiate the procedure and where necessary seek the opinion of the European Food Safety Authority (hereinafter referred to as 'the Authority') established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([6]) as soon as possible after the validity and applicability of the application have been assessed.

(11) In accordance with the framework for risk assessment in matters of food safety established by Regulation (EC) No 178/2002, the authorisation to place substances on the market must be preceded by a scientific assessment, of the highest possible standard, of the risks that they pose to human health. This assessment, which must be carried out under the responsibility of the Authority, must be followed by a risk management decision taken by the Commission under a regulatory procedure that ensures close cooperation between the Commission and the Member States.

(12) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

([6]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

(13) In order to ensure that both business operators in the sectors concerned and the public are kept informed of the authorisations in force, the authorised substances should be included on a Community list created, maintained and published by the Commission.

(14) Networking between the Authority and the Member States' organisations operating in the fields within the Authority's mission is one of the basic principles of the Authority's operation. In consequence, in preparing its opinion, the Authority may use the network made available to it by Article 36 of Regulation (EC) No 178/2002 and by Commission Regulation (EC) No 2230/2004 ([7]).

(15) The common authorisation procedure for the substances must fulfil transparency and public information requirements while guaranteeing the right of applicants to preserve the confidentiality of certain information.

(16) Protecting the confidentiality of certain aspects of an application should be maintained as a consideration in order to protect the competitive position of an applicant. However, information relating to the safety of a substance, including, but not limited to, toxicological studies, other safety studies and raw data as such, should under no circumstances be confidential.

(17) Pursuant to Regulation (EC) No 178/2002, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ([8]) applies to documents held by the Authority.

(18) Regulation (EC) No 178/2002 establishes procedures for taking emergency measures in relation to foodstuffs of Community origin or imported from third countries. It authorises the Commission to adopt such measures in situations where foodstuffs are likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.

(19) In the interests of efficiency and legislative simplification, there should be a medium-term examination of the question whether to extend the scope of the common procedure to other legislation in the area of food.

([7]) Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64).

([8]) OJ L 145, 31.5.2001, p. 43.

(20) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States on account of differences between national laws and provisions and can therefore 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) 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 ([9]).

(22) In particular the Commission should be empowered to update the Community lists. Since those measures are of general scope and are designed to amend non-essential elements of each sectoral food law, *inter alia* by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(23) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the addition of substances to the Community lists and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community lists.

(24) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the removal of a substance from the Community lists and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community lists,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**GENERAL PRINCIPLES**

*Article 1*

**Subject matter and scope**

1. This Regulation lays down a common assessment and authorisation procedure (hereinafter referred to as the 'common procedure') for food additives, food enzymes, food flavourings and source materials of food flavourings and of food ingredients with flavouring properties used or intended for use in or on foodstuffs (hereinafter referred to as the 'substances'), which facilitates the free movement of these substances within the Community. This Regulation shall not apply to smoke flavourings falling within the scope of Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods ([10]).

2. The common procedure shall lay down the procedural arrangements for updating the lists of substances the marketing of which is authorised in the Community pursuant to Regulation (EC) No …/2008 (*), Regulation (EC) No …/2008 (**) and Regulation (EC) No …/2008 (***) (hereinafter referred to as the 'sectoral food laws').

3. The criteria according to which substances can be included on the Community list provided for in Article 2, the content of the regulation referred to in Article 7 and, where applicable, the transitional provisions concerning ongoing procedures are laid down in each sectoral food law.

*Article 2*

**Community list of substances**

1. Under each sectoral food law, substances that have been authorised to be placed on the Community market shall be included on a list the content of which is determined by the said law (hereinafter referred to as the 'Community list'). The Community list shall be updated by the Commission. It shall be published in the *Official Journal of the European Union*.

2. 'Updating the Community list' means:

(a) adding a substance to the Community list;

(b) removing a substance from the Community list;

(c) adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

CHAPTER II

**COMMON PROCEDURE**

*Article 3*

**Main stages of the common procedure**

1. The common procedure for updating the Community list may be started either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may represent several interested parties, in accordance with the conditions provided for by the implementing measures referred to in Article 9(1)(a) (hereinafter referred to as the 'applicant'). Applications shall be sent to the Commission.

([9]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Council Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

([10]) OJ L 309, 26.11.2003, p. 1.

(*) See page 10 of this Official Journal.

(**) See page 32 of this Official Journal.

(***) See page 46 of this Official Journal.

2. The Commission shall seek the opinion of the European Food Safety Authority (hereinafter referred to as the 'Authority'), to be given in accordance with Article 5.

However, for the updates referred to in Article 2(2)(b) and (c), the Commission shall not be required to seek the opinion of the Authority if the updates in question are not liable to have an effect on human health.

3. The common procedure shall end with the adoption by the Commission of a regulation implementing the update, in accordance with Article 7.

4. By way of derogation from paragraph 3, the Commission may end the common procedure and decide not to proceed with a planned update, at any stage of the procedure, if it judges that such an update is not justified. Where applicable, it shall take account of the opinion of the Authority, the views of Member States, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

In such cases, where applicable, the Commission shall inform the applicant and the Member States directly, indicating in its letter the reasons for not considering the update justified.

*Article 4*

**Initiating the procedure**

1. On receipt of an application to update the Community list, the Commission:

(a) shall acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;

(b) where applicable, shall as soon as possible notify the Authority of the application and request its opinion in accordance with Article 3(2).

The application shall be made available to the Member States by the Commission.

2. Where it starts the procedure on its own initiative, the Commission shall inform the Member States and, where applicable, request the opinion of the Authority.

*Article 5*

**Opinion of the Authority**

1. The Authority shall give its opinion within six months of receipt of a valid application.

2. The Authority shall forward its opinion to the Commission, the Member States and, where applicable, the applicant.

*Article 6*

**Additional information concerning risk assessment**

1. In duly justified cases where the Authority requests additional information from applicants, the period referred to in Article 5(1) may be extended. After consulting the applicant, the Authority shall lay down a period within which this information can be provided and shall inform the Commission of the additional period needed. If the Commission does not object within eight working days of being informed by the Authority, the period referred to in Article 5(1) shall be automatically extended by the additional period. The Commission shall inform the Member States of the extension.

2. If the additional information is not sent to the Authority within the additional period referred to in paragraph 1, the Authority shall finalise its opinion on the basis of the information already provided.

3. Where applicants submit additional information on their own initiative, they shall send it to the Authority and to the Commission. In such cases, the Authority shall give its opinion within the original period without prejudice to Article 10.

4. The additional information shall be made available to the Member States and the Commission by the Authority.

*Article 7*

**Updating the Community list**

1. Within nine months of the Authority giving its opinion, the Commission shall submit to the Committee referred to in Article 14(1) a draft regulation updating the Community list, taking account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

In those cases where an opinion of the Authority has not been requested, the nine-month period shall start from the date the Commission receives a valid application.

2. Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall provide an explanation of the reasons for the differences.

3. The measures, designed to amend non-essential elements of each sectoral food law, relating to the removal of a substance from the Community list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

4. On grounds of efficiency, the measures designed to amend non-essential elements of each sectoral food law, *inter alia* by supplementing it, relating to the addition of a substance to the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Community list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(4).

5. On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14(5) for the removal of a substance from the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

*Article 8*

**Additional information concerning risk management**

1. Where the Commission requests additional information from applicants on matters concerning risk management, it shall determine, together with the applicant, a period within which that information can be provided. In such cases, the period referred to in Article 7 may be extended accordingly. The Commission shall inform the Member States of the extension and shall make the additional information available to the Member States once it has been provided.

2. If the additional information is not sent within the additional period referred to in paragraph 1, the Commission shall act on the basis of the information already provided.

CHAPTER III

**MISCELLANEOUS PROVISIONS**

*Article 9*

**Implementing measures**

1. In accordance with the regulatory procedure referred to in Article 14(2), within a period of no longer than 24 months from the adoption of each sectoral food law, the implementing measures for this Regulation shall be adopted by the Commission, and shall concern in particular:

(a) the content, drafting and presentation of the application referred to in Article 4(1);

(b) the arrangements for checking the validity of applications;

(c) the type of information that must be included in the opinion of the Authority referred to in Article 5.

2. With a view to the adoption of the implementing measures referred to in paragraph 1(a), the Commission shall consult the Authority, which, within six months of the date of entry into force of each sectoral food law, shall present it with a proposal concerning the data required for risk assessment of the substances concerned.

*Article 10*

**Extension of time periods**

In exceptional circumstances, the periods referred to in Article 5(1) and Article 7 may be extended by the Commission on its own initiative or, where applicable, at the Authority's request, if the nature of the matter in question so justifies, without prejudice to Article 6(1) and Article 8(1). In such cases the Commission shall, where appropriate, inform the applicant and the Member States of the extension and the reasons for it.

*Article 11*

**Transparency**

The Authority shall ensure the transparency of its activities in accordance with Article 38 of Regulation (EC) No 178/2002. In particular, it shall make its opinions public without delay. It shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1).

*Article 12*

**Confidentiality**

1. Among the information provided by applicants, confidential treatment may be given to information the disclosure of which might significantly harm their competitive position.

Information relating to the following shall not, in any circumstances, be regarded as confidential:

(a) the name and address of the applicant;

(b) the name and a clear description of the substance;

(c) the justification for the use of the substance in or on specific foodstuffs or food categories;

(d) information that is relevant to the assessment of the safety of the substance;

(e) where applicable, the analysis method(s).

2. For the purposes of implementing paragraph 1, applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

3. The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants and the Member States accordingly.

4. After being made aware of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.

5. The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

6. If an applicant withdraws, or has withdrawn, its application, the Commission, the Authority and the Member States shall not disclose confidential information, including information the confidentiality of which is the subject of disagreement between the Commission and the applicant.

7. The implementation of paragraphs 1 to 6 shall not affect the circulation of information between the Commission, the Authority and the Member States.

*Article 13*

**Emergencies**

In the event of an emergency concerning a substance on the Community list, particularly in the light of an opinion of the Authority, measures shall be adopted in accordance with the procedures referred to in Articles 53 and 54 of Regulation (EC) No 178/2002.

*Article 14*

**Committee**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002.

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.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be 2 months, 2 months and 4 months respectively.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 15*

**Competent authorities of the Member States**

Not later than six months after the entry into force of each sectoral food law, Member States shall forward to the Commission and to the Authority, in relation to each sectoral food law, the name and address of the national competent authority for the purposes of the common procedure, as well as a contact point therein.

CHAPTER IV

**FINAL PROVISION**

*Article 16*

**Entry into force**

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

For each sectoral food law, it shall apply from the date of application of the measures referred to in Article 9(1).

Article 9 shall apply from … (*).

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*

(*) Date of entry into force of this Regulation.

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 28 July 2006, the Commission adopted the proposal for a Regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([1]). The proposal is based on Article 95 of the Treaty establishing the European Community.

The European Parliament adopted its Opinion at first reading on 10 July 2007 ([2]).

Following the European Parliament's first reading Opinion, the Commission submitted an amended proposal on 24 October 2007 ([3]).

On 10 March 2008, the Council adopted its Common Position in accordance with Article 251(2) of the Treaty.

In carrying out its work, the Council also took account of the opinion of the European Economic and Social Committee adopted on 25 April 2007 ([4]).

### II. OBJECTIVE

The aim of the proposed Regulation, as part of four proposals designed to overhaul the Community's rules on food improvement agents, is to ensure the proper functioning of the internal market, including fair practices in food trade, while also guaranteeing a high level of protection of human health, of consumer interests and of the environment, by introducing a harmonised Community approval procedure for food additives, flavourings and enzymes.

The common authorisation procedure should be centralised, effective, expedient and transparent, and based on risk assessment carried out by the European Food Safety Authority (EFSA) and on a risk management system in which the Commission takes action within the framework of a regulatory committee procedure (comitology).

It assigns to the Commission the task of creating, maintaining and updating a general positive list for each category of substances concerned. The inclusion of a substance on one of these lists means that its use is authorised in general for all operators in the Community.

### III. ANALYSIS OF THE COMMON POSITION

#### 1. Introductory remarks

The Common Position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced several changes in the text, some of them inspired by the amendments proposed by the European Parliament.

The Commission has accepted the Common Position agreed by the Council.

#### 2. The amendments of the European Parliament

In its Plenary vote on 10 July 2007, the European Parliament adopted 31 amendments to the proposal.

The Council incorporated, in full or in principle, 11 amendments in its Common Position.

([1]) COM(2006) 425 final.
([2]) Doc. 11639/07 CODEC 775.
([3]) COM(2007) 672 final.
([4]) OJ C 168, 20.7.2007, p. 34.

***Amendments accepted in the Common Position***

— *Introduction of the regulatory comitology procedure with scrutiny* (in line with amendments 34, 35, 36, 37)

The Council introduced the regulatory procedure with scrutiny. The Council also introduced the urgency procedure (Article 14(5)) for removal of substances from the list of authorised substances and for adding, changing or removing conditions for their use in order to protect human health. The efficiency procedure was also introduced (Article 14(4)) for adding a substance to the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Community list.

— *Smoke flavourings*

The Council clarified that the authorization for smoke flavourings is excluded from the scope of the proposal (in line with amendment 12).

— *Protection of the environment*

The Council referred to the fact that risk management would also need to take into account other legitimate factors, such as environment, which was introduced in Recital 12 (in line with amendment 6).

— *Confidentiality*

The Council clarified which aspects of the application can be kept confidential to protect competitiveness (in line with amendment 8).

— *Information to Member States*

The Council agreed that information on the stages of the procedure should be provided also to Member States (in line with amendments 27, 28, 32).

In addition, the substance of amendment 25 is reflected in Article 6(3), which mentions the principle of exceptional extension of deadlines pursuant to Article 10.

***Amendments not introduced***

The Council was not able to introduce all the amendments, either on account of rules on legal drafting (amendment 31) or for other specific reasons as outlined below:

— *Issues already regulated in Regulation (EC) No 178/2002 on general principles and requirements of food law* ([1])*, which do not need to be addressed in this Regulation* (amendments 3, 5, 9, 10, 23)

The requirement to have an independent risk assessment (amendment 5 — recital 10) is already provided for in Article 22(2) of Regulation (EC) No 178/2002.

Amendment 3 (new recital) was not accepted as transparency in the production and handling of food is of a general nature. Under Regulation (EC) No 178/2002 the primary responsibility for food safety rests with food business operators. The latters' responsibility is reinforced though legislation imposing the Hazard Analysis Critical Control Point System (HACCP) principle and good hygiene practice provided for in other Community legislation.

— *Consultation of stakeholders by the Commission* (amendments 9, 10 — recitals 19 and 21) is provided for in Article 9 of the Regulation (EC) No 178/2002 as well as in other documents of a general nature, such as the Commission White Paper on European governance and the Commission's Communication on general principles and minimum standards for consultation of interested parties. Similarly, the provision that EFSA should publish its opinions without delay is provided for in Article 38 of that Regulation, thus amendment 23 (Article 5(2)) is not necessary.

([1]) JO L 31, 1.2.2002, p. 1.

— *Criteria for authorisation* (amendment 4 — new recital)

The general criteria for authorisation of substances are laid down in the legislation for each sector and they have to be respected. Therefore, the Council did not consider repetition necessary.

