

Official Journal

of the European Union

L 354

Volume 51

English edition

Legislation

31 December 2008

Contents

I Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory

REGULATIONS

- ★ **Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings** ⁽¹⁾ 1
- ★ **Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 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⁾ 7
- ★ **Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives** ⁽¹⁾ 16
- ★ **Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC** ⁽¹⁾ 34
- ★ **Regulation (EC) No 1335/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation (EC) No 881/2004 establishing a European Railway Agency (Agency Regulation)** ⁽¹⁾ 51
- ★ **Regulation (EC) No 1336/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation (EC) No 648/2004 in order to adapt it to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures** ⁽¹⁾ 60
- ★ **Regulation (EC) No 1337/2008 of the European Parliament and of the Council of 16 December 2008 establishing a facility for rapid response to soaring food prices in developing countries** 62

⁽¹⁾ Text with EEA relevance

Price: EUR 18

(Continued overleaf)

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

This issue closes the L series for 2008.

★ Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work ⁽¹⁾	70
★ Regulation (EC) No 1339/2008 of the European Parliament and of the Council of 16 December 2008 establishing a European Training Foundation (recast)	82
<hr/>	
Note to the reader (see page 3 of the cover)	s3

⁽¹⁾ Text with EEA relevance



I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

**REGULATION (EC) No 1331/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
establishing a common authorisation procedure for food additives, food enzymes and food flavourings
(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽³⁾, Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes ⁽⁴⁾ and Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods ⁽⁵⁾ (hereinafter referred to as the sectoral food laws) 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 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods], 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) Ensuring transparency in the production and handling of food is absolutely crucial in order to maintain consumer confidence.

- (7) 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.

⁽¹⁾ OJ C 168, 20.7.2007, p. 34.

⁽²⁾ Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 134), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 1), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

⁽³⁾ See page 16 of this Official Journal.

⁽⁴⁾ See page 7 of this Official Journal.

⁽⁵⁾ See page 34 of this Official Journal.

- (8) This common procedure must be founded on the principles of good administration and legal certainty and must be implemented in compliance with those principles.
- (9) 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.
- (10) The deadlines laid down in the procedure take into account the time needed to consider the different criteria set in each sectoral food 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.
- (11) 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 ⁽¹⁾ as soon as possible after the validity and applicability of the application have been assessed.
- (12) 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 an independent 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.
- (13) The authorisation to place substances on the market should be granted pursuant to this Regulation provided that the criteria for authorisation laid down under the sectoral food laws are satisfied.
- (14) 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.
- (15) 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.
- (16) Where appropriate and under certain circumstances, the specific sectoral food law may provide for protection of scientific data and other information submitted by the applicant for a certain period of time. In this case, the sectoral food law should lay down the conditions under which these data may not be used for the benefit of another applicant.
- (17) 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 ⁽²⁾.
- (18) 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.
- (19) 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.
- (20) 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 ⁽³⁾ applies to documents held by the Authority.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ 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).

⁽³⁾ OJ L 145, 31.5.2001, p. 43.

- (21) 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.
- (22) 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.
- (23) 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.
- (24) 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⁾.
- (25) 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.
- (26) 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.
- (27) 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 procedure for the assessment and authorisation (hereinafter referred to as the common procedure) of 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 contributes to the free movement of food within the Community and to a high level of protection of human health and to a high level of consumer protection, including the protection of consumer interests. 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 ⁽²⁾.

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 1333/2008 [on food additives], Regulation (EC) No 1332/2008 [on food enzymes] and Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods] (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;

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 309, 26.11.2003, p. 1.

- (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.

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 nine 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. In the Regulation updating the Community list, the considerations on which it is based shall be explained.

3. Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the reasons for its decision.

4. 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).

5. 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).

6. 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.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

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 two months, two months and four 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 20th 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 20 January 2009.

**REGULATION (EC) No 1332/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008**

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)

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.

⁽¹⁾ OJ C 168, 20.7.2007, p. 34.

⁽²⁾ Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 162), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 32), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

- (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 or digestive 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 1333/2008 of the European Parliament and of the Council of 16 December 2008 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, the precautionary principle 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

⁽³⁾ See page 16 of this Official Journal.

- 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 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 1331/2008 of the European Parliament and of the Council of 16 December 2008 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 authorised in accordance with that Regulation as well as 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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], in order to give applicants sufficient time to submit the information on existing enzymes which may be included in the Community list to be drawn up under this Regulation. It should also be possible to submit applications for the authorisation of new enzymes during the initial two-year period. The Authority should evaluate without delay all applications for food enzymes for which sufficient information has been submitted during that period.
- (14) In order to ensure fair and equal conditions for all applicants, the Community list should be drawn up in a single step. That list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two-year period. However, the risk assessments of the Authority for individual enzymes should be published as soon as they are completed.
- (15) A significant number of applications is expected to be submitted during the initial two-year period. A lengthy period may therefore be needed before the risk assessment of these has been completed and the Community list is drawn up. In order to ensure equal access to the market for new food enzymes after the initial two-year period, a transitional period should be provided for during which food enzymes and food using food enzymes may be placed on the market and used, in accordance with the existing national rules in the Member States, until the Community list has been drawn up.

(1) OJ L 10, 12.1.2002, p. 58.

(2) OJ L 237, 26.8.1983, p. 25.

(3) OJ L 179, 14.7.1999, p. 1.

(4) OJ L 43, 14.2.1997, p. 1.

(5) See page 1 of this Official Journal.

(6) OJ L 31, 1.2.2002, p. 1.

(7) OJ L 268, 18.10.2003, p. 1.

- (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 423/2008 of 8 May 2008 on laying down certain detailed rules for implementing Council Regulation (EC) No 1493/1999 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 423/2008.
- (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 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,

⁽¹⁾ OJ L 61, 18.3.1995, p. 1.

⁽²⁾ OJ L 127, 15.5.2008, p. 13.

⁽³⁾ OJ L 109, 6.5.2000, p. 29.

⁽⁴⁾ OJ L 268, 18.10.2003, p. 24.

⁽⁵⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁶⁾ OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1.

HAVE ADOPTED THIS REGULATION:

Article 3

Definitions

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, with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and 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 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 1333/2008 [on food additives];
- (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.

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 1333/2008 [on food additives] 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;
- (b) there is a reasonable technological need, and
- (c) its use does not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness and quality of the ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product.

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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], be included in the Community list.

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

- (a) the name of the food enzyme;
- (b) the specifications of the food enzyme, including its origin, purity criteria and any other necessary information;
- (c) the foods to which the food enzyme may be added;
- (d) 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 *quantum satis* principle;
- (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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

Article 8

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

1. 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.

2. When a food enzyme already included in the Community list is produced from a different source falling within the scope of Regulation (EC) No 1829/2003, it will not require a new authorisation under this Regulation, as long as the new source is covered by an authorisation in accordance with Regulation (EC) No 1829/2003 and the food enzyme complies with the specifications established under this Regulation.

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 such a name, the accepted name laid down in the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB);
 - (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 such a name, the accepted name laid down in the nomenclature of the IUBMB;

⁽¹⁾ OJ L 186, 30.6.1989, p. 21.

(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.

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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

3. The Commission shall establish a Register of all food enzymes to be considered for inclusion in the Community list in respect of which an application complying with the validity criteria to be laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] 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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], once the Authority has issued an opinion on each food enzyme included in the Register.

However, by way of derogation from that procedure:

(a) Article 5(1) of Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] shall not apply to the Authority's adoption of its opinion;

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

5. If necessary, any appropriate transitional measures for the purposes of this Article 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 20 January 2010 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 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (*);
- other milk-coagulating enzymes meeting the requirements of Regulation (EC) No 1332/2008.

(*) OJ L 354, 31.12.2008, p. 7.'

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 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (*).

(*) OJ L 354, 31.12.2008, p. 7.'

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 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (*);

— Proteolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008;

— Amylolytic enzymes meeting the requirements of Regulation (EC) No 1332/2008.

(*) OJ L 354, 31.12.2008, p. 7.'

*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 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (*).

(*) OJ L 354, 31.12.2008, p. 7.

*Article 24***Entry into force**

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

Article 4 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 20 January 2010.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
on food additives
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

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 whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests, 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 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes ⁽⁴⁾, which excludes the application of this Regulation.

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

⁽¹⁾ OJ C 168, 20.7.2007, p. 34.

⁽²⁾ Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 142), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 10), Position of the European Parliament of 8 July 2008 (not yet published in the Official Journal) and Council Decision of 18 November 2008.

⁽³⁾ OJ L 186, 30.6.1989, p. 27.