— *Reference to consumer protection and public health* (amendment 11 — Article 1)

This proposal deals with procedural arrangements for updating the lists of authorised substances. The reference that the Regulations aim at human health, consumer interests, including fair practices in food trade, taking into account, where appropriate, the protection of the environment, is set out in the proposed Regulations for each sector.

— *Protection of data* (amendments 14, 33 — Article 2(1a), 12(6a))

A 5-year period of data protection and, as a result, preferential authorisation of the substance during this time for the company that provided the data would change the present system in the field of food law, notably for food additives, which is generally applied internationally. A provision on the protection of data in this legislative act would complicate administrative procedures, and thus is not in line with the objective of simplification of the regulatory framework. Therefore, the Council does not consider these amendments acceptable.

— *Deadline for an EFSA opinion* (amendment 22 — Article 5(1))

The Council did not agree with extension of the time limit for an EFSA opinion from 6 to 9 months as proposed in amendment 22. The set periods are further clarified in Recital 8a(new) of the Common Position. It should be noted that time limits are also important from the industry's point of view.

— *Extension of the 6 months deadline when additional information is needed* (amendment 24 — Article 6(1))

The Council considers that this deadline should be extended only in justified cases.

Other amendments that have not been introduced include amendments 1, 2, 19, 21 and 30.

IV. **Conclusions**

The Council believes that the Common Position represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation, ensuring a high level of human health and consumer protection.

# COMMON POSITION (EC) No 7/2008

## adopted by the Council of 10 March 2008

## with a view to adopting Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food additives

**(Text with EEA relevance)**

(2008/C 111 E/02)

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,

Having regard to the Opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

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. This has not previously been regulated at Community level.

(5) Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose described in this Regulation, such as the preservation of food. All food additives should be covered by this Regulation, and therefore in the light of scientific progress and technological development the list of functional classes should be updated. However, substances should not be considered as food additives when they are used for the purpose of imparting flavour and/or taste or for nutritional purposes, such as salt replacers, vitamins and minerals. 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. However, preparations obtained from foods and other natural source material that are intended to have a technological effect in the final food and which are obtained by selective extraction of constituents (e.g. pigments) relative to the nutritive or aromatic constituents, should be considered additives within the meaning of this Regulation. Finally, food enzymes are covered by Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC and Regulation (EC) No 258/97 ([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.

([1]) OJ C 168, 20.7.2007, p. 34.

([2]) Opinion of the European Parliament of 10 July 2007 (not yet published in the Official Journal), Council Common Position of 10 March 2008, Position of the European Parliament of … (not yet published in the Official Journal) and Council Decision of …

([3]) OJ L 186, 30.6.1989, p. 27. 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).

([4]) See page 32 of this Official Journal.

(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 need for their use, and their use must not mislead the consumer and must be of benefit to the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. 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) Food additives must comply with the approved specifications, which 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 ([1]), Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs ([2]) and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners ([3]) 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 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.

(10) In order to ensure harmonisation, the risk assessment and approval of food additives should be carried out in accordance with the procedure laid down in Regulation (EC) No …/2008 of the European Parliament and of the Council of … establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([4]).

(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 ([5]), the European Food Safety Authority (hereinafter referred to as 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 ([6]) 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 additive should be granted under this Regulation.

(13) A food additive already approved under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the specifications laid down, should be submitted for evaluation by the Authority. 'Significantly different' could mean *inter alia* 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, a change in starting materials, or a change in particle size.

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

(15) Member States which maintained on 1 January 1992 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', this Regulation should be without prejudice to more restrictive rules linked to the use of certain denominations under Council Regulation (EC) No 510/2006 of 20 March 2006

([1]) OJ L 178, 28.7.1995, p. 1. Directive as last amended by Directive 2006/128/EC (OJ L 346, 9.12.2006, p. 6).
([2]) OJ L 226, 22.9.1995, p. 1. Directive as last amended by Directive 2006/33/EC (OJ L 82, 21.3.2006, p. 10).
([3]) OJ L 339, 30.12.1996, p. 1. Directive as last amended by Directive 2006/129/EC (OJ L 346, 9.12.2006, p. 15).
([4]) See page 1 of this Official Journal.
([5]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).
([6]) OJ L 268, 18.10.2003. p. 1.

on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ([1]) and Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates for specific character for agricultural products and foodstuffs ([2]).

(16) Unless subject to further restrictions, an additive may be present in food, other than by direct addition, as a result of carry-over from an ingredient in which the additive was permitted, provided that the level of the additive in the final food is no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice.

(17) Food additives remain subject to the general labelling obligations as provided for in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([3]) and, as the case may be, in Regulation (EC) No 1829/2003 and in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms ([4]). In addition, specific provisions on the labelling of food additives sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

(18) Sweeteners authorised under this Regulation may be used in table-top sweeteners sold directly to consumers. Manufacturers of such products should make information available to the consumer by appropriate means to allow them to use the product in a safe manner. Such information could be made available in a number of ways including on product labels, internet websites, consumer information lines or at the point of sale. In order to adopt a uniform approach to the implementation of this requirement, guidance drawn up at Community level may be necessary.

(19) 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 ([5]).

(20) In particular the Commission should be empowered 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, *inter alia* by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(21) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of certain amendments to Annexes II and III relating to substances already authorised under other Community law as well as any appropriate transitional measures related to these substances.

(22) In order to develop and update Community law 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 a view to facilitating the decision-making process. It is appropriate that the Community 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 ([6]).

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

(24) Since the objective of this Regulation, namely to lay down Community rules on food additives, cannot be sufficiently achieved by the Member States and can therefore, in the interests of market unity and a 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 that objective.

(25) Following the adoption of this Regulation the Commission, assisted by the Standing Committee on the 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

([1]) OJ L 93, 31.3.2006, p. 12. Regulation as amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).
([2]) OJ L 208, 24.7.1992, p. 9. Regulation as repealed by Regulation (EC) No 509/2006 (OJ L 93, 31.3.2006, p. 1).
([3]) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).
([4]) OJ L 268, 18.10.2003, p. 24.
([5]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Council Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
([6]) OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1. Regulation as amended by Council Regulation (EC) No 1791/2006.

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 …/2008 (*). 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 January 2011.

(26) Until the future Community lists of food additives are established, it is necessary to provide for a simplified procedure allowing the current lists of food additives contained in the existing Directives to be updated.

(27) Without prejudice to the outcome of the review referred to in recital 25, 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.

(28) 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 ([1]), 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 ([2]), 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 ([3]), 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 ([4]), 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 ([5]), 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 ([6]), Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ([7]), Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs ([8]), Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ([9]), Decision No 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 ([10]) 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 ([11]). 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 this Regulation,

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 of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of the environment.

For those purposes, this Regulation provides for:

(a) Community lists of approved food additives as set out in Annexes II and III;

(b) conditions of use of food additives in foods, including in food additives and in food enzymes as covered by Regulation (EC) No …/2008 (**), and in food flavourings as covered by Regulation (EC) No …/2008 of the European Parliament and of the Council of … on flavourings and

(*) See page 1 of this Official Journal.
([1]) OJ 115, 11.11.1962, p. 2645/62. Directive as last amended by Directive 95/45/EC (OJ L 226, 22.9.1995, p. 1).
([2]) OJ 22, 9.2.1965, p. 373/65. Directive as last amended by Commission Directive 96/77/EC (OJ L 339, 30.12.1996, p. 1).
([3]) OJ L 223, 14.8.1978, p. 7. Directive as amended by Commission Directive 92/4/EEC (OJ L 55, 29.2.1992, p. 96).
([4]) OJ L 223, 14.8.1978, p. 30. Directive as last amended by Commission Directive 96/77/EC.
([5]) OJ L 257, 10.9.1981, p. 1.
([6]) 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.
([7]) OJ L 237, 10.9.1994, p. 3. Directive as last amended by Directive 2006/52/EC (OJ L 204, 26.7.2006, p. 10).
([8]) OJ L 237, 10.9.1994, p. 13. Directive as amended by Regulation (EC) No 1882/2003.
([9]) OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2006/52/EC.
([10]) OJ L 48, 19.2.1997, p. 13.
([11]) OJ L 84, 28.3.2002, p. 69.
(**) See page 32 of this Official Journal.

certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2001/13/EC [1];

(c) rules on the 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 accordance 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 of 3 November 1998 on the quality of water intended for human consumption [2];

(e) flavourings falling within the scope of Regulation (EC) No …/2008 (*).

3. This Regulation shall not apply to food enzymes falling within the scope of Regulation (EC) No …/2008 (**).

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.

*Article 3*

**Definitions**

1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002 and (EC) No 1829/2003 shall apply.

2. For the purposes of this Regulation 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;

The following are not considered to be food additives:

(i) monosaccharides, disaccharides or oligosaccharides and foods containing these substances 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 quinces, or from a mixture of them, 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;

[1] See page 46 of this Official Journal.
[2] OJ L 330, 5.12.1998, p. 32. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council.
(*) See page 46 of this Official Journal.
(**) See page 32 of this Official Journal.

(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;

(ii) any added food containing monosaccharides or disaccharides 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 numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.

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 under the conditions of use specified therein.

2. Only food additives included in the Community list in Annex III may be used in food additives, in food enzymes and in food flavourings under the conditions of use specified therein.

3. Food additives in Annex II shall be listed on the basis of the categories of food to which they may be added.

4. Food additives in Annex III shall be listed on the basis of the food additives, food enzymes, food flavourings and nutrients or categories thereof to which they may be added.

5. Food additives shall comply with the specifications as referred to in Article 13.

*Article 5*

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

No person shall place on the market a food additive or any food in which such a food additive is present if the use of the food additive does not comply with this Regulation.

*Article 6*

### 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; and

(b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and

(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, including food additives, food enzymes and food flavourings, 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 paragraph 2(a), 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 7*

**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 6(2), it 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; or

(b) replacing sugars where this permits an increase in the shelf-life of the food; or

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

*Article 8*

**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 6(2), it 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 and helping to identify flavours normally associated with particular foods;

(c) giving colour to food otherwise colourless.

*Article 9*

**Functional classes of food additives**

1. Food additives may be assigned in Annexes II and III 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 which may be added to Annex I shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(3).

*Article 10*

**The content of the Community lists of food additives**

1. A food additive which complies with the conditions set out in Articles 6, 7 and 8 may, in accordance with the procedure referred to in Regulation (EC) No …/2008 (*), be included in:

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

(b) the Community list in Annex III to this 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;

(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 the final consumer.

3. The Community lists in Annexes II and III shall be amended in accordance with the procedure referred to in Regulation (EC) No …/2008 (*).

(*) See page 1 of this Official Journal.

*Article 11*

**Levels of use of food additives**

1. When establishing the conditions of use referred to in Article 10(2)(c):

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

(b) the levels 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 numerical 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*.

3. The maximum levels of food additives set out in Annex II shall apply to the food as marketed, unless otherwise stated. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted the maximum levels shall apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor.

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

*Article 12*

**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 this Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.

*Article 13*

**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) No …/2008 (*).

(*) See page 1 of this Official Journal.

CHAPTER III

**USE OF FOOD ADDITIVES IN FOODS**

*Article 14*

**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 15*

**Use of food additives in foods for infants and young children**

Food additives 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 this Regulation.

*Article 16*

**Use of colours for markings**

Only food colours listed in Annex II to this Regulation may be used for the purpose of health marking as provided for in Council Directive 91/497/EEC of 29 July 1991 amending and consolidating Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat ([1]) and other markings required on meat products, for the decorative colouring of eggshells and for the stamping of eggshells as provided for in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([2]).

*Article 17*

**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;

([1]) OJ L 268, 24.9.1991, p. 69. Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

([2]) OJ L 139, 30.4.2004, p. 55. Corrected version in OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

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

(i) is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and

(ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and

(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 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 food flavouring, food additive or food enzyme is added to a food and has a technological function in that food, it shall be considered a food additive of that food and not a food additive of the added flavouring, food additive or food enzyme, and must then comply with the conditions of use for that food as provided for.

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

*Article 18*

**Interpretation decisions**

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 26(2) 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 11(2); or

(c) a given substance meets the definition of food additive in Article 3.

*Article 19*

**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**

*Article 20*

**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 only be marketed with the labelling provided for in Article 21 of this Regulation, which must be easily visible, clearly legible and indelible. The information 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 Treaty, stipulate that the information provided for in Article 21 shall be given in one or more of the 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 21*

**General labelling requirements for food additives not intended for sale to the final consumer**

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 with other substances added to them, their packaging or containers shall bear the following information:

(a) the name and/or 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) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;

(c) if necessary, the special conditions of storage and/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) an indication of the maximum quantity of each component or group of components subject to 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 law; 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 or use-by-date;

(j) where relevant, information on a food additive or other substances referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC as regards the indication of the ingredients present in foodstuffs.

2. Where food additives are sold mixed with each other and/or with other food ingredients, their packaging or containers shall bear a list of all ingredients in descending order of their 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) 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 the delivery, provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question.

5. By way of derogation from paragraphs 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 22*

**Labelling of food additives intended for sale to the final consumer**

1. Without prejudice to Directive 2000/13/EC, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [1] and Regulation (EC) No 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:

(a) the name and E-number 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;

(b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use.

2. By way of 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. Manufacturers of table-top sweeteners shall make available by appropriate means the necessary information to allow their safe use by consumers. Guidance for the implementation of this paragraph may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(3).

5. For the information provided for in paragraphs 1 to 3 of this Article, Article 13(2) of Directive 2000/13/EC shall apply accordingly.

*Article 23*

**Other labelling requirements**

Articles 20, 21 and 22 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.

[1] OJ L 186, 30.6.1989, p. 21. Directive as last amended by Directive 92/11/EEC (OJ L 65, 11.3.1992, p. 32).

CHAPTER V

**PROCEDURAL PROVISIONS AND IMPLEMENTATION**

*Article 24*

**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. For a food additive already approved under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the European Food Safety Authority (hereinafter referred to as the 'Authority'), a producer or user shall, before marketing the food additive, submit to the Commission the necessary data to allow an evaluation of the food additive with regard to the modified production method or characteristics to be undertaken by the Authority.

3. 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. Such information shall be made available to Member States by the Commission.

*Article 25*

**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 with appropriate frequency to the Commission and 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 shall be adopted in accordance with the regulatory procedure referred to in Article 26(2).

*Article 26*

**Committee**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

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.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be 2 months, 2 months and 4 months respectively.

*Article 27*

**Community financing of harmonised policies**

The legal basis for the financing of measures resulting from this Regulation shall be Article 66(1)(c) of Regulation (EC) No 882/2004.

CHAPTER VI

**TRANSITIONAL AND FINAL PROVISIONS**

*Article 28*

**Establishment of Community lists of food additives**

1. Food additives which are permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC, as amended on the basis of Article 29 of this Regulation, and their conditions of use shall be entered in Annex II to this Regulation after a review of their compliance with Articles 6, 7 and 8 thereof. 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 26(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by … (*).

Food additives and uses which are no longer needed shall not be entered in Annex II.

(*) Two years after the date of entry into force of this Regulation.

2. Food additives authorised for use in food additives in Directive 95/2/EC and their conditions of use shall be entered in Part 1 of Annex III to this Regulation after a review of their compliance with Article 6 thereof. 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 referred to in Article 26(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by … (*).

Food additives and uses which are no longer needed shall not be entered in Annex III.