⁽⁴⁾ See page 7 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, including its fruit and vegetable content. The approval of food additives should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors, the precautionary principle 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 1331/2008 of the European Parliament and of the Council of 16 December 2008 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 authorised in accordance with that Regulation as well as 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, including the use of nanotechnology.
- (14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Where necessary, the Commission together with the Member States should consider appropriate action.
- (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 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽⁷⁾ and Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed ⁽⁸⁾.

⁽¹⁾ OJ L 178, 28.7.1995, p. 1.

⁽²⁾ OJ L 226, 22.9.1995, p. 1.

⁽³⁾ OJ L 339, 30.12.1996, p. 1.

⁽⁴⁾ See page 1 of this Official Journal.

⁽⁵⁾ OJ L 31, 1.2.2002, p. 1.

⁽⁶⁾ OJ L 268, 18.10.2003, p. 1.

⁽⁷⁾ OJ L 93, 31.3.2006, p. 12.

⁽⁸⁾ OJ L 93, 31.3.2006, p. 1.

- (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 ⁽¹⁾ 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 ⁽²⁾. 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 ⁽³⁾.
- (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 ⁽⁴⁾.
- (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 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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings]. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives and food additives in flavourings, should not apply until 1 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.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

⁽²⁾ OJ L 268, 18.10.2003, p. 24.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁴⁾ OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.

(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 of 23 October 1962 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 down specific criteria of 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 with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, 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 1332/2008 [on food enzymes], and in food flavourings as covered by Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods ⁽¹²⁾;
- (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 ⁽¹³⁾;

⁽¹⁾ OJ 115, 11.11.1962, p. 2645/62.

⁽²⁾ OJ 22, 9.2.1965, p. 373.

⁽³⁾ OJ L 223, 14.8.1978, p. 7.

⁽⁴⁾ OJ L 223, 14.8.1978, p. 30.

⁽⁵⁾ OJ L 257, 10.9.1981, p. 1.

⁽⁶⁾ OJ L 40, 11.2.1989, p. 27.

⁽⁷⁾ OJ L 237, 10.9.1994, p. 3.

⁽⁸⁾ OJ L 237, 10.9.1994, p. 13.

⁽⁹⁾ OJ L 61, 18.3.1995, p. 1.

⁽¹⁰⁾ OJ L 48, 19.2.1997, p. 13.

⁽¹¹⁾ OJ L 84, 28.3.2002, p. 69.

⁽¹²⁾ See page 34 of this Official Journal.

⁽¹³⁾ OJ L 330, 5.12.1998, p. 32.

(e) flavourings falling within the scope of Regulation (EC) No 1334/2008 [on flavourings and certain food ingredients with flavouring properties for use in and on foods].

3. This Regulation shall not apply to food enzymes falling within the scope of Regulation (EC) No 1332/2008 [on food enzymes], with effect from the date of adoption of the Community list of food enzymes in accordance with Article 17 of that Regulation.

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 Regulations (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 amylolytic enzymes;

(vii) ammonium chloride;

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

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

(x) caseinates and casein;

(xi) inulin;

(b) 'processing aid' shall mean any substance which:

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

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

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

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

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

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

(i) any added monosaccharides 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 14.

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, including environmental factors:

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;

(b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; 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;
- (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 28(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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings] 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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

*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

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

When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.

Article 13

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

1. 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.

2. When a food additive already included in the Community list is produced from a different source falling within the scope of Regulation (EC) No 1829/2003, it will not require a new authorisation under this Regulation, as long as the new source is covered by an authorisation in accordance with Regulation (EC) No 1829/2003 and the food additive complies with the specifications established under this Regulation.

Article 14

Specifications of food additives

The specifications of food additives relating, in particular, to origin, purity criteria and any other necessary information, shall be adopted when the food additive is included in the Community lists in Annexes II and III for the first time, in accordance with the procedure referred to in Regulation (EC) No 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings].

CHAPTER III

USE OF FOOD ADDITIVES IN FOODS

Article 15

Use of food additives in unprocessed foods

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

Article 16

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 17

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 18

Carry-over principle

1. The presence of a food additive shall be permitted:
 - (a) in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food;
 - (b) in a food to which a food additive, food enzyme or 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

⁽¹⁾ OJ L 268, 24.9.1991, p. 69.

⁽²⁾ OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.

(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 19

Interpretation decisions

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 28(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 20

Traditional foods

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

CHAPTER IV

LABELLING

Article 21

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

1. Food additives not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with food ingredients, as defined in Article 6(4) of Directive 2000/13/EC, may only be marketed with the labelling provided for in Article 22 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 22 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 22

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 23

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 28(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 24

Labelling requirement for foods containing certain food colours

1. Without prejudice to Directive 2000/13/EC, the labelling of food containing the food colours listed in Annex V to this Regulation shall include the additional information set out in that Annex.

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

3. Where necessary as a result of scientific progress or technical development, Annex V shall be amended by measures, designed to amend non-essential elements of this Regulation, in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).

(1) OJ L 186, 30.6.1989, p. 21.

*Article 25***Other labelling requirements**

Articles 21, 22, 23 and 24 shall be without prejudice to more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or applying to the transport of such substances and preparations.

CHAPTER V

PROCEDURAL PROVISIONS AND IMPLEMENTATION*Article 26***Information obligation**

1. A producer or user of a food additive shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive.
2. A producer or user of a food additive shall, at the request of the Commission, inform it of the actual use of the food additive. Such information shall be made available to Member States by the Commission.

*Article 27***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 28(2).

*Article 28***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 29***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 30***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 31 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 28(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by 20 January 2011.

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

2. Food additives authorised for use in food additives in Directive 95/2/EC and their conditions of use shall be entered in Part I 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 28(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by 20 January 2011.

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 28(4). The review shall not include a new risk assessment by the Authority. The review shall be completed by 20 January 2011.

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 1331/2008 [establishing a common authorisation procedure for food additives, food enzymes and food flavourings], at the moment those food additives are entered in the Annexes in accordance with those paragraphs.

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 28(3).

Article 31

Transitional measures

Until the establishment of the Community lists of food additives as provided for in Article 30 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 28(4).

Foods placed on the market or labelled before 20 January 2010 which do not comply with Article 22(1)(i) and (4) may be marketed until their date of minimum durability or use-by-date.

Foods placed on the market or labelled before 20 July 2010 which do not comply with Article 24 may be marketed until their date of minimum durability or use-by-date.

Article 32

Re-evaluation of approved food additives

1. Food additives which were permitted before 20 January 2009 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 20 January 2010, in accordance with the regulatory procedure referred to in Article 28(2). The evaluation programme shall be published in the *Official Journal of the European Union*.

Article 33

Repeals

1. The following acts shall be repealed:
 - (a) Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption;
 - (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 34

Transitional provisions

By way of derogation from Article 33, the following provisions shall continue to apply until the transfer under Article 30(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;
- (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 1332/2008 [on food enzymes].

*Article 35***Entry into force**

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

It shall apply from 20 January 2010.

However, Article 4(2) shall apply to Parts 2, 3 and 5 of Annex III from 1 January 2011 and Article 23(4) shall apply from 20 January 2011. Article 24 shall apply from 20 July 2010. Article 31 shall apply from 20 January 2009.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

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.
-

ANNEX II

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

ANNEX III

Community list of food additives approved for use in food additives, 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
-

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 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 zamponi'	All except preservatives, antioxidants, pH-adjusting agents, flavour enhancers, stabilisers and packaging gas

ANNEX V

List of the food colours referred to in Article 24 for which the labelling of foods shall include additional information

Foods containing one or more of the following food colours	Information
Sunset yellow (E 110) (*)	‘name or E number of the colour(s)’: may have an adverse effect on activity and attention in children.
Quinoline yellow (E 104) (*)	
Carmoisine (E 122) (*)	
Allura red (E 129) (*)	
Tartrazine (E 102) (*)	
Ponceau 4R (E 124) (*)	

(*) With the exception of foods where the colour(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells.

REGULATION (EC) No 1334/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008

on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

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 are used to improve or modify the odour and/or taste of foods for the benefit of the consumer. 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. Where possible, attention should be focused on whether or not the use of certain flavourings could have any negative consequences on vulnerable groups. The use of flavourings must not mislead the consumer and their presence in food should, therefore, always be indicated by appropriate labelling. Flavourings should, in particular, not be used in a way as to mislead the consumer about issues related to, amongst other things, 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, the precautionary principle and the feasibility of controls.

⁽¹⁾ OJ C 168, 20.7.2007, p. 34.

⁽²⁾ Opinion of the European Parliament of 10 July 2007 (OJ C 175 E, 10.7.2008, p. 176), Council Common Position of 10 March 2008 (OJ C 111 E, 6.5.2008, p. 46). Position of the European Parliament of 8 July 2008 (not yet published) and Council Decision of 18 November 2008.

⁽³⁾ OJ L 184, 15.7.1988, p. 61.

⁽⁴⁾ OJ L 184, 15.7.1988, p. 67.

⁽⁵⁾ OJ L 42, 15.2.1991, p. 25.

- (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 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. Should additional naturally occurring undesirable substances pose a risk to the health of the consumer, maximum levels should be set following the opinion of the Authority. Member States should 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 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 1331/2008 of the European Parliament and of the Council of 16 December 2008 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 1331/2008.
- (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.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1.

⁽³⁾ See page 1 of this Official Journal.

⁽⁴⁾ OJ L 299, 23.11.1996, p. 1.

- (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, 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 1333/2008 of the European Parliament and of the Council of 16 December 2008 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 authorised in accordance with that Regulation as well as 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. As the use of flavourings should not mislead the consumer, 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.
- (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.

⁽¹⁾ OJ L 309, 26.11.2003, p. 1.

⁽²⁾ See page 16 of this Official Journal.

⁽³⁾ OJ L 268, 18.10.2003, p. 1.

⁽⁴⁾ OJ L 109, 6.5.2000, p. 29.

⁽⁵⁾ OJ L 268, 18.10.2003, p. 24.

- (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 1331/2008. 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 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.
- (36) 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 ⁽²⁾ and Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks ⁽³⁾ need to be adapted to certain new definitions laid down in this Regulation.
- (37) Regulations (EEC) No 1601/91, (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC should be amended accordingly,

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 with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 149, 14.6.1991, p. 1.

⁽³⁾ OJ L 39, 13.2.2008, p. 16.

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 such as, but not exclusively, fresh, dried or frozen 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) No 178/2002 and (EC) No 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 or modify 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, without prejudice to the listing of traditional food preparation processes in Annex II, 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 1333/2008 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 110/2008, 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.
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, 5 and 6 of Regulation (EC) No 1331/2008 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 1331/2008, 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 1331/2008.

Article 12

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

1. 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.

2. When a flavouring already included in the Community list is produced from a different source falling within the scope of Regulation (EC) No 1829/2003, it will not require a new authorisation under this Regulation, as long as the new source is covered by an authorisation in accordance with Regulation (EC) No 1829/2003 and the flavouring complies with the specifications established under this Regulation.

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 of this Article 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 description shall read 'natural "food(s) or food category or source(s)" flavouring'.

5. The term '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.

⁽¹⁾ OJ L 186, 30.6.1989, p. 21.

*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 and preparations.

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. The information provided in this context shall be treated as confidential insofar as this information is not required for the safety assessment.

Information on the use levels for specific food categories in the Community 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 is known and accessible to him and which might affect the assessment of the safety of the flavouring substance.

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 20 January 2011.

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 20 January 2011.

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.

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 1331/2008 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 period of nine months referred to in Article 5(1) and Article 7 of Regulation (EC) No 1331/2008 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

Amendments 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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (*), and/or

(*) OJ L 354, 31.12.2008, p. 34.’

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 1334/2008, 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 1334/2008, and/or’.

Article 27

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 2010 at the latest.’

Article 28

Amendments to Regulation (EC) No 110/2008

Regulation (EC) No 110/2008 is hereby amended as follows:

1. in Article 5(2), point (c) shall be replaced by the following:

‘(c) contain flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (*) and flavouring preparations as defined in Article 3(2)(d) of that Regulation;

(*) OJ L 354, 31.12.2008, p. 34.’

2. in Article 5(3), point (c) shall be replaced by the following:

‘(c) contain one or more flavourings as defined in Article 3(2)(a) of Regulation (EC) No 1334/2008;’

3. in Annex I, point (9) shall be replaced by the following:

‘(9) *Flavouring*

Flavouring means using in the preparation of a spirit drink one or more of the flavourings defined in Article 3(2)(a) of Regulation (EC) No 1334/2008.’

4. Annex II shall be amended as follows:

- (a) paragraph 19(c) shall be replaced by the following:

‘(c) Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation, 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.’;

- (b) paragraph 20(c) shall be replaced by the following:

‘(c) Only flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in

Article 3(2)(d) of that Regulation shall be used for the production of gin so that the taste is predominantly that of juniper.’;

- (c) paragraph 21(a) (ii) shall be replaced by the following:

‘(ii) the 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 as specified in category 20(c) may also be used to flavour distilled gin.’;

- (d) paragraph 23(c) shall be replaced by the following:

‘(c) Other flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 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.’;

- (e) paragraph 24(c) shall be replaced by the following:

‘(c) Other natural flavouring substances as defined in Article 3(2)(c) of Regulation (EC) No 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation may additionally be used, but the flavour of these drinks is largely attributable to distillates of caraway (*Carum carvi* L.) and/or dill (*Anethum graveolens* L.) seeds, the use of essential oils being prohibited.’;

- (f) paragraph 30(a) shall be replaced by the following:

‘(a) Bitter-tasting spirit drinks or bitter are 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 1334/2008 and/or flavouring preparations as defined in Article 3(2)(d) of that Regulation.’;

- (g) in paragraph 32(c), the first subparagraph and the introductory part of the second subparagraph shall be replaced by the following:

‘(c) Flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and flavouring preparations as defined in Article 3(2)(d) of that Regulation may be used in the preparation of liqueur. However, only natural flavouring substances as defined in Article 3(2)(c) of Regulation (EC) No 1334/2008 and flavouring preparations as defined in Article 3(2)(d) of that Regulation shall be used in the preparation of the following liqueurs.’;

(h) paragraph 41(c) shall be replaced by the following:

‘(c) Only flavouring substances as defined in Article 3(2)(b) of Regulation (EC) No 1334/2008 and flavouring preparations as defined in Article 3(2)(d) of that Regulation may be used in the preparation of egg liqueur or advocaat or avocát or advokát.’;

(i) paragraph 44(a) shall be replaced by the following:

‘(a) Vákevá glögi or spritglögg is a spirit drink produced by flavouring ethyl alcohol of agricultural origin with flavour 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 natural flavouring substances as defined in Article 3(2)(c) of Regulation (EC) No 1334/2008 of cloves or cinnamon or a combination of these methods.’;

(j) paragraph 44(c) shall be replaced by the following:

‘(c) Other flavourings, flavouring substances and/or flavouring preparations as defined in Article 3(2)(b), (d) and (h) of Regulation (EC) No 1334/2008 may also be used, but the flavour of the specified spices must be predominant.’;

(k) In point (c) of paragraphs 25, 26, 27, 28, 29, 33, 34, 35, 36, 37, 38, 39, 40, 42, 43, 45 and 46, the word ‘preparations’ shall be replaced by ‘flavouring preparations’.

Article 29

Amendment to Directive 2000/13/EC

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

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

‘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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (*);
 - “smoke flavouring(s)”, or “smoke flavouring(s) produced from “food(s) or food category or source(s)”” (e.g. smoke flavouring produced from beech), if the flavouring component contains flavourings as defined in Article 3(2)(f) of Regulation (EC) No 1334/2008 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 1334/2008.

(*) OJ L 354, 31.12.2008, p. 34.’

Article 30

Entry into force

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

It shall apply from 20 January 2011.

Article 10 shall apply from 18 months after the date of application of the Community list.

Articles 26 and 28 shall apply from the date of application of the Community list.

Article 22 shall apply from 20 January 2009. Foods lawfully placed on the market or labelled prior to 20 January 2011 which do not comply with this Regulation may be marketed until their date of minimum durability or use-by-date.

ANNEX I

Community list of flavourings and source materials approved for use in and on foods

—

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*

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

(*) The maximum levels shall not apply where a compound food contains no added flavourings and the only food ingredients with flavouring properties which have been added are fresh, dried or frozen herbs and spices. After consultation with the Member States and the Authority, based on data made available by the Member States and on the newest scientific information, and taking into account the use of herbs and spices and natural flavouring preparations, the Commission, if appropriate, proposes amendments to this derogation.

(1) As defined in Annex II, paragraph 30 of Regulation (EC) No 110/2008.

(2) As defined in Annex II, paragraph 32 of Regulation (EC) No 110/2008.

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 <i>Acorus calamus</i> 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	
<i>Quassia amara</i> L. and <i>Picrasma excelsa</i> (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
<i>Laricifomes officinales</i> (Vill.: Fr) Kotl. et Pouz or <i>Fomes officinalis</i>	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
<i>Hypericum perforatum</i> L.	St John's wort	
<i>Teucrium chamaedrys</i> L.	Wall germander	

ANNEX V

Conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavouringsPart 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

REGULATION (EC) No 1335/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
amending Regulation (EC) No 881/2004 establishing a European Railway Agency (Agency Regulation)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

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

Whereas:

(1) Regulation (EC) No 881/2004 of the European Parliament and of the Council ⁽³⁾ of 29 April 2004 established a European Railway Agency, hereinafter referred to as 'the Agency', to make a technical contribution to creating a European railway area without frontiers. Following developments in Community legislation on rail interoperability and safety and market developments and on the basis of the experience gained in operating the Agency and the relationship between the Agency and the Commission, certain amendments need to be made to that Regulation, and in particular certain tasks need to be added.