3. Food additives authorised for use in food flavourings in Directive 95/2/EC and their conditions of use shall be entered in Part 4 of Annex III to this Regulation after a review of their compliance with Article 6 thereof. 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 referred to in Article 26(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by … (*).

Food additives and uses which are no longer needed shall not be entered in Annex III.

4. Specifications of the food additives covered under paragraphs 1 to 3 of this Article shall be adopted, in accordance with Regulation (EC) No …/2008 (**), at the moment those food additives are entered in the Annexes in accordance with those paragraphs.

5. The measures relating to any appropriate transitional measures, which are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 26(3).

*Article 29*

**Transitional measures**

Until the establishment of the Community lists of food additives as provided for in Article 28 is completed, the Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC shall be amended, where necessary, by measures, designed to amend non-essential elements of those Directives, adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 26(4).

(*) Two years after the date of entry into force of this Regulation.
(**) See page 1 of this Official Journal.

Foods placed on the market or labelled before … (***) which do not comply with Article 21(1)(i) and (4) of this Regulation may be marketed until their date of minimum durability or use-by-date.

*Article 30*

**Re-evaluation of approved food additives**

1. Food additives which were permitted before … (****) 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 by … (*****), in accordance with the regulatory procedure referred to in Article 26(2). The evaluation programme shall be published in the *Official Journal of the European Union*.

*Article 31*

**Repeals**

1. The following acts shall be 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 No 292/97/EC;

(k) Decision 2002/247/EC.

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

*Article 32*

**Transitional provisions**

By way of derogation from Article 31, the following provisions shall continue to apply until the transfer under Article 28(1), (2) and (3) of this Regulation of food additives already permitted in Directives 94/35/EC, 94/36/EC and 95/2/EC has been completed:

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

(***) 12 months after the date of entry into force of this Regulation.
(****) Date of entry into force of this Regulation.
(*****) One year after the date of entry into force of this Regulation.

(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 shall be repealed with effect from the date of application of the Community list on food enzymes in accordance with Article 17 of Regulation (EC) No …/2008 (*).

*Article 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 … (**).

However, Article 4(2) shall apply to Parts 2, 3 and 5 of Annex III from 1 January 2011 and Article 22(4) shall apply from … (***). Article 29 shall apply from … (****).

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*

(*) See page 32 of this Official Journal.

(**) One year after the date of entry into force of this Regulation.
(***) Two years after the date of entry into force of this Regulation.
(****) Date of entry into force of this Regulation.

*ANNEX I*

**FUNCTIONAL CLASSES OF FOOD ADDITIVES IN FOODS AND OF FOOD ADDITIVES IN FOOD ADDITIVES AND FOOD ENZYMES**

1. 'Sweeteners' are substances 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 edible 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 and/or which protect against growth of pathogenic 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, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food 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.

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*ANNEX II*

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

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*ANNEX III*

Community list of food additives approved for use in food additives, food enzymes and 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 Food additives other than carriers in food additives

Part 3 Food additives including carriers in food enzymes

Part 4 Food additives including carriers in food flavourings

Part 5 Carriers in nutrients and other substances added for nutritional and/or for other physiological purposes

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*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 duck preserves ('confit') | All |
| Austria | Traditional Austrian 'Bergkäse' | All except preservatives |
| Finland | Traditional Finnish 'Mämmi' | All except preservatives |
| Sweden<br>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 |

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 28 July 2006, the Commission adopted the proposal for a Regulation on food additives ([1]). The proposal is based on Article 95 of the Treaty establishing the European Community.

The European Parliament adopted its Opinion at first reading on 10 July 2007 ([2]).

Following the European Parliament's first reading opinion, the Commission submitted an amended proposal on 24 October 2007 ([3]).

On 10 March 2008, the Council adopted its Common Position in accordance with Article 251(2) of the Treaty.

In carrying out its work, the Council also took account of the opinion of the European Economic and Social Committee adopted on 25 April 2007 ([4]).

### II. OBJECTIVE

The proposed Regulation, as part of four proposals designed to overhaul the Community's rules on food improvement agents, would update and simplify the existing Community legislation with regard to food additives.

Through the proposed Regulation, a Community list of food additives and of food additives approved for use in food additives, food enzymes and food flavourings including their conditions of use, will be established. The proposed Regulation will also establish rules on the labelling of food additives.

The objective of the proposed Regulation is to ensure the proper functioning of the internal market, including fair practices in food trade, and a high level of protection of human health, of consumer interests and of the environment.

### III. ANALYSIS OF THE COMMON POSITION

#### 1. Introductory remarks

The Common Position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced a number of modifications in the text, some of them inspired by the amendments proposed by the European Parliament. On its own initiative, the Council introduced some of the European Parliament amendments in each of the three sectoral proposals, with a view to harmonising their provisions. The modifications introduced by the Council may be summed up as follows:

— *'Misleading the consumer'* (in line with amendments 3 and 26)

The Council included, in recital 7 and Article 6, elements integrating the notion of misleading the consumer.

— *Protection of the environment* (in line with amendments 1 and 7)

The Council considered that, apart from scientific evidence, the authorisation of the food additives should also take into account other relevant factors, such as the protection of the environment. The Council also included a reference to the protection of the environment among the objectives of the proposed Regulation.

([1]) COM(2006) 428 final.
([2]) Doc. 11640/07 CODEC 776.
([3]) COM(2007) 673.
([4]) OJ C 168, 20.7.2007, p. 29.

— *Protection of consumers with a food intolerance or allergy* (in line with amendment 1)

The Council recognised that the use and maximum levels of food additives should take into account the exposure of special groups of consumers, e.g. consumers with allergies.

— *Regulatory comitology procedure with scrutiny* (in line with amendment 48, 51, 64/rev, 67/rev, 68/rev, 79 and 80)

The Council adapted the proposal to the new comitology procedure rules, requiring the regulatory procedure with scrutiny to be applied for the adoption of measures supplementing the proposed Regulation.

The Council decided, on grounds of efficiency, to use the regulatory procedure with scrutiny with curtailed time limits for the establishment of Community lists of additives and for transitional measures, until the establishment of Community lists, to amend Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC.

— *Interpretation decisions*

The Council regrouped all the provisions on interpretation decisions into a new single Article and, as they would not supplement the Regulation, left them subject to the regulatory comitology procedure without scrutiny.

— *Provision prohibiting the placing on the market of non compliant food additives* (in line with amendments 9 and 22)

For reasons of clarity, legal certainty and proper functioning of the market, the Council inserted an Article on the prohibition on placing non-compliant food additives on the market. This is consistent with the proposals on flavourings and on food enzymes.

— *Authorisation of additives falling 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 [1] (in line with amendment 4)

The Council agrees that the two authorisation procedures for any substance can be carried out simultaneously, although the final authorisation should be granted under the additives Regulation. The Council subjected that principle to some drafting changes in order to make the provision more compatible with Regulation (EC) No 1829/2003.

— *Transitional measures for products already on the market* (in line with amendment 56)

The Council provided for a 1 year transition period from the date of entry into force of the Regulation. Foods lawfully placed on the market or labelled during this year may be marketed until their date of minimum durability or use-by-date.

— *Labelling*

The Council streamlined the labelling provisions in order to duplicate the provisions already laid down by Directive 2000/13/EC, respecting the distinction between 'business to business' labelling and labelling requirements for products intended for the sale to the final consumer. Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are in line with amendments 42 and 44.

[1] OJ L 268, 18. 10.2003, p. 1.

— *Nanotechnology* (in line with amendment 35)

Similar to the proposal of the European Parliament, the Council considered that a new evaluation of a food additive is necessary if a food additive is produced by production methods significantly different from those included in the previous risk assessment. Different conditions of use can be imposed in consequence of the new evaluation.

The Commission has accepted the Common Position agreed by the Council.

2. **The amendments of the European Parliament**

In its Plenary vote, on 10 July 2007, the European Parliament adopted 59 amendments to the proposal.

In its Common Position, the Council, incorporated, in full or in principle, 33 amendments.

(a) ***Amendments incorporated in the Common Position***

In addition to amendments already mentioned in part 1 above, the Common Position incorporates other European Parliament's first reading amendments, either in full or in part, that are of a technical/editorial nature and aimed at improving the clarity of the text of the proposal (amendments 8, 13, 14, 18, 19, 21, 36, 37, 39, 46, 55, 57, 58, 59, 60).

(b) ***Amendments not introduced*** ([1])

The Council was not able to accept all the amendments, for the following reasons:

— *Precautionary principle* (amendment 78 — recital 10)

The precautionary principle is one of the general principles underlying the general food law ([2]). Consequently, it applies to the proposed Regulation with no need for a specific reference to it. Moreover, in the risk analysis framework, the precautionary principle can only be taken into account in the context of risk management, never in the risk assessment phase, as suggested by the European Parliament.

— *Food additives not to be used with other food additives* (amendment 34 — Article 10(2))

Articles 1 and 10(2)(c) already stipulate that conditions of use of food additives have to be specified in the Community list, hence amendment 34 is superfluous.

— *Re-evaluation programme to review authorisations* (amendments 5, 54 — recital 14, Article 30(2a new))

For the Council, a system of continuous observation and of re-evaluation whenever necessary in the light of changing conditions and of new scientific information, will guarantee food safety. An additional review would represent an unnecessary administrative burden for producers, users, EFSA, the Commission and the Member States.

([1]) Numbering of Articles in this part refers to the text of the Common Position.
([2]) 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 (OJ L 31, 1.2.2002, p. 1). Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 34).

— *Review of existing authorisations* (amendment 6, 52, 69rev — recital 21, Article 30(1) and (2))

The Council maintains that the additives already authorised shall be transferred into the list of authorised additives after review of the criteria other then safety. However, EFSA is tasked to undergo the re-evaluation of currently authorised food additives with respect to their safety. It is not appropriate to link these two reviews.

— *Definition of food additives and scope of the proposed Regulation*

— *to include in the scope post-harvest plant protection products* (amendment 10 — Article 2(b)): Plant protection products used for post-harvest treatment are subject to Directive 91/414/EEC, which already provides that if a plant protection product falls under the definition of other Community law, the latter will be applicable.

— *to exclude from the scope microbial cultures* (amendment 11 — Article 2(da) new): Some cultures are added to foods towards the end of their manufacture for an intended preservation effect and therefore could be considered to be food additives. For that reason, they should not be excluded from the scope of the proposed Regulation.

— *blood protein not to be considered as an additive* (amendment 16 — Article 3(2)(a)(viii)): At present substances consisting of blood proteins are considered as falling under the scope of Community law on food additives. The Council considers that the exclusion of blood protein as an additive in Article 3(2) is not appropriate.

— *Decisions submitted to the regulatory comitology procedure* (amendment 12, 40, 47 — Articles 2(5), 18(c) introduction, 25(2))

Decisions on whether or not a given substance falls within the scope of the Regulation are of merely interpretative nature. Therefore, they do not fall within the scope of the regulatory comitology procedure with scrutiny.

— *Definitions and exclusions (additional technological effect)* (amendment 15 — Article 3(2)(a)(ii))

The Council considers that the addition of 'an additional technological effect' in Article 3(2)(a)(ii) is too broad and may exclude from the definition substances used as food additives.

— *Food reduced in sugars* (amendment 20, 29 — Articles 3(2)(i), 7(a))

The introduction of this concept into the Regulation would result in an increase in variety of products in which sweeteners may be used and may lead to the increased consumption of such additives, which would not benefit the consumers.

— *Benefits to the consumer* (amendment 24 — Article 6(1)(b))

Amendment 24 provides that one of the conditions for including a food additive into the Community list should be a reasonable technological need in terms of benefits to the consumer. However, Article 6(2) already stipulates that an additive needs to have benefits and advantages for the consumers in order to be included in the Community list. Amendment 24 is therefore not necessary.

— *Explanation of the basis for the final decision* (amendment 28 — Article 6(3a new))

The decision whether or not to include food additives in the Community list is taken through the regulatory procedure with scrutiny on the basis of the proposal from the Commission. These proposals include recitals explaining their background, thus amendment 28 is superfluous.

— *Specific conditions for sweeteners* (amendment 73 — Article 7(b))

The Council considered that the deletion of the sentence would be too restrictive.

— *Additives potentially misleading the consumers (e.g. colors)* (amendment 30 — Article 8(1a new))

The provision in Article 6 concerning general conditions for authorisation of food additives provide that an additive should not mislead the consumer. In addition the Council, in order to define the term 'misleading the consumers' clarified this notion in recital 7.

— *Specifications in the Community lists:*

— *Identification of the additive group* (amendment 33 — Article 10(2)(a)): Article 9 provides that a food additive will be allocated to a functional class. As an additive can fall into several functional classes, the Council could not support such an amendment requiring the identification of all the classes to which an additive can belong.

— *Specification of the substances to which additives can be added* (amendment 33 — Article 10(2)(b)): The amendment is not necessary as enzymes, flavourings and additives are considered as food.

— *Labelling of genetically modified organisms (GMO's)* (amendment 38 and 63 — Article 12)

As mentioned in recital 16, food additives remain subject to the labelling provisions defined in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [1] and in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2] (The labelling of food ingredients, including additives, produced from, containing and consisting of GMO's, is provided for in Articles 12 and 13 of Regulation (EC) No 1829/2003). The Council adopted a prudent approach, not accepting amendments that could interfere with the scope of the horizontal Regulations in force.

— *Labelling* (amendments 43 and 45 — Articles 21(4), 22(3a new))

First of all, the Council considered that only certain information can be provided by the accompanying documents supplied with or prior to the delivery. Secondly, as there are already provisions on the labelling of allergens, which are listed in Annex IIIa of Directive 2000/13/EC, the Council considered that it is not appropriate to go beyond those provisions in this legislative act.

[1] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).
[2] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 34).

IV. **Conclusions**

The Council believes that the Common Position represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation, ensuring a high level of human health and consumer protection.

# COMMON POSITION (EC) No 8/2008

## adopted by the Council on 10 March 2008

## with a view to adopting Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97

**(Text with EEA relevance)**

(2008/C 111 E/03)

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,

Having regard to the Opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

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) Food enzymes other than those used as food additives are not currently regulated or are regulated as processing aids under the legislation of the Member States. Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of food enzymes may hinder their free movement, creating conditions for unequal and unfair competition. It is therefore necessary to adopt Community rules harmonising national provisions relating to the use of enzymes in foods.

(4) This Regulation should only cover enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids (hereinafter referred to as 'food enzymes'). The scope of this Regulation should therefore not extend to enzymes that are not added to food to perform a technological function but are intended for human consumption, such as enzymes for nutritional purposes. Microbial cultures traditionally used in the production of food, such as cheese and wine, and which may incidentally produce enzymes but are not specifically used to produce them should not be considered food enzymes.

(5) Food enzymes used exclusively in the production of food additives falling within the scope of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food additives [3] should be excluded from the scope of this Regulation, since the safety of these foods is already assessed and regulated. However, when these food enzymes are used as such in food, they are covered by this Regulation.

(6) Food enzymes should be approved and used only if they fulfil the criteria laid down in this Regulation. Food enzymes must be safe when used, there must be a technological need for their use and their use must not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. The approval of food enzymes 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.

(7) Some food enzymes are permitted for specific uses, such as in fruit juices and certain similar products and certain lactoproteins intended for human consumption, and for certain authorised oenological practices and processes. The use of such food enzymes should comply with this Regulation and with the specific provisions laid down in the relevant Community legislation. Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human

[1] OJ C 168, 20.7.2007, p. 34.

[2] Opinion of the European Parliament of 10 July 2007 (not yet published in the Official Journal), Council Common Position of 10 March 2008, Position of the European Parliament of … (not yet published in the Official Journal) and Council Decision of …

[3] See page 10 of this Official Journal.

consumption ([1]), Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption ([2]) and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ([3]) should therefore be amended accordingly. Since all food enzymes should be covered by this Regulation, Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([4]) should be amended accordingly.

(8) Food enzymes the use of which is permitted within the Community should appear in a Community list that should clearly describe the enzymes and specify any conditions governing their use, including where necessary information on their function in the final food. This list should be supplemented by specifications, in particular on their origin, including where relevant information about allergenic properties, and purity criteria.

(9) In order to ensure harmonisation, the risk assessment of food enzymes and their inclusion in the Community list should be carried out in accordance with the procedure laid down in Regulation (EC) No …/2008 of the European Parliament and of the Council of … establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([5]).

(10) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([6]), the European Food Safety Authority (hereinafter referred to as the 'Authority') is to be consulted on matters likely to affect public health.

(11) A food enzyme which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([7]) 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 enzyme should be granted under this Regulation.

(12) A food enzyme already included in the Community list under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the authorisation and the specifications under this Regulation, should be submitted for evaluation by the Authority. 'Significantly different' could mean *inter alia* 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, a change in starting materials, or a change in particle size.

(13) Since many food enzymes are already on the Community market, provision should be made to ensure that the switchover to a Community list of food enzymes takes place smoothly and does not disturb the existing food enzyme market. Sufficient time should be allowed for applicants to make available the information necessary for the risk assessment of these products. An initial two-year period should therefore be allowed following the date of application of the implementing measures to be laid down in accordance with Regulation (EC) No …/2008 (*), in order to give applicants sufficient time to submit the information on existing enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period.

(14) In order to ensure fair and equal conditions for all applicants, the Community list should be drawn up in a single step. That list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period.

(15) A significant number of applications is expected to be submitted during the initial two-year period. A lengthy period may therefore be needed before the risk assessment of these has been completed and the Community list is drawn up. In order to ensure equal access to the

([1]) OJ L 10, 12.1.2002, p. 58. Directive as amended by Regulation (EC) No 1182/2007 (OJ L 273, 17.10.2007, p. 1).
([2]) OJ L 237, 26.8.1983, p. 25. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
([3]) OJ L 179, 14.7.1999, p. 1. Regulation as last amended by Regulation (EC) No 1234/2007 (OJ L 299, 16.11.2007, p. 1).
([4]) OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
([5]) See page 1 of this Official Journal.
([6]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 34).
([7]) OJ L 268, 18.10.2003, p. 1.

(*) See page 1 of this Official Journal.

market for new food enzymes after the initial two-year period, a transitional period should be provided for during which food enzymes and food using food enzymes may be placed on the market and used, in accordance with the existing national rules in the Member States, until the Community list has been drawn up.

(16) The food enzymes E 1103 Invertase and E 1105 Lysozyme, that have been authorised as food additives under Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ([1]), and the conditions governing their use should be carried over from Directive 95/2/EC to the Community list when it is drawn up by this Regulation. In addition, Council Regulation (EC) No 1493/1999 authorises the use of urease, beta-glucanase and lysozyme in wine subject to the conditions laid down in Commission Regulation (EC) No 1622/2000 of 24 July 2000 laying down certain detailed rules for implementing Regulation (EC) No 1493/1999 on the common organisation of the market in wine and establishing a Community code of oenological practices and processes ([2]). Those substances are food enzymes and they should fall within the scope of this Regulation. They should therefore also be added to the Community list when it is drawn up for their use in wine in accordance with Regulation (EC) No 1493/1999 and Regulation (EC) No 1622/2000.

(17) Food enzymes remain subject to the general labelling obligations provided for in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([3]) and, as the case may be, in Regulation (EC) No 1829/2003 and in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms ([4]). In addition, specific provisions on the labelling of food enzymes sold as such to the manufacturer or to the consumer should be contained in this Regulation.

(18) Food enzymes are covered by the definition of food in Regulation (EC) No 178/2002 and are therefore, when used in food, required to be indicated as ingredients in the labelling of the food in compliance with Directive 2000/13/EC. Food enzymes should be designated by their technological function in food, followed by the specific name of the food enzyme. However, provision should be made for a derogation from the provisions on labelling in cases where the enzyme performs no technological function in the final product but is present in the foodstuff only as a result of carry-over from one or more of the ingredients of the foodstuff or where it is used as a processing aid. Directive 2000/13/EC should be amended accordingly.

(19) Food enzymes should be kept under continuous observation and should be re-evaluated whenever necessary in the light of changing conditions governing their use and new scientific information.

(20) 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 ([5]).

(21) In particular the Commission should be empowered to adopt appropriate transitional measures. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(22) In order to develop and update Community law on food enzymes in a proportionate and effective way, it is necessary to collect data, share information and coordinate work between Member States. For that purpose, it may be useful to undertake studies to address specific issues with a view to facilitating the decision-making process. It is appropriate that the Community 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 ([6]).

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

(24) Since the objective of this Regulation, namely to lay down Community rules on food enzymes, cannot be sufficiently achieved by the Member States and can therefore, in the interests of market unity and a high level of consumer protection, be better achieved at Community level, the Community may adopt measures, in accordance

([1]) OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2006/52/EC (OJ L 204, 26.7.2006, p. 10).
([2]) OJ L 194, 31.7.2000, p. 1. Regulation as last amended by Regulation (EC) No 1300/2007 (OJ L 289, 7.11.2007, p. 8).
([3]) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).
([4]) OJ L 268, 18.10.2003, p. 24.
([5]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Council Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
([6]) OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1. Regulation as amended by Council Regulation (EC) No 1791/2006.

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 that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**SUBJECT MATTER, SCOPE AND DEFINITIONS**

*Article 1*

**Subject matter**

This Regulation lays down rules on food enzymes used in foods, including such enzymes used as processing aids, to ensure the effective functioning of the internal market and a high level of protection of human health and protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of the environment.

For those purposes, this Regulation provides for:

(a) a Community list of approved food enzymes;

(b) conditions of use of food enzymes in foods;

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

*Article 2*

**Scope**

1. This Regulation shall apply to food enzymes as defined in Article 3.

2. This Regulation shall not apply to food enzymes when and insofar as they are used in the production of:

(a) food additives falling within the scope of Regulation (EC) No …/2008 (*);

(b) processing aids.

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

(a) in specific foods;

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

4. This Regulation shall not apply to microbial cultures that are traditionally used in the production of food and which may incidentally produce enzymes, but which are not specifically used to produce them.

(*) See page 10 of this Official Journal.

*Article 3*

**Definitions**

1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002, Regulation (EC) No 1829/2003 and Regulation (EC) No …/2008 (*) shall apply.

2. The following definitions shall also apply:

(a) 'food enzyme' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms:

  (i) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and

  (ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods;

(b) 'food enzyme preparation' means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

CHAPTER II

**COMMUNITY LIST OF APPROVED FOOD ENZYMES**

*Article 4*

**Community list of food enzymes**

Only food enzymes included in the Community list may be placed on the market as such and used in foods, in accordance with the specifications and conditions of use provided for in Article 7(2).

*Article 5*

**Prohibition of non-compliant food enzymes and/or non-compliant food**

No person shall place on the market a food enzyme or any food in which such a food enzyme has been used if the use of the food enzyme does not comply with this Regulation and its implementing measures.

*Article 6*

**General conditions for inclusion of food enzymes in the Community list**

A food enzyme may be included in the Community list 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 and

(b) there is a reasonable technological need and

(c) its use does not mislead the consumer.

*Article 7*

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

1. A food enzyme which complies with the conditions set out in Article 6 may, in accordance with the procedure referred to in Regulation (EC) No …/2008 (*), be included in the Community list.

2. The entry of a food enzyme in the Community list shall specify:

(a) the name of the food enzyme;

(b) the specifications of the food enzyme, including its origin, purity criteria and any other necessary information;

(c) if necessary, the foods to which the food enzyme may be added;

(d) if necessary, the conditions under which the food enzyme may be used; where appropriate, no maximum level shall be fixed for a food enzyme. In that case, the food enzyme shall be used in accordance with the principle of *quantum satis*;

(e) if appropriate, whether there are any restrictions on the sale of the food enzyme directly to the final consumer;

(f) where necessary, specific requirements in respect of the labelling of food in which the food enzymes have been used in order to ensure that the final consumer is informed of the physical condition of the food or the specific treatment it has undergone.

3. The Community list shall be amended in accordance with the procedure referred to in Regulation (EC) No …/2008 (*).

(*) See page 1 of this Official Journal.

*Article 8*

**Food enzyme falling within the scope of Regulation (EC) No 1829/2003**

A food enzyme falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community list in accordance with this Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.

*Article 9*

**Interpretation decisions**

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 15(2) whether or not:

(a) a given substance meets the definition of food enzyme in Article 3;

(b) a particular food belongs to a category of food in the Community list of food enzymes.

CHAPTER III

**LABELLING**

*Article 10*

**Labelling of food enzymes and food enzyme preparations not intended for sale to the final consumer**

1. Food enzymes and food enzyme preparations not intended for sale to the final consumer, whether sold singly or mixed with each other and/or other food ingredients, as defined in Article 6(4) of Directive 2000/13/EC, may only be marketed with the labelling provided for in Article 11 of this Regulation, which must be easily visible, clearly legible and indelible. The information provided for in Article 11 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 Treaty, stipulate that the information provided for in Article 11 shall be given in one or more of the 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 11*

**General labelling requirements for food enzymes and food enzyme preparations not intended for sale to the final consumer**

1. Where food enzymes and food enzyme preparations not intended for sale to the final consumer are sold singly or mixed with each other and/or other food ingredients, their packaging or containers shall bear the following information:

(a) the name laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme or in the absence of a name, a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused;

(b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;

(c) if necessary, the special conditions of storage and/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 enzyme;

(f) the name or business name and address of the manufacturer, packager or seller;

(g) an indication of the maximum quantity of each component or group of components subject to 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 law; 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 activity of the food enzyme(s);

(j) the date of minimum durability or use-by-date;

(k) where relevant, information on a food enzyme or other substances as referred to in this Article and listed in Annex IIIa to Directive 2000/13/EC.

2. Where food enzymes and/or food enzyme preparations are sold mixed with each other and/or with other food ingredients, their packaging or containers shall bear a list of all ingredients in descending order of their percentage by weight of the total.

3. The packaging or containers of food enzyme preparations shall bear a list of all components 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) 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 the delivery, provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question.

5. By way of derogation from paragraphs 1, 2 and 3, where food enzymes and food enzyme preparations 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 12*

**Labelling of food enzymes and food enzyme preparations intended for sale to the final consumer**

1. Without prejudice to Directive 2000/13/EC, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [1] and Regulation (EC) No 1829/2003, food enzymes and food enzyme preparations 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:

(a) the name laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme or in the absence of a name, a description of the food enzyme that is sufficiently precise to distinguish it from products with which it could be confused;

(b) the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use.

2. For the information provided for in paragraph 1 of this Article, Article 13(2) of Directive 2000/13/EC shall apply accordingly.

[1] OJ L 186, 30.6.1989, p. 21. Directive as last amended by Directive 92/11/EEC (OJ L 65, 11.3.1992, p. 32).

*Article 13*

**Other labelling requirements**

Articles 10 to 12 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 and preparations.

CHAPTER IV

**PROCEDURAL PROVISIONS AND IMPLEMENTATION**

*Article 14*

**Information obligation**

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

2. For a food enzyme already approved under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the European Food Safety Authority (hereinafter referred to as the 'Authority'), a producer or user shall, before marketing the food enzyme, submit to the Commission the necessary data to allow an evaluation of the food enzyme with regard to the modified production method or characteristics to be undertaken by the Authority.

3. A producer or user of a food enzyme shall, at the request of the Commission, inform it of the actual use of the food enzyme. Such information shall be made available to Member States by the Commission.

*Article 15*

**Committee**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

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.

*Article 16*

**Community financing of harmonised policies**

The legal basis for the financing of measures resulting from this Regulation shall be Article 66(1)(c) of Regulation (EC) No 882/2004.

CHAPTER V

**TRANSITIONAL AND FINAL PROVISIONS**

*Article 17*

**Establishment of the Community list of food enzymes**

1. The Community list of food enzymes shall be drawn up on the basis of applications made pursuant to paragraph 2.

2. Interested parties may submit applications for the inclusion of a food enzyme in the Community list.

The deadline for submitting such applications shall be 24 months after the date of application of the implementing measures to be laid down in accordance with Article 9(1) of Regulation (EC) No …/2008 (*).

3. The Commission shall establish a Register of all food enzymes to be considered for inclusion in the Community list in respect of which an application complying with the validity criteria to be laid down in accordance with Article 9(1) of Regulation (EC) No …/2008 (*) has been submitted in accordance with paragraph 2 of this Article (hereinafter referred to as 'the Register'). The Register shall be made available to the public.

The Commission shall submit the applications to the Authority for its opinion.

4. The Community list shall be adopted by the Commission in accordance with the procedure laid down in Regulation (EC) No …/2008 (*), once the Authority has issued an opinion on each food enzyme included in the Register.

However, by way of derogation from that procedure:

(a) Article 5(1) of Regulation (EC) No …/2008 (*) shall not apply to the Authority's adoption of its opinion;

(b) the Commission shall adopt the Community list for the first time after the Authority has delivered its opinion on all the food enzymes listed in the Register.

(*) See page 1 of this Official Journal.

5. If necessary, any appropriate transitional measures for the purposes of this Article which are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(3).

*Article 18*

**Transitional measures**

1. Notwithstanding Articles 7 and 17 of this Regulation, the Community list shall, when drawn up, include the following food enzymes:

(a) E 1103 Invertase and E 1105 Lysozyme, stating the conditions governing their use as specified in Annex I and Part C of Annex III to Directive 95/2/EC;

(b) Urease, beta-glucanase and lysozyme for use in wine in accordance with Regulation (EC) No 1493/1999 and the implementing rules for that Regulation.

2. Food enzymes, food enzyme preparations and food containing food enzymes placed on the market or labelled before … (*) which do not comply with the provisions of Articles 10 to 12 may be marketed until their date of minimum durability or use-by-date.

*Article 19*

**Amendments to Directive 83/417/EEC**

In Directive 83/417/EEC, in Annex I, Section III(d), the indents shall be replaced by the following:

'— rennet meeting the requirements of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (*),

— other milk-coagulating enzymes meeting the requirements of Regulation (EC) No …/2008.

(*) OJ L …'.

*Article 20*

**Amendment to Regulation (EC) No 1493/1999**

In Regulation (EC) No 1493/1999, the following paragraph shall be added to Article 43:

'3. Enzymes and enzymatic preparations used in the authorised oenological practices and processes listed in Annex IV shall meet the requirements of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (*).

(*) OJ L …'.

*Article 21*

**Amendments to Directive 2000/13/EC**

Directive 2000/13/EC is hereby amended as follows:

1. Article 6(4) shall be amended as follows:

(a) point (a) shall be replaced by the following:

'(a) "Ingredient" shall mean any substance, including additives and enzymes, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.';

(b) in point (c)(ii), the introductory word 'additives' shall be replaced by 'additives and enzymes';

(c) in point (c)(iii), the words 'additives or flavouring' shall be replaced by 'additives or enzymes or flavourings';

2. the following indent shall be added to Article 6(6):

'— enzymes other than as referred to in paragraph 4(c)(ii) shall be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name.'.