(2) National rules are to be notified to the Commission both in accordance with Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (recast) ⁽⁴⁾, (hereinafter referred to as the 'Railway Interoperability Directive'), and Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways (Railway Safety Directive) ⁽⁵⁾. The two sets of rules should therefore be

examined in order to assess, in particular, if they are compatible with the common safety methods and the technical specifications for interoperability (TSIs) in force, as well as if they enable the common safety targets in force to be achieved.

(3) In order to facilitate the procedure for authorising the placing in service of vehicles which do not conform to the relevant TSIs, all the technical and safety rules in force in each Member State should be classified into three groups and the results of this classification should be presented in a reference document. The Agency is therefore required to draw up a draft for creating and updating this document by cross-referencing the national rules for each of the relevant technical parameters and by providing ad hoc technical opinions on specific aspects of cross-accepting projects. After reviewing the list of the parameters, the Agency may recommend that it be modified.

(4) Due to its legal competence and its high level of technical expertise, the Agency is the entity which should provide clarification on complex matters emerging from the activity in the sector. Therefore, in the context of the procedures authorising the placing in service of vehicles, it should be possible to request the Agency to issue technical opinions in the case of a negative decision by a national safety authority or on the equivalence of national rules for the technical parameters established in the Railway Interoperability Directive.

(5) It should be possible to request the opinion of the Agency on urgent modifications to TSIs.

(6) Under Article 13 of Regulation (EC) No 881/2004, the Agency may monitor the quality of the work of the bodies notified by the Member States. A study conducted by the Commission has shown that there is much scope for interpretation of the criteria to be applied for notifying these bodies. Without prejudice to the Member States' responsibility with regard to the bodies that they choose to notify and the checks that they make to ensure that these criteria have been met, it is important to assess the impact of such differences in interpretation and to check that they do not cause difficulties with regard to the mutual recognition of conformity certificates and the EC declaration of verification. Therefore, at the request of the Commission, the

⁽¹⁾ OJ C 256, 27.10.2007, p. 39.

⁽²⁾ Opinion of the European Parliament of 29 November 2007 (OJ C 297 E, 20.11.2008, p. 140), Council Common Position of 3 March 2008 (OJ C 93 E, 15.4.2008, p. 1) and Position of the European Parliament of 9 July 2008 (not yet published in the Official Journal). Council Decision of 1 December 2008.

⁽³⁾ OJ L 164, 30.4.2004, p. 1. Corrected version in OJ L 220, 21.6.2004, p. 3.

⁽⁴⁾ OJ L 191, 18.7.2008, p. 1.

⁽⁵⁾ OJ L 164, 30.4.2004, p. 44. Corrected version in OJ L 220, 21.6.2004, p. 16.

Agency should be able to monitor the activity of the notified bodies and, if justified, perform checks with a view to ensuring that the criteria referred to in the Railway Interoperability Directive are met by the relevant notified body.

- (7) Article 15 of Regulation (EC) No 881/2004 authorises the Agency to assess, at the request of the Commission and from the point of view of interoperability, applications for Community funding for railway infrastructure projects. The definition of these projects should be extended so that the coherence of the system can also be assessed, as in the case of projects implementing the European Rail Traffic Management System (ERTMS), for example.
- (8) Following developments of an international dimension, and in particular the entry into force of the 1999 Convention concerning International Carriage by Rail (COTIF), the Agency should be asked to assess the relationship between railway undertakings and keepers, particularly with regard to maintenance, as an extension of its work in the area of maintenance workshop certification. In this context, it should be possible for the Agency to address recommendations regarding the implementation of the system of certification of maintenance in accordance with Article 14a of the Railway Safety Directive.
- (9) When developing the certification schemes of entities in charge of maintenance and maintenance workshops, the Agency should make sure that these schemes are consistent with the responsibilities already allocated to railway undertakings and the future role of entities in charge of maintenance. These schemes should facilitate the safety certification procedure of railway undertakings and avoid undue administrative burden and duplication of controls, inspections and/or audits.
- (10) Following adoption of the third railway package, reference should be made to Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community ⁽¹⁾ (hereinafter referred to as the 'Train Drivers Directive'), which lays down various tasks to be performed by the Agency and gives it the possibility to address recommendations as well.
- (11) As far as railway staff are concerned, the Agency should also identify possible options for the certification of other crew members performing safety-critical tasks and assess the impact of these different options. It is intended that, besides train drivers and other crew members performing safety-critical tasks, the Agency reflects on specifying

criteria for defining vocational competences of other staff involved in the operation and maintenance of the rail system.

- (12) The Railway Interoperability Directive and the Railway Safety Directive provide for various types of documents, namely, EC declarations of verification, licences and safety certificates and national rules notified to the Commission. Therefore, it should be the Agency's task to ensure public access to those documents as well as to the national registers on vehicles and infrastructure and to the registers kept by the Agency.
- (13) The Agency should examine the appropriate revenues for the tasks related to the accessibility of documents and registers in accordance with Article 38(2) of Regulation (EC) No 881/2004.
- (14) Since the adoption of the second railway package, several initiatives relating to the development and implementation of the ERTMS have been taken. These include the signing of a cooperation agreement between the Commission and the various stakeholders in the sector, the setting up of a steering committee for implementing this cooperation agreement, the adoption by the Commission of a Communication to the European Parliament and the Council on the deployment of the European rail signalling system ERTMS/ETCS, the appointment, by the Commission, of a European coordinator for the ERTMS project as a priority project of Community interest, the definition of the Agency's role as system authority in the context of the various annual work programmes, and the adoption of the 'control-command and signalling' TSI for conventional rail ⁽²⁾. Given the growing importance of the Agency's input in this area, its tasks should be specified.
- (15) The Agency plays a leading role in the future deployment of the ERTMS in the whole rail system. To that end, coherence of timing between national migration plans should be ensured.
- (16) The version of ERTMS adopted by the Commission on 23 April 2008 should enable railway undertakings which have invested in interoperable rolling stock to secure an adequate return on their investment. This version should be completed with harmonised test specifications. Any additional specification requested by a national safety authority should not unduly prevent the movement of rolling stock fitted with future ERTMS versions or the version adopted by the Commission on 23 April 2008 on lines which are already equipped in accordance with the latter version.

⁽¹⁾ OJ L 315, 3.12.2007, p. 51.

⁽²⁾ Commission Decision 2006/679/EC of 28 March 2006 concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European conventional rail system (OJ L 284, 16.10.2006, p. 1).

(17) In order to promote interoperability, the Agency should assess the impact of the adaptation of any version of ERTMS installed prior to the version adopted by the Commission on 23 April 2008 towards this version.

(18) The Agency now has a large number of experts specialising in the interoperability and safety of the European rail system. It should be authorised to carry out ad hoc tasks at the Commission's request, subject to the compatibility of those tasks with the Agency's mission and compliance with the Agency's other priorities. In that light, the Agency's Executive Director should evaluate the admissibility of this assistance and report at least once a year on its provision to the Administrative Board. The Board may assess this report in accordance with the powers attributed to it by Regulation (EC) No 881/2004.

(19) The recruitment of project officers with a contract of a maximum of five years was intensive during the first year the Agency was established, which means that many of the technical staff have to leave the Agency within a short time span. In order to ensure an adequate quantity and quality of expertise and to anticipate possible difficulties in the recruitment procedures, the Agency should be allowed to extend the working contracts of specially qualified staff for another three years.

(20) The date by which the Agency's annual work programme is to be adopted should be amended to allow for better synchronisation with the budgetary decision-making process.

(21) The Agency's work programme should identify the objective of each activity and to whom it is to be addressed. The Commission should also be informed of the technical results of each activity, as this information goes well beyond the scope of the general report, which is addressed to all the institutions.

(22) Since the objective of this Regulation, namely the extension of the Agency's mission to include its participation in the simplification of the Community procedure for the certification of railway vehicles, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity 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.