*Article 22*

**Amendments to Directive 2001/112/EC**

In Directive 2001/112/EC, in Annex I, Section II(2), the fourth, fifth and sixth indents shall be replaced by the following:

'— Pectolytic enzymes meeting the requirements of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 ([1]).

(*) 12 months after the date of entry into force of this Regulation.

— Proteolytic enzymes meeting the requirements of Regulation (EC) No …/2008.

— Amylolytic enzymes meeting the requirements of Regulation (EC) No …/2008.

(1) OJ L …'.

*Article 23*

**Amendment to Regulation (EC) No 258/97**

In Regulation (EC) No 258/97, the following point shall be added to Article 2(1):

'(d) food enzymes falling within the scope of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (1).

(1) OJ L …'.

*Article 24*

**Entry into force**

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

Article 4 shall apply from the date of application of the Community list. Until that date, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes shall continue to apply in the Member States.

Articles 10 to 13 shall apply from … (*).

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*

(*) 12 months after the date of entry into force of this Regulation.

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 28 July 2006, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on food enzymes ([1]). The proposal is based on Article 95 of the Treaty establishing the European Community.

The European Parliament adopted its Opinion at first reading on 10 July 2007 ([2]).

Following the European Parliament's first reading opinion, the Commission submitted an amended proposal on 24 October 2007 ([3]).

On 10 March 2008, the Council adopted its Common Position in accordance with Article 251(2) of the Treaty.

In carrying out its work, the Council also took account of the opinion of the European Economic and Social Committee adopted on 25 April 2007 ([4]).

### II. OBJECTIVE

The proposed Regulation, as part of four proposals designed to overhaul the Community's rules on food improvement agents, introduces for the first time harmonized rules on food enzymes used in food, establishes a Community list of food enzymes and rules on labelling of food enzymes and food enzymes preparations.

The harmonised rules aim to ensure proper functioning of the internal market, including fair practices in food trade, and a high level of protection of human health, of consumer interests and of the environment.

### III. ANALYSIS OF THE COMMON POSITION

#### 1. Introductory remarks

The Common Position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced a number of modifications in the text, some of them inspired by the amendments proposed by the European Parliament. On its own initiative, the Council introduced some of the European Parliament amendments in each of the three sectoral proposals, with a view to harmonising their provisions. The modifications introduced by the Council may be summed up as follows:

— *Preference for a single legal basis:* Article 95 of the Treaty (in line with amendment 35)

According to established case-law ([5]), the legal basis for an act must be determined having regard to its own aim and content. If the examination of a Community measure reveals that it serves a two-fold purpose or that it has a two-fold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the act must be based on a single legal basis, namely that required by the main or predominant purpose or component ([6]). In this case, the Council considered that the agricultural aspects of the proposal are merely incidental while the internal market objective is the main or predominant purpose or component and as such, in line with the case law of the ECJ, it decided to retain Article 95 as the sole legal basis.

([1]) COM(2006) 425 final.
([2]) Doc. 11641/07 CODEC 777.
([3]) COM(2007) 670 final.
([4]) OJ C 168, 20.7.2007, p. 29.
([5]) See Case 45/86, *Commission* v *Council* [1987] ECR 1493, paragraph 11; Case C-300/89, *Commission* v *Council* (*Titanium Dioxide*) [1991] ECR I-2867, paragraph 10; Case C-268/94, *Portugal* v *Council* [1996] ECR I-6177, paragraph 22; and Case C-176/03, *Commission* v *Council* [2005] ECR I-0000, paragraph 45.
([6]) See Case C-36/98, *Spain* v *Council* [2001] ECR I-779, paragraph 59; Case C-211/01, *Commission* v *Council* [2003] ECR I-8913, paragraph 39; and Case C-338/01, *Commission* v *Council* [2004] ECR I-4829, paragraph 55.

— *Misleading the consumer* (in line with amendment 4)

The Council included, in recital 6, elements integrating the notion of misleading the consumer.

— *Protection of the environment*

The Council considered that, apart from scientific evidence, the authorisation of the food enzymes should also take into account other relevant factors, such as the protection of the environment. The Council also included a reference to the protection of the environment among the objectives of the Regulation;

— *Regulatory comitology procedure with scrutiny* (in line with amendments 28 and 30)

The Council adapted the proposal to the new comitology procedure rules, requiring the regulatory procedure with scrutiny to be applied for the adoption of measures supplementing the Regulation.

— *Submission of the interpretation decisions to the regulatory comitology procedure*

The Council regrouped all the provisions on interpretation decisions into a new single Article, and, as they would not supplement the proposed Regulation, made them subject to the regulatory comitology procedure without scrutiny.

— *Transitional measures for products already on the market* (in line with amendment 36)

The Council provided for a 1 year transition period from the date of entry into force of the proposed Regulation. Foods lawfully placed on the market or labelled during this year may be marketed until their date of minimum durability or use-by-date.

— *Provision prohibiting the placing on the market of non-compliant food enzymes* (in line with amendment 15)

For reasons of clarity, legal certainty and proper functioning of the market, the Council inserted an Article on the prohibition of placing non-compliant food enzymes on the market. This is consistent with the proposals on flavourings and on food additives.

— *Authorisation of enzymes falling 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 ([1]) (in line with Amendments 7 and 34 (second part))

The Council agrees that the two authorisation procedures for any substance can be carried out simultaneously. The Council subjected that principle to some drafting changes in order to make the provision more compatible with Regulation (EC) No 1829/2003.

— *Labelling*

The Council streamlined and reinforced the labelling provisions, respecting the distinction between 'business to business' labelling and labelling requirements for products intended for the sale to the final consumer. Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are in line with amendments 21 (first and second parts), 22, 23, 24, 25, 27.

The Commission has accepted the Common Position agreed by the Council.

([1]) OJ L 268, 18.10.2003, p. 1.

2. **The amendments of the European Parliament**

In its Plenary vote on 10 July 2007, the European Parliament adopted 33 amendments to the proposal.

In its Common Position, the Council incorporated, in full or in principle, 21 amendments.

(a) ***Amendments incorporated in the Common Position***

In addition to amendments mentioned in part 1 above, the Common Position incorporates, in full or in principle, other European Parliament's first reading amendments, aimed at improving or clarifying the text of the proposal, in particular, amendments 10, 12 (first part), 14 (third and fifth parts), 16 (second part), 20, 31, 34 (first part).

(b) ***Amendments not introduced*** ([1])

The Council was not able to incorporate all the amendments, for following reasons:

— *Enzymes added to food for nutritional purposes and digestive aids* (amendment 3, 11, and 12 — recital 4, Articles 2(2)(c new), 2(4))

The Council considers that there is no need to mention explicitly that the enzymes intended for direct human consumption (such as enzymes used for nutritional purposes or as digestive aids) are excluded from the scope of the proposed Regulation. In fact, the scope of the proposed Regulation only includes enzymes added to food to perform a technological function.

With regard to amendment 12 (first part), the Council emphasises the exclusion of cultures that are 'traditionally' used in the production of food (e.g. cheese, wine, etc.) and which may incidentally produce enzymes. In reality, the deletion of the word 'traditionally' would enlarge the scope of the exclusion and could result in cultures, which are added to food for the technological function of the enzyme that they produce, (e.g. preservation) not being regulated.

— *Enzymes having a benefit for the consumer* (amendments 4, 16 (third part) — recital 6, Article 6(c))

The proposed Regulation covers enzymes that are added to food for a technological function and hence the use of enzymes in most cases improves the environmental performance of the production process which brings an indirect rather than direct benefit for the consumer.

— *Genetically modified organisms (GMO's)*

(a) *Labelling of GMO* (amendment 14 (fourth part), 32, 37 (point ba), 38 — Articles 3(3 new), 13, 21(2) and recital 11)

As mentioned in recital 17, the food enzymes remain subject to the labelling provisions defined in Directive 2000/13 of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([2]) and in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([3]). The Council adopted a prudent approach, not accepting amendments that could interfere with the scope of the horizontal Regulations in force.

([1]) Numbering of Articles in this part refers to the text of the Common Position.
([2]) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).
([3]) OJ L 268, 18.10.2003, p. 1.

(b) *Unique identifier as defined in Regulation (EC) No 1830/2003* (amendment 18 — Article 7(2)(b))

On account of proportionality and simplification, the Council deleted the reference requiring that the enzyme specification in the Community list of food enzymes, would indicate the unique identifier of GMOs as defined in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability of food and feed products produced from genetically modified organisms ([1]). Where relevant, the provisions in Article 6(2)(b) would be sufficient to cover this information. Thus amendment 18 is superfluous.

— *Requirements already addressed in the Regulation (EC) No 178/2002 on general provisions and requirements of food law* (amendments 6, 8, 16)

(a) *Precautionary principle* (amendments 6, 16 (first part) — recital 9 and Article 6)

The precautionary principle is one of the general principles underlying the general food law ([2]). Consequently, it applies to the proposed Regulation with no need for a specific reference to it. Moreover, in the risk analyses framework, the precautionary principle can only be taken into account the context of risk management, never in the risk assessment phase, as suggested by the European Parliament.

(b) *Publication of the opinions of the European Food Safety Authority (EFSA)* (amendment 8 — recital 14)

Publication of the opinions of EFSA is already provided for by Article 38(1)(b) of Regulation (EC) No 178/2002.

— *Re-evaluation every 10 years* (amendment 9 — recital 19)

For the Council, a system of continuous observation and of re-evaluation whenever necessary in the light of changing conditions and of new scientific information, will guarantee food safety. An additional review every 10 years would represent an unnecessary administrative burden for producers, users, EFSA, the Commission and the Member States.

— *Decisions submitted to the comitology procedure without scrutiny* (amendment 13 — Article 9(a)

Decisions on whether or not a given substance falls within the scope of the proposed Regulation are of interpretative nature and will not supplement the Regulation. Therefore, they would not fall within the scope of the regulatory comitology procedure with scrutiny.

— *Definition of enzymes* (amendment 14, 17 — Article 3(2), 7(2)(a))

The subject of this Regulation is 'food enzymes', which is defined. An additional definition of 'enzymes' did not seem to be essential.

— *Specifications of the entries of food enzymes in the list* (amendment 19 — Article (7)(2) (c) to (f))

In Article 7(2)(c) to (e) the Council preferred to provide for certain specifications only if necessary and not more often than needed.

([1]) OJ L 268, 18.10.2003, p. 24.
([2]) 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 (OJ L 31, 1.2.2002, p. 1). Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 34).

In Article 7(2)(f), the Council considers that the words 'where necessary' should be kept. The need for such a labelling concerns only a restricted number of cases, where the physical condition of the food has been changed due to the use of food enzyme. Only in this cases, the consumer has to be informed of the fact.

— *Labelling*

Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are in line with some of the amendments related to Articles 10 to 13. However, the Council could not accept some amendments proposed by the European Parliament, as the Council considers that the provisions are either already incorporated or form part of other specific Community legislation.

Amendment 21 (third part) requires the inclusion in the label of information on the side-effects of the use of enzymes in excessive quantities. However, EFSA already took such information into account during the evaluation procedure and, if applicable, the authorisation for the food enzyme would be subject to appropriate conditions of use.

Amendments 32 and 37 (last part) are incompatible with Directive 2000/13/EC, which excludes from labelling substances used as processing aids which are present in the final product only as technically unavoidable residue and which do not have any technological effect on the food.

Information on the technological function of the enzyme, required by amendment 37 (second part), would not be useful to non-specialists.

— *'Fast track' procedure for enzymes currently on the market* (amendment 29 — Article 17(4)(c new))

The Council considers that all food enzymes should undergo the same safety evaluation procedure, by EFSA, the Community risk assessment body.

Amendment 2 is of editorial nature and has not been introduced.

## IV. **Conclusions**

The Council believes that the Common Position represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation, ensuring a high level of human health and consumer protection.

# COMMON POSITION (EC) No 9/2008

## adopted by the Council on 10 March 2008

## with a view to adopting Regulation (EC) No …/2008 of the European Parliament and of the Council of … on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC

**(Text with EEA relevance)**

(2008/C 111 E/04)

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,

Having regard to the Opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([3]) needs to be updated in the light of technical and scientific developments. In the interests of clarity and efficiency Directive 88/388/EEC should be replaced by this Regulation.

(2) Council Decision 88/389/EEC of 22 June 1988 on the establishment, by the Commission, of an inventory of the source materials and substances used in the preparation of flavourings ([4]) provides for the establishment of that inventory within 24 months of its adoption. That Decision is now obsolete and should be repealed.

(3) Commission Directive 91/71/EEC of 16 January 1991 completing Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([5]) lays down rules on the labelling of flavourings. Those rules are replaced by this Regulation and the Directive should now be repealed.

(4) 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.

(5) In order to protect human health, this Regulation should cover flavourings, source materials for flavourings and foods containing flavourings. It should also cover certain food ingredients with flavouring properties which are added to food for the main purpose of adding flavour and which contribute significantly to the presence in food of certain naturally occurring undesirable substances (hereinafter referred to as 'food ingredients with flavouring properties'), their source material and foods containing them.

(6) Raw foodstuffs which have not undergone any processing treatment and non-compound foodstuffs such as spices, herbs, teas and infusions (e.g. fruit or herbal tea) as well as mixtures of spices and/or herbs, mixtures of tea and mixtures for infusion, as long as they are consumed as such and/or not added to the food, do not fall within the scope of this Regulation.

(7) Flavourings and food ingredients with flavouring properties should only be used if they fulfil the criteria laid down in this Regulation. They must be safe when used, and certain flavourings should, therefore, undergo a risk assessment before they can be permitted in food. Their use must not mislead the consumer and their presence in food should, therefore, always be indicated by appropriate labelling. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. The approval of flavourings 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.

(8) Since 1999, the Scientific Committee on Food and subsequently the European Food Safety Authority (hereinafter referred to as 'the Authority') established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down

([1]) OJ C 168, 20.7.2007, p. 34.
([2]) Opinion of the European Parliament of 10 July 2007 (not yet published in the Official Journal), Council Common Position of 10 March 2008, Position of the European Parliament of … (not yet published in the Official Journal) and Council Decision of …
([3]) OJ L 184, 15.7.1988, p. 61. 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).
([4]) OJ L 184, 15.7.1988, p. 67.
([5]) OJ L 42, 15.2.1991, p. 25.

procedures in matters of food safety ([1]) have expressed opinions on a number of substances occurring naturally in source materials for flavourings and food ingredients with flavouring properties which, according to the Committee of Experts on Flavouring Substances of the Council of Europe, raise toxicological concern. Substances for which the toxicological concern was confirmed by the Scientific Committee on Food should be regarded as undesirable substances which should not be added as such to food.

(9) Due to their natural occurrence in plants, undesirable substances might be present in flavouring preparations and food ingredients with flavouring properties. The plants are used traditionally as food or food ingredients. Appropriate maximum levels should be established for the presence of these undesirable substances in foods which contribute most to the human intake of these substances, taking into account both the need to protect human health and their unavoidable presence in traditional foods.

(10) Maximum levels for certain naturally occurring undesirable substances should focus on the food or food categories which contribute most to dietary intake. This would allow Member States to organise controls on a risk basis in line with 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 ([2]). Food producers are however obliged to take into account the presence of these substances when using food ingredients with flavouring properties and/or flavourings for preparation of all food to ensure that food which is not safe is not placed on the market.

(11) Provisions should be established at Community level in order to prohibit, or restrict the use of, certain plant, animal, microbiological or mineral materials which raise concern for human health in the production of flavourings and food ingredients with flavouring properties and their applications in food production.

(12) Risk assessments should be carried out by the Authority.

(13) In order to ensure harmonisation, the risk assessment and approval of flavourings and source materials that need to undergo an evaluation should be carried out in accordance with the procedure laid down in Regulation (EC) No …/2008 of … establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([3]).

(14) Flavouring substances are defined chemical substances, which include flavouring substances obtained by chemical synthesis or isolated using chemical processes, and natural flavouring substances. An evaluation programme of flavouring substances is ongoing in accordance with Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs ([4]). Under that Regulation a list of flavouring substances is to be adopted within five years of adoption of that programme. A new deadline should be set for the adoption of that list. That list will be proposed for inclusion in the list referred to in Article 2(1) of Regulation (EC) No …/2008 (*).

(15) Flavouring preparations are flavourings other than defined chemical substances obtained from materials of vegetable, animal or microbiological origin, by appropriate physical, enzymatic or microbiological processes, either in the raw state of the material or after processing for human consumption. Flavouring preparations produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the safety of flavouring preparations produced from non-food material should be evaluated and approved.

(16) Regulation (EC) No 178/2002 defines food as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. Materials of vegetable, animal or microbiological origin, for which it can be sufficiently demonstrated that they have hitherto been used for the production of flavourings, are considered to be food materials for this purpose, even though some of these source materials, such as rose wood and strawberry leaves, may not have been used for food as such. They do not need to be evaluated.

(17) Likewise, thermal process flavourings produced from food under specified conditions need not undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However,

([1]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).
([2]) OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1. Regulation as amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).
([3]) See page 1 of this Official Journal.
([4]) OJ L 299, 23.11.1996, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.
(*) See page 1 of this Official Journal.

the safety of thermal process flavourings produced from non-food material or not complying with certain conditions of production should be evaluated and approved.

(18) Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods [1] lays down a procedure for the safety assessment and approval of smoke flavourings and aims to establish a list of primary smoke condensates and primary tar fractions the use of which is authorised to the exclusion of all others.

(19) Flavour precursors such as carbohydrates, oligo-peptides and amino acids impart flavour to food by chemical reactions which occur during food processing. Flavour precursors produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the safety of flavour precursors produced from non-food material should be evaluated and approved.

(20) Other flavourings which do not fall under the definitions of the previously mentioned flavourings may be used in and on foods after they have undergone an evaluation and approval procedure. An example could be flavourings which are obtained by heating oil or fat to an extremely high temperature for a very short period of time, resulting in a grill-like flavour.

(21) Material of vegetable, animal, microbiological or mineral origin other than food may only be authorised for the production of flavourings after its safety has been evaluated scientifically. It might be necessary to authorise the use of only certain parts of the material or to set conditions of use.

(22) Flavourings can contain food additives as permitted by Regulation (EC) No …/2008 of the European Parliament and of the Council of … on food additives [2] and/or other food ingredients for technological purposes such as for their storage, standardisation, dilution or dissolution and stabilisation.

(23) A flavouring or a source material 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 [3] 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 flavouring or source material should be granted under this Regulation.

(24) Flavourings remain subject to the general labelling obligations provided for in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [4] and, as the case may be, in Regulations (EC) No 1829/2003 and Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms [5]. In addition, specific provisions on the labelling of flavourings sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

(25) Flavouring substances or flavouring preparations should only be labelled as 'natural' if they comply with certain criteria which ensure that consumers are not misled.

(26) Specific information requirements should ensure that consumers are not misled concerning the source material used for the production of natural flavourings. In particular, if the term natural is used to describe a flavour, the flavouring components used should be entirely of natural origin. In addition, the source of the flavourings should be labelled, except when the source materials referred to would not be recognised in the flavour or taste of the food. If a source is mentioned, at least 95 % of the flavouring component should be obtained from the material referred to. The other maximum 5 % can only be used for standardisation or to give a, for example, more fresh, pungent, ripe or green note to the flavouring. When less than 95 % of the flavouring component derived from the source referred to has been used and the flavour of the source can still be recognised, the source should be revealed together with a statement that other natural flavourings have been added, for example cacao extract in which other natural flavourings have been added to impart a banana note. When a source material is claimed in the description of natural flavourings, the fraction of the flavouring component other than that derived from this particular source should not reproduce or imitate the flavour of the source referred to.

[1] OJ L 309, 26.11.2003, p. 1.
[2] See page 10 of this Official Journal.
[3] OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).
[4] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Commission Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).
[5] OJ L 268, 18.10.2003, p. 24.

(27) Consumers should be informed if the smoky taste of a particular food is due to the addition of smoke flavourings. In accordance with Directive 2000/13/EC, the labelling should not confuse the consumer as to whether the product is smoked conventionally with fresh smoke or treated with smoke flavourings. Directive 2000/13/EC needs to be adapted to the definitions of flavourings, smoke flavourings and the term 'natural' for the description of flavourings laid down in this Regulation.

(28) For the evaluation of the safety of flavouring substances for human health, information on the consumption and use of flavouring substances is crucial. The amounts of flavouring substances added to food should therefore be checked on a regular basis.

(29) 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 ([1]).

(30) In particular the Commission should be empowered to amend the Annexes to this Regulation and to adopt appropriate transitional measures regarding the establishment of the Community list. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(31) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures described in Article 8(2) and amendments to Annexes II to V to this Regulation.

(32) Annexes II to V to this Regulation should be adapted as necessary to scientific and technical progress, taking into account the information provided by producers and users of flavourings and/or resulting from the monitoring and controls by the Member States.

(33) In order to develop and update Community law on flavourings in a proportionate and effective way, it is necessary to collect data, share information and coordinate work between Member States. For that purpose, it may be useful to undertake studies to address specific issues with a view to facilitating the decision-making process. It is appropriate that the Community finance such studies as part of its budgetary procedure. The financing of such measures is covered by Regulation (EC) No 882/2004.

(34) Pending the establishment of the Community list, provision should be made for the evaluation and approval of flavouring substances which are not covered by the evaluation programme provided for in Regulation (EC) No 2232/96. A transitional regime should therefore be laid down. Under that regime such flavouring substances should be evaluated and approved in accordance with the procedure laid down in Regulation (EC) No …/2008 (*). However, the time periods provided for in that Regulation for the adoption by the Authority of its opinion and for the submission by the Commission to the Standing Committee on the Food Chain and Animal Health of a draft Regulation updating the Community list should not apply, because priority should be given to the ongoing evaluation programme.

(35) Since the objective of this Regulation, namely to lay down Community rules on the use of flavourings and certain food ingredients with flavouring properties in and on foods, cannot be sufficiently achieved by the Member States and can therefore, in the interests of market unity and a high level of consumer protection, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiary 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 that objective.

(36) Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks ([2]) and Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails ([3]) need to be adapted to certain new definitions laid down in this Regulation.

(37) Regulations (EEC) No 1576/89, (EEC) No 1601/91 and (EC) No 2232/96 and Directive 2000/13/EC should be amended accordingly,

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(*) See page 1 of this Official Journal.

([2]) OJ L 160, 12.6.1989, p. 1. Regulation as last amended by the 2005 Act of Accession.

([3]) OJ L 149, 14.6.1991, p. 1. Regulation as last amended by the 2005 Act of Accession.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**SUBJECT MATTER, SCOPE AND DEFINITIONS**

*Article 1*

**Subject matter**

This Regulation lays down rules on flavourings and food ingredients with flavouring properties for use in and on foods to 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 into account, where appropriate, the protection of the environment.

For those purposes, this Regulation provides for:

(a) a Community list of flavourings and source materials approved for use in and on foods, set out in Annex I (hereinafter referred to as the 'Community list');

(b) conditions of use of flavourings and food ingredients with flavouring properties in and on foods;

(c) rules on the labelling of flavourings.

*Article 2*

**Scope**

1. This Regulation shall apply to:

(a) flavourings which are used or intended to be used in or on foods, without prejudice to more specific provisions laid down in Regulation (EC) No 2065/2003;

(b) food ingredients with flavouring properties;

(c) food containing flavourings and/or food ingredients with flavouring properties;

(d) source materials for flavourings and/or source materials for food ingredients with flavouring properties.

2. This Regulation shall not apply to:

(a) substances which have exclusively a sweet, sour or salty taste;

(b) raw foods;

(c) non-compound foods and mixtures of spices and/or herbs, mixtures of tea and mixtures for infusion as such as long as they have not been used as food ingredients.

*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. For the purposes of this Regulation, the following definitions shall also apply:

(a) 'flavourings' shall mean products:

(i) not intended to be consumed as such, which are added to food in order to impart odour and/or taste;

(ii) made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof;

(b) 'flavouring substance' shall mean a defined chemical substance with flavouring properties;

(c) 'natural flavouring substance' shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;

(d) 'flavouring preparation' shall mean a product, other than a flavouring substance, obtained from:

(i) food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II;

and/or

(ii) material of vegetable, animal or microbiological origin, other than food, by appropriate physical, enzymatic or microbiological processes, the material being taken as such or prepared by one or more of the traditional food preparation processes listed in Annex II;

(e) 'thermal process flavouring' shall mean a product obtained after heat treatment from a mixture of ingredients not necessarily having flavouring properties themselves, of which at least one contains nitrogen (amino) and another is a reducing sugar; the ingredients for the production of thermal process flavourings may be:

(i) food;

and/or

(ii) source material other than food;

(f) 'smoke flavouring' shall mean a product obtained by fractionation and purification of a condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived smoke flavourings as defined in points (1), (2) and (4) of Article 3 of Regulation (EC) No 2065/2003;

(g) 'flavour precursor' shall mean a product, not necessarily having flavouring properties itself, intentionally added to food for the sole purpose of producing flavour by breaking down or reacting with other components during food processing; it may be obtained from:

(i) food;

and/or

(ii) source material other than food;

(h) 'other flavouring' shall mean a flavouring added or intended to be added to food in order to impart odour and/or taste and which does not fall under definitions (b) to (g);

(i) 'food ingredient with flavouring properties' shall mean a food ingredient other than flavourings which may be added to food for the main purpose of adding flavour to it or modifying its flavour and which contributes significantly to the presence in food of certain naturally occurring undesirable substances;

(j) 'source material' shall mean material of vegetable, animal, microbiological or mineral origin from which flavourings or food ingredients with flavouring properties are produced; it may be:

(i) food;

or

(ii) source material other than food;

(k) 'appropriate physical process' shall mean a physical process which does not intentionally modify the chemical nature of the components of the flavouring and does not involve, *inter alia*, the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.

3. For the purpose of the definitions listed in paragraph 2(d), (e), (g) and (j), source materials for which hitherto there is significant evidence of use for the production of flavourings shall be considered as food for the purpose of this Regulation.

4. Flavourings may contain food additives as permitted by Regulation (EC) No …/2008 (*) and/or other food ingredients incorporated for technological purposes.

CHAPTER II

## CONDITIONS FOR USE OF FLAVOURINGS, FOOD INGREDIENTS WITH FLAVOURING PROPERTIES AND SOURCE MATERIALS

*Article 4*

### General conditions for use of flavourings or food ingredients with flavouring properties

Only flavourings or food ingredients with flavouring properties which meet the following conditions may be used in or on foods:

(a) they do not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer; and

(b) their use does not mislead the consumer.

*Article 5*

### Prohibition of non-compliant flavourings and/or non-compliant food

No person shall place on the market a flavouring or any food in which such a flavouring and/or food ingredients with flavouring properties are present if their use does not comply with this Regulation.

*Article 6*

### Presence of certain substances

1. Substances listed in Part A of Annex III shall not be added as such to food.

2. Without prejudice to Regulation (EC) No 1576/89, maximum levels of certain substances, naturally present in flavourings and/or food ingredients with flavouring properties, in the compound foods listed in Part B of Annex III shall not be exceeded as a result of the use of flavourings and/or food ingredients with flavouring properties in and on those foods. The maximum levels of the substances set out in Annex III shall apply to foods as marketed, unless otherwise stated. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted, the maximum levels shall apply to the food as reconstituted according to the instructions on the label, taking into account the minimum dilution factor.

3. Detailed rules for the implementation of paragraph 2 may be adopted in accordance with the regulatory procedure referred to in Article 21(2), following the opinion of the European Food Safety Authority (hereinafter referred to as the 'Authority'), where necessary.

*Article 7*

### Use of certain source materials

1. Source materials listed in Part A of Annex IV shall not be used for the production of flavourings and/or food ingredients with flavouring properties.

(*) See page 10 of this Official Journal.

2. Flavourings and/or food ingredients with flavouring properties produced from source materials listed in Part B of Annex IV may be used only under the conditions indicated in that Annex.

*Article 8*

**Flavourings and food ingredients with flavouring properties for which evaluation and approval are not required**

1. The following flavourings and food ingredients with flavouring properties may be used in or on foods without an evaluation and approval under this Regulation, provided that they comply with Article 4:

(a) flavouring preparations referred to in Article 3(2)(d)(i);

(b) thermal process flavourings referred to in Article 3(2)(e)(i) which comply with the conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings set out in Annex V;

(c) flavour precursors referred to in Article 3(2)(g)(i);

(d) food ingredients with flavouring properties.

2. Notwithstanding paragraph 1, if the Commission, a Member State or the Authority expresses doubts concerning the safety of a flavouring or food ingredient with flavouring properties referred to in paragraph 1, a risk assessment of such flavouring or food ingredient with flavouring properties shall be carried out by the Authority. Articles 4 to 6 of Regulation (EC) No …/2008 (*) shall then apply *mutatis mutandis*. If necessary, the Commission shall adopt measures, following the opinion of the Authority, which are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it, in accordance with the regulatory procedure with scrutiny referred to in Article 21(3). Such measures shall be laid down in Annexes III, IV and/or V where appropriate. On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 21(4).

CHAPTER III

**COMMUNITY LIST OF FLAVOURINGS AND SOURCE MATERIALS APPROVED FOR USE IN OR ON FOODS**

*Article 9*

**Flavourings and source materials for which an evaluation and approval is required**

This Chapter shall apply to:

(a) flavouring substances;

(b) flavouring preparations referred to in Article 3(2)(d)(ii);

(c) thermal process flavourings obtained by heating ingredients which fall partially or totally within Article 3(2)(e)(ii) and/or for which the conditions for the production of thermal process flavourings and/or the maximum levels for certain undesirable substances set out in Annex V are not met;

(d) flavour precursors referred to in Article 3(2)(g)(ii);

(e) other flavourings referred to in Article 3(2)(h);

(f) source materials other than food referred to in Article 3(2)(j)(ii).

*Article 10*

**Community list of flavourings and source materials**

Of the flavourings and source materials referred to in Article 9, only those included in the Community list may be placed on the market as such and used in or on foods under the conditions of use specified therein, where applicable.