(23) Regulation (EC) No 881/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments

Regulation (EC) No 881/2004 is hereby amended as follows:

1) Article 2 shall be replaced by the following:

'Article 2

Types of acts of the Agency

The Agency may:

(a) address recommendations to the Commission concerning the application of Articles 6, 7, 9b, 12, 14, 16, 16a, 16b, 16c, 17 and 18; and

(b) issue opinions to the Commission pursuant to Articles 9a, 10, 13 and 15, and to the authorities concerned in the Member States pursuant to Article 10.;

2) Article 3 shall be amended as follows:

(a) the first sentence in paragraph 1 shall be replaced by the following:

'1. For drawing up the recommendations provided for in Articles 6, 7, 9b, 12, 14, 16, 17 and 18 the Agency shall establish a limited number of working parties.;

(b) paragraph 3 shall be replaced by the following:

'3. The national safety authorities defined in Article 16 of the Railway Safety Directive, or, depending on the subject, the competent national authorities, shall appoint their representatives for the working parties in which they wish to participate.;

3) Article 8 shall be deleted;

4) the following Chapter title shall be inserted immediately after Article 9:

'CHAPTER 2a

NATIONAL RULES, CROSS-ACCEPTANCE AND TECHNICAL OPINIONS';

5) the following Articles shall be inserted:

'Article 9a

National rules

1. At the request of the Commission, the Agency shall carry out a technical examination of the new national rules submitted to the Commission in accordance with Article 8 of the Railway Safety Directive or Article 17(3) of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (recast) (*), (hereinafter referred to as the "Railway Interoperability Directive").

2. The Agency shall examine the compatibility of the rules referred to in paragraph 1 with the CSMs and with the TSIs in force. The Agency shall also examine whether these rules enable the CSTs in force to be achieved.

3. If, after taking account of the reasons given by the Member State, the Agency considers that any of these rules either is incompatible with the TSIs or the CSMs or does not allow CSTs to be reached, it shall submit an opinion to the Commission within two months of transmission of the rules to the Agency by the Commission.

Article 9b

Classification of national rules

1. The Agency shall facilitate Member States' acceptance of vehicles placed in service in another Member State in accordance with the procedures laid down in paragraphs 2 to 4.

2. The Agency shall, by 19 January 2009 review the list of parameters in Section 1 of Annex VII to the Railway Interoperability Directive and make the recommendations it considers appropriate to the Commission.

3. The Agency shall draw up a draft for a reference document cross-referencing all the national rules applied by the Member States for placing vehicles in service. This document shall contain the national rules of each Member State for each of the parameters listed in Annex VII to the Railway Interoperability Directive and specify the group referred to in Section 2 of that Annex to which these rules belong. These rules shall comprise those notified under Article 17(3) of the Railway Interoperability Directive, including those notified following adoption of TSIs (specific cases, open points, derogations) and those notified under Article 8 of the Railway Safety Directive.

4. With a view to gradually reducing the national rules in Group B referred to in Section 2 of Annex VII of the Railway Interoperability Directive, the Agency shall regularly draw up a draft for updating the reference document and forward it to the Commission. The first version of the document shall be presented to the Commission no later than 1 January 2010.

5. For the purpose of implementation of this Article, the Agency shall make use of the cooperation of the national safety authorities established under Article 6(5) and set up a working party in accordance with the principles of Article 3.

6) the following paragraphs shall be inserted in Article 10:

'2a. The Agency may be called upon to provide technical opinions:

(a) by a national safety authority or the Commission, on the equivalence of national rules for one or more parameters listed in Section 1 of Annex VII to the Railway Interoperability Directive;

(b) by the competent appeal body referred to in Article 21(7) of the Railway Interoperability Directive, in the case of a decision by a competent national safety authority refusing the placing in service of a railway vehicle.

2b. The Agency may be called upon by the Commission to provide technical opinions on urgent modifications to TSIs, in accordance with Article 7(1) of the Railway Interoperability Directive.;

7) Article 11 shall be deleted;

8) Article 13 shall be replaced by the following:

'Article 13

Notified bodies

1. Without prejudice to the responsibility of Member States for the notified bodies which they designate, the Agency may, at the request of the Commission, monitor the quality of the work of those bodies. It shall submit an opinion to the Commission where appropriate.

2. Without prejudice to the responsibility of Member States, the Agency shall, at the request of the Commission when it, in accordance with Article 28(4) of the Railway Interoperability Directive, considers that a notified body does not meet the criteria referred to in Annex VIII to that Directive, check to ensure that those criteria are met. The Agency shall issue an opinion to the Commission.;

9) Article 15 shall be replaced by the following:

'Article 15

Interoperability within the Community rail system

Without prejudice to the derogations provided for by Article 9 of the Railway Interoperability Directive, the Agency shall, at the request of the Commission, examine, from the point of view of interoperability, any project involving the design and/or construction or the renewal or upgrading of the subsystem for which an application for Community financial aid has been submitted. Within a period to be agreed with the Commission according to the importance of the project and the resources available and which cannot extend beyond two months, the Agency shall give an opinion on whether the project conforms with the relevant TSIs.;

(*) OJ L 191, 18.7.2008, p. 1.;

- 10) the following Chapter title shall be inserted immediately before Article 16:

‘CHAPTER 3a

MAINTENANCE OF VEHICLES’;

- 11) the following paragraph shall be added to Article 16:

‘These recommendations shall be consistent with the responsibilities already allocated to railway undertakings as provided for in Article 4 of the Railway Safety Directive and the entity in charge of maintenance as provided for in Article 14a of that Directive, and shall take full account of the certification mechanisms of railway undertakings and entities in charge of maintenance.’;

- 12) the following Article shall be inserted:

‘Article 16a

Certification of entities in charge of maintenance

1. The Agency shall by 1 July 2010 send to the Commission a recommendation in view of the implementation of the system of certification of entities in charge of maintenance in accordance with Article 14a(5) of the Railway Safety Directive.

The Agency’s assessment and recommendation shall in particular cover the following aspects taking due account of relations an entity in charge of maintenance can have with other parties such as keepers, railway undertakings and infrastructure managers:

- (a) whether the entity in charge of maintenance has adequate systems in place, including operational and management processes, to ensure the effective and safe maintenance of vehicles;
- (b) the content and the specifications of a system of certification adapted to the maintenance of wagons;
- (c) the type of bodies competent for certification and the requirements to be imposed on such bodies;
- (d) the format and validity of the certificates to be delivered to the entities in charge of maintenance;
- (e) the technical and operational inspections and controls.

2. Within a period of three years from the adoption by the Commission of the system of certification of maintenance referred to in Article 14a(5) of the Railway Safety Directive, the Agency shall send to the Commission a report evaluating the implementation of such system. By the same date, the

Agency shall also send to the Commission a recommendation with a view to defining the content and the specifications of a similar certification system in the case of entities in charge of the maintenance for other vehicles, such as locomotives, passenger cars, electrical multiple units (EMUs) and diesel multiple units (DMUs).

3. The Agency shall analyse the alternative measures decided in accordance with Article 14a(8) of the Railway Safety Directive in the context of its report on safety performance referred to in Article 9(2) of this Regulation.’;

- 13) the following Chapter title shall be inserted immediately after Article 16a:

‘CHAPTER 3b

RAILWAY STAFF’;

- 14) the following Article shall be inserted:

‘Article 16b

Train drivers

1. On matters related to Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (*) (hereinafter referred to as the “Train Drivers Directive”) the Agency shall:

- (a) prepare a draft of a Community model for the licence, the certificate and the certified copy of the certificate, their physical characteristics, taking into account therein anti-forgery measures;
- (b) cooperate with the competent authorities in order to ensure the interoperability of the registers for train drivers’ licences and certificates. To this end the Agency shall prepare a draft on the basic parameters of the registers to be set up, such as data to be recorded, their format and the data exchange protocol, access rights, the duration of data retention and the procedures to be followed in cases of bankruptcy;
- (c) prepare draft Community criteria on the choice of examiners and examinations;
- (d) evaluate the development of the certification of train drivers by submitting to the Commission, not later than four years following the adoption of the basic parameters of the registers, as provided for in Article 22(4) of the Train Drivers Directive, a report containing, where appropriate, improvements to be made to the system and measures regarding the theoretical and practical examination of the professional knowledge of applicants for the harmonised certificate for rolling stock and relevant infrastructure;

- (e) by 4 December 2012, examine the possibility of using a smartcard combining the licence and certificates provided for in Article 4 of the Train Drivers Directive, and shall prepare a cost/benefit analysis thereof. The Agency shall prepare a draft for the technical and operating specifications for such a smartcard;
- (f) assist the cooperation amongst Member States in the implementation of the Train Drivers Directive and organise appropriate meetings with representatives of the competent authorities;
- (g) if asked by the Commission, carry out a cost/benefit analysis of the application of the provisions of the Train Drivers Directive to train drivers operating exclusively on the territory of the requesting Member State. The cost/benefit analysis shall cover a period of ten years. This cost/benefit analysis shall be submitted to the Commission within two years of the setting-up of the registers in accordance with point 1 of Article 37 of the Train Drivers Directive;
- (h) if asked by the Commission, carry out another cost/benefit analysis which is to be submitted to the Commission no later than 12 months prior to the expiry of the temporary exemption period possibly granted by the Commission;
- (i) ensure that the system set up under paragraph 2(a) and (b) of Article 22 of the Train Drivers Directive complies with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (*).
2. On matters related to the Train Drivers Directive, the Agency shall make recommendations on:
- (a) modification of the Community Codes for the different types in categories A and B as referred to in Article 4(3) of the Train Drivers Directive;
- (b) the codes reflecting additional information, or medical restrictions for use imposed by a competent authority in accordance with Annex II to the Train Drivers Directive.
3. The Agency may make a reasoned request to the competent authorities for information on the status of train driver licences.