*Article 11*

**Inclusion of flavourings and source materials in the Community list**

1. A flavouring or source material may be included in the Community list, in accordance with the procedure laid down by Regulation (EC) No …/2008 (*), only if it complies with the conditions set out in Article 4 of this Regulation.

2. The entry for a flavouring or source material in the Community list shall specify:

(a) the identification of the flavouring or the source material approved;

(b) where necessary, the conditions under which the flavouring may be used.

3. The Community list shall be amended in accordance with the procedure referred to in Regulation (EC) No …/2008 (*).

*Article 12*

**Flavourings or source materials falling within the scope of Regulation (EC) No 1829/2003**

A flavouring or source material falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community list in Annex I in accordance with this Regulation only when it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003.

(*) See page 1 of this Official Journal.

*Article 13*

**Interpretation decisions**

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 21(2):

(a) whether or not a given substance or mixture of substances, material or type of food falls within the categories listed in Article 2(1);

(b) to which specific category, defined in Article 3(2)(b) to (j), a given substance belongs;

(c) whether or not a particular product belongs to a food category or is a food referred to in Annex I or Annex III, Part B.

CHAPTER IV

**LABELLING**

*Article 14*

**Labelling of flavourings not intended for sale to the final consumer**

1. Flavourings not intended for sale to the final consumer may only be marketed with the labelling provided for in Articles 15 and 16, which must be easily visible, clearly legible and indelible. The information provided for in Article 15 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 Treaty, stipulate that the information provided for in Article 15 shall be given in one or more of the 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 15*

**General labelling requirements for flavourings not intended for sale to the final consumer**

1. Where flavourings not intended for sale to the final consumer are sold singly or mixed with each other and/or with other food ingredients and/or with other substances added to them in accordance with Article 3(4), their packaging or containers shall bear the following information:

(a) the sales description: either the word 'flavouring' or a more specific name or description of the flavouring;

(b) the statement either 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use;

(c) if necessary, the special conditions for storage and/or use;

(d) a mark identifying the batch or lot;

(e) in descending order of weight, a list of:

(i) the categories of flavourings present; and

(ii) the names of each of the other substances or materials in the product or, where appropriate, their E-number;

(f) the name or business name and address of the manufacturer, packager or seller;

(g) an indication of the maximum quantity of each component or group of components subject to 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 law;

(h) the net quantity;

(i) a date of minimum durability or use-by-date;

(j) where relevant, information on a flavouring or other substances referred to in this Article 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 (e) and (g) 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 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question.

3. By way of derogation from paragraph 1, where flavourings 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 16*

**Specific requirements for use of the term 'natural'**

1. If the term 'natural' is used to describe a flavouring in the sales description referred to in Article 15(1)(a) the provisions of paragraphs 2 to 6 shall apply.

2. The term 'natural' for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances.

3. The term 'natural flavouring substance(s)' may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances.

4. The term 'natural' may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95 % by w/w from the source material referred to. The maximum of 5 % (w/w) of the flavouring component derived from other source materials shall not reproduce the flavour of the source material referred to.

The description shall read 'natural (food(s) or food category or source(s)) flavouring'.

5. 'Natural (food(s) or food category or source(s)) flavouring with other natural flavourings' may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.

6. The term 'natural flavouring' may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

*Article 17*

**Labelling of flavourings intended for sale to the final consumer**

1. Without prejudice to Directive 2000/13/EC, Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs [1] and Regulation (EC) No 1829/2003, flavourings sold singly or mixed with each other and/or with other food ingredients and/or to which other substances are added and which are intended for sale to the final consumer may be marketed only if their packaging contains the statement either 'for food' or 'restricted use in food' or a more specific reference to their intended food use, which must be easily visible, clearly legible and indelible.

2. If the term 'natural' is used to describe a flavouring in the sales description referred to in Article 15(1)(a), Article 16 shall apply.

*Article 18*

**Other labelling requirements**

Articles 14 to 17 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.

[1] OJ L 186, 30.6.1989, p. 21. Directive as last amended by Directive 92/11/EEC (OJ L 65, 11.3.1992, p. 32).

CHAPTER V

**PROCEDURAL PROVISIONS AND IMPLEMENTATION**

*Article 19*

**Reporting by the food business operators**

1. A producer or user of a flavouring substance, or the representative of such producer or user, shall, at the request of the Commission, inform it of the amount of the substance added to foods in the Community in a period of 12 months as well as the use levels for specific food categories in the Community. Such information shall be made available to Member States by the Commission.

2. Where applicable, for a flavouring 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, a producer or user shall, before marketing the flavouring, submit to the Commission the necessary data to allow an evaluation of the flavouring to be undertaken by the Authority with regard to the modified production method or characteristics.

3. A producer or user of flavourings and/or source materials shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the flavouring and/or source materials.

4. Detailed rules for the implementation of paragraph 1 shall be adopted in accordance with the regulatory procedure referred to in Article 21(2).

*Article 20*

**Monitoring and reporting by the Member States**

1. Member States shall establish systems to monitor the consumption and use of flavourings set out in the Community list and the consumption of the substances listed in Annex III on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to the Authority.

2. After the Authority has been consulted, a common methodology for the gathering by Member States of information on the consumption and use of flavourings set out in the Community list and of the substances listed in Annex III shall be adopted in accordance with the regulatory procedure referred to in Article 21(2) by … (*).

(*) Two years after the entry into force of this Regulation.

*Article 21*

**Committee**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

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.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 22*

**Amendments to Annexes II to V**

Amendments to Annexes II to V to this Regulation to reflect scientific and technical progress 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 21(3), following the opinion of the Authority, where necessary.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 21(4).

*Article 23*

**Community financing of harmonised policies**

The legal basis for the financing of measures resulting from this Regulation shall be Article 66(1)(c) of Regulation (EC) No 882/2004.

CHAPTER VI

**TRANSITIONAL AND FINAL PROVISIONS**

*Article 24*

**Repeals**

1. Directive 88/388/EEC, Decision 88/389/EEC and Directive 91/71/EEC shall be repealed from … (*).

2. Regulation (EC) No 2232/96 shall be repealed from the date of application of the list referred to in Article 2(2) of that Regulation.

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

(*) Two years after the entry into force of this Regulation.

*Article 25*

**Introduction of the list of flavouring substances into the Community list of flavourings and source materials and transitional regime**

1. The Community list shall be established by introducing the list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 into Annex I to this Regulation at the time of its adoption.

2. Pending the establishment of the Community list, Regulation (EC) No …/2008 (**) shall apply for the evaluation and approval of flavouring substances which are not covered by the evaluation programme provided for in Article 4 of Regulation (EC) No 2232/96.

By way of derogation from that procedure, the periods of six months and nine months referred to in Article 5(1) and Article 7 of Regulation (EC) No …/2008 (**) shall not apply to such evaluation and approval.

3. Any appropriate transitional measures which are designed to amend non-essential elements of this Regulation, *inter alia* by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).

*Article 26*

**Amendment to Regulation (EEC) No 1576/89**

Regulation (EEC) No 1576/89 is hereby amended as follows:

1. Article 1(4)(m) shall be amended as follows:

(a) In point (1)(a), the second subparagraph shall be replaced by the following:

'Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1575/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (*), and/or aromatic plants or parts of aromatic plants may be used in addition, but the organoleptic characteristics of juniper must be discernible, even if they are sometimes attenuated.

(*) OJ L …'.

(b) Point 2(a) shall be replaced by the following:

'The drink may be called "*gin*" if it is produced by flavouring organoleptically suitable ethyl alcohol of agricultural origin with flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No …/2008 (***) and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation so that the taste is predominantly that of juniper.'.

(**) See page 1 of this Official Journal.
(***) This Regulation.

(c) In point 2(b), the first subparagraph shall be replaced by the following:

'The drink may be called "distilled *gin*" if it is produced solely by redistilling organoleptically suitable ethyl alcohol of agricultural origin of an appropriate quality with an initial alcoholic strength of at least 96 % vol. in stills traditionally used for *gin*, in the presence of juniper berries and of other natural botanicals provided that the juniper taste is predominant. The term "distilled *gin*" may also apply to a mixture of the product of such distillation and ethyl alcohol of agricultural origin with the same composition, purity and alcoholic strength. Flavouring substances and/or flavouring preparations, both of which are specified in (a), may also be used to flavour distilled *gin*. *London gin* is a type of distilled *gin*.'.

2. In Article 1(4)(n)(1), the second subparagraph shall be replaced by the following:

'Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No …/2008 (*) and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation may additionally be used but there must be a predominant taste of caraway.'.

3. In Article 1(4)(p), the first subparagraph shall be replaced by the following:

'Spirit drinks with a predominantly bitter taste produced by flavouring ethyl alcohol of agricultural origin with flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No …/2008 (*) and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation.'.

4. In Article 1(4)(u), the first subparagraph shall be replaced by the following:

'A spirit drink produced by flavouring ethyl alcohol of agricultural origin with flavouring of cloves and/or cinnamon using one of the following processes: maceration and/or distillation, redistillation of the alcohol in the presence of parts of the plants specified above, addition of flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No …/2008 (*) of cloves or cinnamon or a combination of these methods.'.

5. In Article 4(5), the first and second paragraphs, excluding the lists in points (a) and (b), shall be replaced by the following:

'Only natural flavouring substances and flavouring preparations as defined in Article 3(2)(c) and (d) of Regulation (EC) No …/2008 (*) may be used in the preparation of the spirit drinks defined in Article 1(4), except in the case of those defined in Article 1(4)(m), (n) and (p). However, flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No …/2008 (*) shall be authorised in liqueurs except those mentioned below.'.

(*) This Regulation.

*Article 27*

**Amendment to Regulation (EEC) No 1601/91**

Article 2(1) is hereby amended as follows:

1. In point (a), the first sub-indent of the third indent shall be replaced by the following:

'— flavouring substances and/or flavouring preparations as defined in Article 3(2)(b) and (d) of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (**), and/or

(**) OJ L …'.

2. In point (b), the first sub-indent of the second indent shall be replaced by the following:

'— flavouring substances and/or flavouring preparations as defined in Article 3(2)(b) and (d) of Regulation (EC) No …/2008 (*), and/or'.

3. In point (c), the first sub-indent of the second indent shall be replaced by the following:

'— flavouring substances and/or flavouring preparations as defined in Article 3(2)(b) and (d) of Regulation (EC) No …/2008 (*), and/or'.

*Article 28*

**Amendment to Regulation (EC) No 2232/96**

Article 5(1) of Regulation (EC) No 2232/96 shall be replaced by the following:

'1. The list of flavouring substances referred to in Article 2(2) shall be adopted in accordance with the procedure referred to in Article 7 by 31 December 2008 at the latest.'.

*Article 29*

**Amendment to Directive 2000/13/EC**

In Directive 2000/13/EC, Annex III shall be replaced by the following:

*'ANNEX III*

**DESIGNATION OF FLAVOURINGS IN THE LIST OF INGREDIENTS**

1. Without prejudice to paragraph 2, flavourings shall be designated by the terms

   — "flavourings" or a more specific name or description of the flavouring, if the flavouring component contains flavourings as defined in Article 3(2)(b), (c), (d), (e), (f), (g) and (h) of Regulation (EC) No …/2008 of the European Parliament and of the Council of … on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) No 1576/89 and (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC (*),

   — "smoke flavouring(s)" if the flavouring component contains flavourings as defined in Article 3(2)(f) of Regulation (EC) No …/2008 (*) and imparts a smoky flavour to the food.

2. The term "natural" for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No …/2008 (*).

(*) OJ L …'.

*Article 30*

**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 … (*).

Articles 10, 26 and 27 shall apply from the date of application of the Community list.

Article 22 shall apply from the date of the entry into force of this Regulation. Foods lawfully placed on the market or labelled prior to … (*) which do not comply with this Regulation may be marketed until their date of minimum durability or use-by-date.

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*

(*) Two years after the entry into force of this Regulation.

*ANNEX I*

**COMMUNITY LIST OF FLAVOURINGS AND SOURCE MATERIALS APPROVED FOR USE IN AND ON FOODS**

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*ANNEX II*

**LIST OF TRADITIONAL FOOD PREPARATION PROCESSES**

| | |
|---|---|
| Chopping | Coating |
| Heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C) | Cooling |
| Cutting | Distillation/rectification |
| Drying | Emulsification |
| Evaporation | Extraction, incl. solvent extraction in accordance with Directive 88/344/EEC |
| Fermentation | Filtration |
| Grinding | |
| Infusion | Maceration |
| Microbiological processes | Mixing |
| Peeling | Percolation |
| Pressing | Refrigeration/Freezing |
| Roasting/Grilling | Squeezing |
| Steeping | |

*ANNEX III*

**PRESENCE OF CERTAIN SUBSTANCES**

PART A: Substances which shall not be added as such to food

Agaric acid

Aloin

Capsaicin

1,2-Benzopyrone, coumarin

Hypericine

Beta-asarone

1-Allyl-4-methoxybenzene, estragole

Hydrocyanic acid

Menthofuran

4-Allyl-1,2-dimethoxybenzene, methyleugenol

Pulegone

Quassin

1-Allyl-3,4-methylene dioxy benzene, safrole

Teucrin A

Thujone (alpha and beta)

PART B: Maximum levels of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have been added.

These maximum levels shall not apply to compound foods which are prepared and consumed on the same site, contain no added flavourings and contain only herbs and spices as food ingredients with flavouring properties.

| Name of the substance | Compound food in which the presence of the substance is restricted | Maximum level mg/kg |
|---|---|---|
| Beta-asarone | Alcoholic beverages | 1,0 |
| 1-Allyl-4-methoxybenzene, estragol | Dairy products | 50 |
| | Processed fruits, vegetables (incl. mushrooms, fungi, roots, tubers, pulses and legumes), nuts and seeds | 50 |
| | Fish products | 50 |
| | Non-alcoholic beverages | 10 |
| Hydrocyanic acid | Nougat, marzipan or its substitutes or similar products | 50 |
| | Canned stone fruits | 5 |
| | Alcoholic beverages | 35 |
| Menthofuran | Mint/peppermint containing confectionery, except micro breath freshening confectionery | 500 |
| | Micro breath freshening confectionery | 3 000 |
| | Chewing gum | 1 000 |
| | Mint/peppermint containing alcoholic beverages | 200 |
| 4-Allyl-1,2-dimethoxy-benzene, methyleugenol | Dairy products | 20 |
| | Meat preparations and meat products, including poultry and game | 15 |
| | Fish preparations and fish products | 10 |
| | Soups and sauces | 60 |
| | Ready-to-eat savouries | 20 |
| | Non-alcoholic beverages | 1 |

| Name of the substance | Compound food in which the presence of the substance is restricted | Maximum level mg/kg |
|---|---|---|
| Pulegone | Mint/peppermint containing confectionery, except micro breath freshening confectionery | 250 |
| | Micro breath freshening confectionery | 2 000 |
| | Chewing gum | 350 |
| | Mint/peppermint containing non-alcoholic beverages | 20 |
| | Mint/peppermint containing alcoholic beverages | 100 |
| Quassin | Non-alcoholic beverages | 0,5 |
| | Bakery wares | 1 |
| | Alcoholic beverages | 1,5 |
| 1-Allyl-3,4-methylene dioxy benzene, safrole | Meat preparations and meat products, including poultry and game | 15 |
| | Fish preparations and fish products | 15 |
| | Soups and sauces | 25 |
| | Non-alcoholic beverages | 1 |
| Teucrin A | Bitter-tasting spirit drinks or bitter [1] | 5 |
| | Liqueurs [2] with a bitter taste | 5 |
| | Other alcoholic beverages | 2 |
| Thujone (alpha and beta) | Alcoholic beverages, except those produced from *Artemisia* species | 10 |
| | Alcoholic beverages produced from *Artemisia* species | 35 |
| | Non-alcoholic beverages produced from *Artemisia* species | 0,5 |
| Coumarin | Traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling | 50 |
| | Breakfast cereals including muesli | 20 |
| | Fine bakery ware, with the exception of traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling | 15 |
| | Desserts | 5 |

[1] As defined in Article 1(4)(p) of Council Regulation (EEC) No 1576/89.
[2] As defined in Article 1(4)(r) of Council Regulation (EEC) No 1576/89.

*ANNEX IV*

**LIST OF SOURCE MATERIALS TO WHICH RESTRICTIONS APPLY FOR THEIR USE IN THE PRODUCTION OF FLAVOURINGS AND FOOD INGREDIENTS WITH FLAVOURING PROPERTIES**

PART A: Source materials which shall not be used for the production of flavourings and food ingredients with flavouring properties

| Source material | |
|---|---|
| Latin name | Common name |
| Tetraploid form of *Acorus calamus* L. | Tetraploid form of Calamus |

PART B: Conditions of use for flavourings and food ingredients with flavouring properties produced from certain source materials

| Source material | | Conditions of use |
|---|---|---|
| Latin name | Common name | |
| *Quassia amara* L. and *Picrasma excelsa* (Sw) | Quassia | Flavourings and food ingredients with flavouring properties produced from the source material may only be used for the production of beverages and bakery wares |
| *Laricifomes officinales (Vill.: Fr) Kotl. et Pouz* or *Fomes officinalis* | White agaric mushroom | Flavourings and food ingredients with flavouring properties produced from the source material may only be used for the production of alcoholic beverages |
| *Hypericum perforatum* L. | St John's wort | |
| *Teucrium chamaedrys* L. | Wall germander | |

*ANNEX V*

**CONDITIONS FOR THE PRODUCTION OF THERMAL PROCESS FLAVOURINGS AND MAXIMUM LEVELS FOR CERTAIN SUBSTANCES IN THERMAL PROCESS FLAVOURINGS**

PART A: Conditions for the production:

(a) The temperature of the products during processing shall not exceed 180 °C.

(b) The duration of the thermal processing shall not exceed 15 minutes at 180 °C with correspondingly longer times at lower temperatures, i.e. a doubling of the heating time for each decrease of temperature by 10 °C, up to a maximum of 12 hours.

(c) The pH during processing should not exceed the value of 8,0.

PART B: Maximum levels for certain substances

| Substance | Maximum levels µg/kg |
|---|---|
| 2-amino-3,4,8-trimethylimidazo [4,5-f] quinoxaline (4,8-DiMeIQx) | 50 |
| 2-amino-1-methyl-6-phenylimidazol [4,5-b] pyridine (PhIP) | 50 |

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 28 July 2006, the Commission adopted its proposal on flavourings and certain food ingredients with flavouring properties for use in foods ([1]). The proposal is based on Article 95 of the Treaty establishing the European Community.

The European Parliament adopted its Opinion in first reading on 10 July 2007 ([2]).

Following the European Parliament's first reading opinion, the Commission submitted an amended proposal on 24 October 2007 ([3]).

On 10 March 2008, the Council adopted its Common Position in accordance with Article 251(2) of the Treaty.

In carrying out its work, the Council also took account of the opinion of the European Economic and Social Committee adopted on 25 April 2007 ([4]).

### II. OBJECTIVE OF THE PROPOSED REGULATION

The aim of the proposed Regulation, as part of four proposals designed to overhaul the Community's rules on food improvement agents, is to update the Community rules on flavourings and certain food ingredients with flavouring properties, taking into account the technological and scientific developments in this area ([5]) as well as the developments in food legislation in the European Community, in particular, the new legislation on food safety ([6]).

The proposed Regulation provides for the establishment of a Community list of flavourings and of source materials approved for use, as well as for rules on labelling the flavourings.

The objective of the proposed Regulation is to ensure the proper functioning of the internal market, including fair practices in food trade, and a high level of protection of human health, of consumer interests and of the environment.

### III. ANALYSIS OF THE COMMON POSITION ([7])

#### 1. Introductory remarks

The Common Position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced a number of modifications in the text, some of them inspired by the amendments proposed by the European Parliament. On its own initiative, the Council introduced some of the European Parliament amendments in each of the three sectoral proposals, with a view to harmonising their provisions. The modifications introduced by the Council may be summed up as follows:

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([1]) COM(2006) 427 final.
([2]) Doc. 11639/07 CODEC 775.
([3]) COM(2007) 671 final.
([4]) OJ C 168, 20.7.2007, p. 29.
([5]) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foods and to source materials for their production (OJ L 184, 15.7.1988, p. 61. 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)) will be replaced.
([6]) Approved by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4)).
([7]) In addition to changes already introduced by the Council, Article 26 will require update due to entry into force on 20 February 2008 of the Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008).

— *Preference for a single legal basis:* Article 95 of the Treaty

According to established case-law ([1]), the legal basis for an act must be determined having regard to its own aim and content. If the examination of a Community measure reveals that it serves a two-fold purpose or that it has a two-fold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the act must be based on a single legal basis, namely that required by the main or predominant purpose or component ([2]). In this case, the Council considered that the agricultural aspects of the proposal are merely incidental while the internal market objective is the main or predominant purpose or component and as such, in line with the case law of the ECJ, it decided to retain Article 95 as the sole legal basis.

— *'Misleading the consumer'* (in line with amendment 1, second part)

The Council included, in recital 7, elements integrating the notion of misleading the consumer.

— *Protection of the environment*

The Council considered that, apart from scientific evidence, the authorisation of the flavourings should also take into account other relevant factors, such as the protection of the environment. The Council also included a reference to the protection of the environment among the objectives of the proposed Regulation.

— *Clarification of the scope and definitions* (in line with amendment 8)

The Council clarified that smoke flavourings are not completely excluded from the scope of the proposed Regulation. It opted for complementary application of two Regulations, i.e. this Regulation would apply in the absence of more specific rules in the Regulation (EC) 2065/2003 on smoke flavourings ([3]).

Furthermore, it was made clear that the Regulation would also not apply to mixtures of herbs and/or spices, mixtures of tea and mixtures for infusions, as long as they are not used as food ingredients (in line with amendment 45).

The clarification of Article 2(2) can be found in recital 6.

The Council paid particular attention to the accuracy of definitions and their consistency with other Community legislation. Clarifications were made in line with amendments 12 and 14. The term 'flavourings not elsewhere specified' in amendment 13 has the same meaning as the Commission formulation 'other flavouring', meaning flavouring not defined under points (b) to (g) of Article 3. The Council favours the latter, which is more clear in the context of Article 3.

— *Introduction of the regulatory comitology procedure with scrutiny* (in line with amendments 24, 33, 34, 35)

The Council adapted the proposal to the new comitology procedure rules, requiring the regulatory procedure with scrutiny to be applied for the adoption of measures supplementing the Regulation.

The Council also introduced the urgency procedure to enable the Commission to modify, on the imperative ground of urgency, restrictions for the use of flavourings and food ingredients with flavouring properties for which an approval is not required and if appropriate to amend Annexes II to V.

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([1]) See Case 45/86, *Commission* v *Council* [1987] ECR 1493, paragraph 11; Case C-300/89, *Commission* v *Council* (*Titanium Dioxide*) [1991] ECR I-2867, paragraph 10; Case C-268/94, *Portugal* v *Council* [1996] ECR I-6177, paragraph 22; and Case C-176/03, *Commission* v *Council* [2005] ECR I-0000, paragraph 45.

([2]) See Case C-36/98, *Spain* v *Council* [2001] ECR I-779, paragraph 59; Case C-211/01, *Commission* v *Council* [2003] ECR I-8913, paragraph 39; and Case C-338/01, *Commission* v *Council* [2004] ECR I-4829, paragraph 55.

([3]) OJ L 309, 26.11.2003, p. 1.

— *Interpretation decisions*

The Council regrouped all the provisions on interpretation decisions into a new single Article and, as they would not supplement the Regulation, made them subject to the regulatory comitology procedure without scrutiny.

— *Provision prohibiting the placing on the market of non compliant flavourings or food containing such flavourings*

For reasons of clarity, legal certainty and proper functioning of the market, the Council inserted an Article on the prohibition on placing non-compliant flavourings and/or food ingredients with flavouring properties on the market. This is consistent with proposals on food additives and on food enzymes.

— *Use of the term 'natural' flavouring*

To safeguard consumer interests, the Council agreed that the term 'natural' may only be used with a reference to a food, food category or a vegetable or animal flavouring source if at least 95 % by w/w has been obtained from the source material referred to (in line with amendment 29).

The Council has however added that the 5 % of the flavouring component derived from other source materials shall not reproduce the flavour of the source material referred to.

— *Authorisation of flavourings falling within the scope of Regulation (EC) 1829/2003* of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]) (in line with amendments 41 and 42)

The Council agrees that, for any substance, the two authorisation procedures (one for its use as a flavouring and the other with respect to its genetic modifications) can be carried out simultaneously, which is in line with the above amendments. The Council subjected that principle to some drafting changes in order to make the provision more compatible with Regulation (EC) No 1829/2003.

— *Labelling*

The Council streamlined labelling provisions, respecting the distinction between 'business to business' labelling and labelling requirements for products intended for the sale to the final consumer. Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are the same and are in line with amendments 5, 29 and 30.

— *Transitional measures for products already on the market* (in line with amendment 39)

The Council provided for a 2 years transition period from the date of entry into force of the proposed Regulation. Foods lawfully placed on the market or labeled during this 2 years may be marketed until their date of minimum durability or use-by-date.

The Commission has accepted the Common Position agreed by the Council.

2. **The amendments of the European Parliament**

In its Plenary vote on 10 July 2007, the European Parliament adopted 43 amendments to the proposal. In its Common Position, the Council incorporated, in full or in principle, 27 amendments.

([1]) OJ L 268, 18.10.2003, p. 1.

***Amendments incorporated in the Common Position***

In addition to amendments mentioned in part 1 above, the Common Position incorporates, in full or in principle, other European Parliament's first reading amendments, aimed at improving or clarifying the text, in particular amendments 4, 6, 7, 9, 12, 14, 31, 36, 41, 42.

***Amendments not introduced*** [1]

The Council was not able to accept all amendments, sometimes because it did not consider that they would bring drafting clarity (see amendments 13 and 37) or for the specific reasons outlined below:

— *Precautionary principle* (amendments 2, 17 — recital 13 and Article 4(a))

The precautionary principle is one of the general principles underlying the general food law [2]. Consequently, it applies to the proposed Regulation with no need for a specific reference to it. Moreover, in the risk analyses framework, the precautionary principle can only be taken into account in the context risk management, never in the risk assessment phase as suggested by the European Parliament.

— *Definition of 'appropriate physical process'* (amendment 15 — Article 3(2)(k))

The traditional food preparation processes listed in Annex II should not be confused with the 'appropriate physical process' defined in Article (3)(2)(k).

— *Definition of 'flavouring substance'* (amendment 49 — Article 3(2)(b))

The Council indicated, in recital 14, through which processes the flavouring substance can be produced. The amendment would restrict the methods that can be used.

— *Decisions submitted to the regulatory comitology procedure without scrutiny* (amendments 11, 16, 23, 32 — Article 13(a), 13(b), 6(3), 20(2))

Decisions on whether or not a given substance falls within the scope of the Regulation (amendment 11); rules implementing methods on how to monitor Annex IIIB (amendment 23) and the common methodology for monitoring of the consumption and use of flavourings (amendment 32) are of an interpretative nature and would not supplement the Regulation. Therefore, they do not fall within the scope of the regulatory comitology procedure with scrutiny.

— *Labelling of genetically modified organisms (GMOs)* (amendments 27, 28, 38 — Article 15(1)(e)(ii) and (g), Article 29 (2a new))

As mentioned in recital 24, flavourings remain subject to the labelling provisions defined in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [3] and in Regulation (EC) No 1829/2003 on genetically modified food and feed and their labelling (Articles 12 and 13 of the later). The Council insisted on retaining the consistency between 'GMOs' Regulation, Directive 2000/13/EC ('Labelling Directive') and this Regulation. Therefore, the Council did not accept amendments 27 and 38 as they are already covered by Regulation (EC) No 1829/2003. Amendment 28 is not necessary as the term 'other relevant Community legislation' in Article 15(1)(g) in the Common Position also includes the above-mentioned Regulation.

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[1] Numbering of Articles in this part refers to the text of the Common Position.

[2] 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 (OJ L 31, 1.2.2002, p. 1). Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 34).

[3] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2007/68/EC (OJ L 310, 28.11.2007, p. 11).

A definition of general scope, such as the one proposed in amendment 52 would have to be part of Regulation (EC) No 1829/2003 and not of the proposed Regulation.

— *Conditions for use* (amendments 19 and 20 — Article 4(ba new) and Article 4(bb new))

The Council did not include a reference to the benefit of the consumer and to the technological need as general conditions for the use of flavourings because their implementation would have been not possible owing to possible subjective interpretations. These two aspects are already covered in the definition of flavourings, which states that they are added to food to impart odour and/or taste.

— *Labelling*

Although the Council organised the labelling chapter in a way different from that proposed by the European Parliament, the principles underlying its content are in line with some of the amendments related to Articles 14 to 18. However, the Council was not able to accept the suggestions relating to labelling of GMOs as explained above (amendments 27, 28, 38) and amendment 26, which is not consistent with other specific Community legislation and may create barriers to trade. Amendment 43 is not in line with the spirit of the provisions of Article 16, which aims at providing adequate information to the consumers and protecting consumer interests.

— *Entry into force of Articles 10, 26, 27* (amendment 44 — Article 30(2)

Amendment 44 was not accepted as Articles 10, 26 and 27 can only apply after the Community list of authorized flavourings and source materials has become applicable. In addition, the date of application of that Community list can only be determined after it has been adopted through the comitology procedure with scrutiny pending the outcome of the evaluation by EFSA as referred to in Article 4 of Regulation (EC) 2232/96.

— *Presence of toxic substances* (amendments 21, 40, 46 — Article 6(2), Annex IIIB, Article 6(2a new))

Substances in Annex III B of the proposed Regulation pose a toxicological problem, confirmed by the Scientific Committee on Food (SCF) or EFSA. Knowing that these substances are a toxicological problem, they must be regulated based on the most recent scientific advice available. The Council attached great importance to using a risk-based approach to set maximum limits in this Regulation. For the Council, amendments 21 and 40 go against the need to provide a high level of protection of human health. The Council considered that a general exclusion, as suggested by amendment 46, in respect of the application of Annex III B to compound food to which only herbs and spices have been added is too broad and would not provide sufficient protection the consumers. The Council considers, in line with the principle of proportionality, that the exclusion from maximum levels set in Annex III B is justified for the use of herbs and spices under the condition that they are used in compound foods which are prepared and consumed on the same site and thus will not affect cross-boarder trade.

IV. **Conclusions**

The Council believes that the Common Position represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation ensuring a high level of human health and consumer protection.