15) the following Article shall be inserted:

'Article 16c

Other on-board staff

In accordance with Article 28 of the Train Drivers Directive, the Agency shall, in a report to be presented by 4 June 2009, and taking into account the TSI on operation and traffic management developed under Directives 96/48/EC and 2001/16/EC, identify the profile and tasks of other crew members performing safety-critical tasks whose professional qualifications accordingly contribute to railway safety which should be regulated at Community level by means of a system of licences and/or certificates which may be similar to the system established by the Train Drivers Directive.;

16) in Article 17, the title and paragraph 1 shall be replaced by the following:

'Article 17

Vocational competences and training

1. The Agency shall make recommendations on specifying common criteria for defining vocational competences and assessing staff in the case of staff involved in the operation and maintenance of the rail system but which is not covered by Articles 16b or 16c.;

17) the following Chapter title shall be inserted immediately after Article 17:

'CHAPTER 3c

REGISTERS AND AGENCY'S PUBLIC DATABASE';

18) Article 18 shall be replaced by the following:

'Article 18

Registers

1. The Agency shall draw up and recommend to the Commission common specifications for:

- (a) the national vehicle registers in accordance with Article 33 of the Railway Interoperability Directive, including arrangements for exchange of data and a standard application form for registration;
- (b) the European register of authorised vehicle types in accordance with Article 34 of the Railway Interoperability Directive, including arrangements for exchange of data with the national safety authorities;
- (c) the register of infrastructure in accordance with Article 35 of the Railway Interoperability Directive.

(*) OJ L 315, 3.12.2007, p. 51.

(**) OJ L 8, 12.1.2001, p. 1.;

2. The Agency shall set up and keep a register of types of vehicles authorised by the Member States for placing in service on the rail network within the Community, in accordance with Article 34 of the Railway Interoperability Directive. The Agency shall also prepare a draft for the model of declaration of conformity to type, in accordance with Article 26(4) of that Directive.;

19) Article 19 shall be replaced by the following:

'Article 19

Accessibility of documents and registers

1. The Agency shall make publicly accessible the following documents and registers provided for by the Railway Interoperability Directive and the Railway Safety Directive:

- (a) the EC declarations of verification of subsystems;
- (b) the EC declarations of conformity of constituents available to the national safety authorities;
- (c) the licences issued in accordance with Directive 95/18/EC;
- (d) the safety certificates issued in accordance with Article 10 of the Railway Safety Directive;
- (e) the investigation reports sent to the Agency in accordance with Article 24 of the Railway Safety Directive;
- (f) the national rules notified to the Commission in accordance with Article 8 of the Railway Safety Directive and Articles 5(6) and 17(3) of the Railway Interoperability Directive;
- (g) the link to the national vehicle registers;
- (h) the link to the registers of infrastructure;
- (i) the European register of authorised types of vehicles;
- (j) the register of requests for changes and planned changes to the ERTMS specifications;
- (k) the register of vehicle keeper markings kept by the Agency in accordance with the TSI on operation and traffic management.

2. The practical arrangements for transmitting the documents referred to in paragraph 1 shall be discussed and agreed by Member States and the Commission on the basis of a draft of the Agency.

3. When transmitting the documents referred to in paragraph 1, the bodies concerned may indicate which documents are not to be disclosed to the public for reasons of security.

4. The national authorities responsible for issuing the documents referred to in paragraph 1(c) and (d) shall notify the Agency within one month of each individual decision to issue, renew, amend or revoke them.

5. The Agency may add to this public database any public document or link relevant to the objectives of this Regulation.;

20) the title of Chapter 4 shall be replaced by the following:

'SPECIAL TASKS';

21) the following Articles shall be inserted:

'Article 21a

ERTMS

1. The Agency, in coordination with the Commission, shall assume the tasks set out in paragraphs 2 to 5 with a view to

- (a) ensuring a coherent development of the ERTMS;
- (b) contributing to the compliance of ERTMS equipment as implemented in Member States with the specifications in force.

2. The Agency shall set up a procedure for managing requests for changes to specifications of the ERTMS. To this end, a register of requests for changes and planned changes to ERTMS specifications shall be set up and maintained by the Agency.

The Agency shall recommend the adoption of a new version only when the previous version has been deployed at a sufficient rate. The development of new versions shall not be detrimental to the rate of deployment of the ERTMS, the stability of the specifications which is needed for the optimisation of the production of ERTMS equipment, the return of investment for railway undertakings and the efficient planning of the deployment of the ERTMS.

3. The Agency shall support the efforts of the Commission in developing an EU deployment plan for the ERTMS and coordinating installation of the ERTMS along the trans-European transport corridors.

4. The Agency shall develop a strategy for managing the different versions of the ERTMS with a view to ensuring technical and operational compatibility between networks and vehicles fitted with different versions and to providing incentives to the swift implementation of the version in force and of possible newer versions.

In accordance with Article 6(9) of the Railway Interoperability Directive, the Agency shall ensure that successive versions of ERTMS equipment are backward compatible, as from the version adopted by the Commission on 23 April 2008.

With regard to ERTMS equipment which was placed in service before 23 April 2008 or whose installation or upgrading was at an advanced stage of deployment on that date, the Agency shall prepare an assessment report which shall identify:

- (a) the additional costs to be borne by early implementers as a consequence of the introduction of the version adopted by the Commission on 23 April 2008;
- (b) all possible mechanisms, including financial ones, to support the migration from the earlier versions to the version referred to in point (a).

The Commission shall take the appropriate measures within one year from the date on which it received the Agency's assessment report.

5. The Agency shall set up and chair an ad hoc working group of notified bodies with a view to checking that the EC procedures of verification carried out by notified bodies in the context of specific ERTMS projects are applied consistently. The Agency shall also cooperate with national safety authorities with a view to checking that the procedures for authorisation for placing in service are applied consistently. Where the Agency finds that there is a risk of lack of technical and operational compatibility between networks and vehicles fitted with equipment being subject to these procedures, it shall forthwith inform the Commission which shall take the appropriate measures.

6. Should technical incompatibilities emerge between networks and vehicles in the context of specific ERTMS projects, notified bodies and national safety authorities shall ensure that the Agency is able to obtain any relevant information on the applied procedures for "EC" verification and placing in service as well as on the operational conditions. The Agency shall, if necessary, recommend appropriate measures to the Commission.

7. The Agency shall evaluate the certification process of the ERTMS equipment by submitting to the Commission by 1 January 2011 a report containing, where appropriate, improvements to be made.

8. On the basis of the report referred to in paragraph 7, the Commission shall assess the costs and benefits of using a single type of laboratory equipment, a single reference track and/or a single certification body at Community level. Such certification body needs to comply with the criteria of Annex VIII of the Railway Interoperability Directive. The Commission may present a report and, if appropriate, bring forward a legislative proposal to improve the ERTMS certification system.

Article 21b

Assistance to the Commission

1. Within the limits of Article 30(2)(b), the Agency shall, at the request of the Commission, assist the Commission in the implementation of the Community legislation aimed at enhancing the level of interoperability of railway systems and at developing a common approach to safety on the European railway system.

2. This assistance shall be limited in time and scope, and carried out without prejudice to all other tasks assigned to the Agency in this Regulation and may include:

- (a) communicating information on how specific aspects of the Community legislation are implemented;
- (b) providing technical advice in matters requiring specific know-how;
- (c) collecting information through the cooperation of national safety authorities and investigation bodies provided for in Article 6(5).

3. The Executive Director shall report at least once a year to the Board on the implementation of this Article, including its impact on resources.;

22) Article 24(3) shall be replaced by the following:

'3. Without prejudice to Article 26(1), the Agency's staff shall consist of:

- temporary employees recruited by the Agency for a maximum of five years from among professionals from the sector on the basis of their qualifications and experience in the field of railway safety and interoperability;
- officials assigned or seconded by the Commission or Member States for a maximum of five years; and
- other servants, as defined in the Conditions of Employment of other servants of the European Communities, to carry out implementing or secretarial tasks.

During the first 10 years of operation of the Agency, the period of 5 years referred to in the first indent of the first subparagraph may be extended for another period of up to a maximum of 3 years when required to guarantee the continuity of its services.;

23) Article 25 shall be amended as follows:

(a) in paragraph 2, point (c) shall be replaced by the following:

‘(c) adopt, by 30 November each year, and taking the opinion of the Commission into account, the work programme of the Agency for the coming year and forward it to the Member States, the European Parliament, the Council and the Commission. That work programme shall be adopted without prejudice to the annual Community budgetary procedure. If, within 15 days of the date of adoption of the work programme, the Commission expresses its disagreement with the programme, the Administrative Board shall re-examine the programme and adopt it, amended if necessary, within a period of two months, in second reading either by a two-thirds majority, including the Commission representatives, or by unanimity of the representatives of the Member States;’;

(b) the following paragraph shall be added:

‘3. The Agency’s work programme shall identify the objectives of each activity. As a general rule, each activity and/or each outcome shall be the subject of a report to the Commission.’;

24) Article 26(1) shall be replaced by the following:

‘1. The Administrative Board shall be composed of one representative of each Member State and four representatives of the Commission, as well as of six representatives, without the right to vote, the latter representing at European level the following groups:

- (a) railway undertakings;
- (b) infrastructure managers;

(c) the railway industry;

(d) worker unions;

(e) passengers;

(f) freight customers.

For each of these groups, the Commission shall appoint a representative and an alternate from a shortlist of four names submitted by their respective European organisations with a view to ensuring appropriate representation of all interests.

Board members and their alternates shall be appointed on the basis of their relevant experience and expertise.’;

25) Article 33(1) shall be replaced by the following:

‘1. In order to perform the tasks entrusted to it by Articles 9, 9a, 10, 13 and 15, the Agency may carry out visits to the Member States in accordance with the policy defined by the Administrative Board. The national authorities of the Member States shall facilitate the work of the Agency’s staff.’;

26) Article 36(1) shall be replaced by the following:

‘1. The Agency shall be open to participation by European countries and countries within the scope of the European Neighbourhood Policy which have concluded agreements with the European Community under which the countries concerned have adopted and are applying Community legislation in the field covered by this Regulation.’.

Article 2

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

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

**REGULATION (EC) No 1336/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008**

**amending Regulation (EC) No 648/2004 in order to adapt it to Regulation (EC) No 1272/2008 on
classification, labelling and packaging of substances and mixtures**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

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) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ⁽³⁾ provides for the harmonisation of the classification and labelling of substances and mixtures within the Community. That Regulation will replace Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽⁴⁾ as well as Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽⁵⁾.

(2) Regulation (EC) No 1272/2008 builds on the experience with Directives 67/548/EEC and 1999/45/EC and incorporates the criteria for classification and labelling of substances and mixtures provided for by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which has been adopted at the international level, within the structure of the United Nations.

(3) Certain provisions on classification and labelling laid down in Directives 67/548/EEC and 1999/45/EC also serve for the purpose of application of other Community legislation, such as Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents ⁽⁶⁾.

(4) An analysis of the potential effects of replacing Directives 67/548/EEC and 1999/45/EC and the introduction of the GHS criteria led to the conclusion that by adapting the references to those Directives in Regulation (EC) No 648/2004, the scope of that act should be maintained.

(5) The transition from the criteria for classification contained in Directives 67/548/EEC and 1999/45/EC should be fully completed on 1 June 2015. Manufacturers of detergents are manufacturers, importers or downstream users within the meaning of Regulation (EC) No 1272/2008 and should therefore be given the possibility under this Regulation to adjust to that transition within a similar timeframe to that provided for in Regulation (EC) No 1272/2008.

(6) Regulation (EC) No 648/2004 should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 648/2004

Regulation (EC) No 648/2004 is hereby amended as follows:

- the word 'preparation' or 'preparations' within the meaning of Article 3(2) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁷⁾, in its version of 30 December 2006, shall be replaced by 'mixture' or 'mixtures' respectively throughout the text;
- in paragraph 1 of Article 9, the introductory phrase shall be replaced by the following:

'Without prejudice to Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ^(*), manufacturers placing on the market the substances and/or mixtures covered by this Regulation shall hold at the disposal of the competent authorities of the Member States:

^(*) OJ L 353, 31.12.2008, p. 1.'

⁽¹⁾ OJ C 120, 16.5.2008, p. 50.

⁽²⁾ Opinion of the European Parliament of 3 September 2008 (not yet published in the Official Journal) and Council Decision of 28 November 2008.

⁽³⁾ OJ L 353, 31.12.2008, p. 1.

⁽⁴⁾ OJ 196, 16.8.1967, p. 1.

⁽⁵⁾ OJ L 200, 30.7.1999, p. 1.

⁽⁶⁾ OJ L 104, 8.4.2004, p. 1.

⁽⁷⁾ OJ L 396, 30.12.2006, p. 1. Corrected version in OJ L 136, 29.5.2007, p. 3.

3. Article 11(1) shall be replaced by the following:

Article 2

Entry into force and application

‘1. Paragraphs 2 to 6 are without prejudice to the provisions relating to the classification, labelling and packaging of substances and mixtures in Regulation (EC) No 1272/2008.’.

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

Points 2 and 3 of Article 1 shall apply from 1 June 2015.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

REGULATION (EC) No 1337/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
establishing a facility for rapid response to soaring food prices in developing countries

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 179(1) thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽¹⁾,

Whereas:

- (1) The volatility of food prices has put numerous developing countries and their populations in a dramatic situation. This food crisis, accompanied by a financial and energy crisis and environmental deterioration, risks putting additional hundreds of millions of people in extreme poverty, and in circumstances of hunger and malnutrition and calls for increased solidarity with those populations. All the data on the outlook for food markets lead to the conclusion that the high volatility of food prices could continue in the years to come.
- (2) As a complement to the European Union's current development policy instruments, a financing facility for a rapid response to the crisis caused by volatile food prices in developing countries should therefore be established by this Regulation.
- (3) The European Consensus on Development ⁽²⁾, adopted by the Council and the Representatives of the Governments of the Member States meeting within the Council, the European Parliament and the Commission on 20 December 2005, states that the European Community (hereinafter referred to as 'the Community') will continue to work to improve food security at international, regional and national level, to which goal this Regulation should contribute.
- (4) The European Parliament adopted on 22 May 2008 a resolution on rising food prices in the European Union and the developing countries, urging the Council to ensure coherence of all food-related national and international policies aiming at implementing the right to food.
- (5) During its meeting of 20 June 2008, the European Council strongly reaffirmed its commitment to achieving a collective Official Development Assistance (ODA) target of 0,56 % of Gross National Income (GNI) by 2010 and 0,7 % of GNI by 2015, as set out in the Council conclusions of 24 May 2005, the European Council conclusions of 16 and 17 June 2005 and the European Consensus on Development.
- (6) Acknowledging in its conclusions of 20 June 2008 that high food prices were affecting the situation of the world's poorest populations and putting at risk progress towards the achievement of all Millennium Development Goals (MDGs), the European Council adopted an EU Agenda for Action on MDGs which states that the European Union is committed, in line with the Food and Agricultural Organisation (FAO) Conference Declaration adopted by the FAO High Level Conference on World Food Security on 5 June 2008 (the 'FAO Conference Declaration'), to promote a global partnership for food and agriculture and wishes to play a substantial role in helping to bridge part of the financing gap by 2010 in the areas of agriculture, food security and rural development.
- (7) The European Council also concluded that in this endeavour the European Union will promote a more coordinated and longer-term international response to the current food crisis, in particular in the United Nations (UN) and in international financial institutions, that it welcomes the establishment of the High-Level Task Force on the Global Food Security Crisis (HLTF) established by the UN Secretary-General and is determined to play its full part in implementing the FAO Conference Declaration. In this regard a Comprehensive Framework of Action (CFA) has been adopted by the HLTF, and international organisations and regional organisations have launched their own initiatives. The European Council also concluded that the European Union will support a strong agricultural supply response in developing countries, providing in particular the necessary financing for agricultural inputs and assistance in using

⁽¹⁾ Opinion of the European Parliament of 4 December 2008 (not yet published in the Official Journal) and Council Decision of 16 December 2008.

⁽²⁾ Joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy: 'The European Consensus' (OJ C 46, 24.2.2006, p. 1).

market-based risk management instruments, that the European Union will significantly enhance its support to public and private investments in agriculture and more generally encourage developing countries to develop better agriculture policies, especially to support food security and reinforce regional integration and that the European Union will also mobilise resources to finance, beyond food aid, safety nets for poor and vulnerable population groups.

(8) Financial and material needs to fully address the consequences and causes of the high food prices are very high. The response should come from the international community in its entirety and the Community has endeavoured to contribute its fair share. The European Council of 20 June 2008 welcomed the Commission's intention to come forward with a proposal for a new fund to support agriculture in developing countries, within the framework of the current financial perspectives.

(9) The Community response strategy should notably aim to strongly encourage a positive short to medium-term supply response from the agricultural sector in developing countries while at the same time also significantly reducing the negative effects of volatility of food prices on the poorest in these countries. A supply-side response is also in the interest of the Community in order to alleviate the current pressure on agricultural prices.

(10) The Community has at its disposal several instruments focused on development assistance with a long-term perspective, in particular Regulation (EC) No 1905/2006 of the European Parliament and the Council of 18 December 2006 establishing a financing instrument for development cooperation ⁽¹⁾, and the European Development Fund, providing ODA to African, Caribbean and Pacific (ACP) countries and Overseas Countries and Territories (OCTs) (hereinafter referred to as 'the EDF'), which have recently been programmed in line with eligible countries' medium and long-term development priorities. Large-scale reprogramming under these instruments to respond to a short-term crisis would jeopardise the balance and coherence of the existing cooperation strategies with those countries. The Community also has at its disposal Council Regulation (EC) No 1257/96 of 20 June 1996 concerning

humanitarian aid ⁽²⁾ to provide emergency assistance and Regulation (EC) No 1717/2006 of the European Parliament and of the Council of 15 November 2006 establishing an Instrument for Stability ⁽³⁾.

(11) Those instruments, however, have already been mobilised or reprogrammed in 2008 to the fullest possible extent to address the negative effects of the volatile food prices situation in developing countries. To a very limited extent the same could be done in 2009; however, that would be far from being sufficient to respond to the needs.

(12) As a consequence, it is necessary to adopt a specific financing facility, complementary to existing external financing instruments, to adopt urgent and supplementary measures that address rapidly the consequences in developing countries of the present situation of volatile food prices.

(13) Assistance under this Regulation should be managed in such a way as to increase the supply of foodstuffs to local populations.

(14) The measures adopted with this financing facility should help developing countries to boost agricultural productivity in the next seasons, to respond rapidly to the immediate needs of the countries and their population and to take initial steps needed to prevent as far as possible further food insecurity situations, and also contribute to mitigating the effects of the volatile food prices globally, to the benefit of the poorest people, of small-holder farmers and also of European consumers and farmers.

(15) The very nature of measures provided for under this Regulation calls for the establishment of efficient, flexible, transparent and rapid decision-making procedures for their financing, with strong cooperation between all institutions concerned.

(16) Coherence and continuity must be ensured between short-term measures aimed at providing relief to the populations most directly and seriously affected by the soaring and/or volatile food prices, and more structural measures intended to prevent the recurrence of the current food crisis.

⁽¹⁾ OJ L 378, 27.12.2006, p. 41.

⁽²⁾ OJ L 163, 2.7.1996, p. 1.

⁽³⁾ OJ L 327, 24.11.2006, p. 1.

- (17) It is necessary to provide for the protection of the Community's financial interests in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests ⁽¹⁾, Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities ⁽²⁾ and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-fraud Office (OLAF) ⁽³⁾.
- (18) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action required, 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 to achieve those objectives.
- (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 ⁽⁴⁾.
- (20) The different development instruments and this financing facility shall be applied so as to ensure continuity of cooperation in particular as regards the transition from emergency to medium-and long-term response. This Regulation should fit in with a long-term strategy to contribute to food security in developing countries, based on their own needs and plans.
- (21) In order to ensure that the measures provided for in this Regulation are effective and given their urgent nature, this Regulation should enter into force on the day following that of its publication,

2. The measures referred to in paragraph 1 shall benefit developing countries, as defined by the Organisation for Economic Cooperation and Development's Development Assistance Committee (OECD/DAC), and their populations, in accordance with the following provisions.

Those measures shall be adopted in accordance with the procedure referred to in Article 13(2). They shall finance initiatives supporting the purpose and objectives of this Regulation.

3. Whenever feasible the action programmes implemented by entities eligible for funding under Article 4(1) shall be drawn up in consultation with civil society organisations and implementation of projects funded through this financing facility shall involve such organisations.

4. To optimise the utility and impact of this Regulation, resources shall be concentrated on a limited list of high-priority target countries, identified on the basis of the set of criteria laid down in the Annex, and in coordination with other donors and other development partners through relevant needs-assessments made available by specialised and international organisations such as those of the UN system, in consultation with partner countries.

5. To ensure the coherence and effectiveness of Community assistance, where the programme to be implemented is of a regional or cross-border nature, it may be decided, in accordance with the procedure referred to in Article 13(2), that populations of other developing countries not belonging to that region can benefit from the programme in question.

6. Where support is to be provided for measures implemented by international organisations, including regional organisations, such organisations shall be selected in accordance with the procedure referred to in Article 13(2) and on the basis of their added value, their comparative advantage and their capacity to implement programmes in a speedy and efficient manner in response to the specific needs of the targeted developing countries in relation to the objectives of this Regulation.

HAVE ADOPTED THIS REGULATION:

Article 2

Objectives and Principles

1. The primary objectives of the assistance and cooperation under this Regulation shall be to:

- (a) encourage a positive supply response from the agricultural sector in target countries and regions;
- (b) support activities to respond rapidly and directly to mitigate the negative effects of volatile food prices on local populations in line with global food security objectives, including UN standards for nutritional requirements;

Article 1

Subject matter and scope

1. The Community shall finance measures aimed at supporting a rapid and direct response to the volatile food prices in developing countries, addressing primarily the period between emergency aid and medium- to long-term development cooperation.

⁽¹⁾ OJ L 312, 23.12.1995, p. 1.

⁽²⁾ OJ L 292, 15.11.1996, p. 2.

⁽³⁾ OJ L 136, 31.5.1999, p. 1.

⁽⁴⁾ OJ L 184, 17.7.1999, p. 23.

(c) strengthen the productive capacities and the governance of the agricultural sector to enhance the sustainability of interventions.

2. A differentiated approach depending on development contexts and the impact of volatile food prices shall be pursued so that target countries or regions and their populations are provided with targeted, tailor-made and well adapted support, based on their own needs, strategies, priorities and response capacities.

3. Measures supported under this Regulation shall be coordinated with those supported under other instruments, including Regulation (EC) No 1257/96, Regulation (EC) No 1905/2006 and Regulation (EC) No 1717/2006, and the ACP-EC Partnership Agreement ⁽¹⁾, so as to ensure continuity of cooperation, in particular as regards the transition from emergency to medium- and long-term response.

4. The Commission shall ensure that measures adopted under this Regulation are consistent with the Community's overall strategic policy framework for the eligible country or countries concerned.

Article 3

Implementation

1. Community assistance and cooperation shall be implemented through a set of decisions to finance supporting measures as described in Article 1, paragraphs (1), (2) and (3), which shall be adopted in accordance with the procedure referred to in Article 13(2). An overall plan for the use of this financing facility, including the list of target countries referred to in Article 1(4) and the balance between eligible entities referred to in Article 4(2) shall be presented by the Commission and adopted in accordance with the procedure referred to in Article 13(2). This overall plan shall receive the opinion of the committee referred to in Article 13(1) before 1 May 2009.

2. Taking into account the specific country-level conditions, supporting measures that shall be eligible for implementation are:

- (a) measures to improve access to agricultural inputs and services including fertilisers and seeds, paying special attention to local facilities and availability;
- (b) safety net measures aiming at maintaining or improving the agricultural productive capacity, and at addressing the

⁽¹⁾ Partnership Agreement between the Members of the African, Caribbean and Pacific Group of States, of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 (OJ L 317, 15.12.2000, p. 3).

basic food needs of the most vulnerable populations, including children;

- (c) other small-scale measures aiming at increasing production based on country needs: microcredit, investment, equipment, infrastructure and storage; as well as vocational training and support to professional groups in the agriculture sector.

3. The implementation of these supporting measures shall be in line with the Declaration on Aid Effectiveness adopted by the High Level Forum on Aid Effectiveness, held in Paris, on 2 March 2005 (the 'Paris Declaration on Aid Effectiveness') and the Agenda for Action adopted by the High Level Forum on Aid Effectiveness, held in Accra, on 4 September 2008 (the 'Accra Agenda for Action'). It shall be focused on small and medium-sized farms for family and food-producing agriculture, particularly those run by women, and poor populations most affected by the food crisis, avoiding any kind of distortion of local markets and production; agricultural inputs and services shall as far as possible be locally purchased.

4. Administrative support measures which meet the objectives of this Regulation may be financed up to a maximum of 2 % of the amount referred to in Article 12.

Article 4

Eligibility

1. The entities eligible for funding shall be, insofar as their programmes contribute to the objectives of this Regulation:

- (a) partner countries and regions, and their institutions;
- (b) decentralised bodies in the partner countries, such as municipalities, provinces, departments and regions;
- (c) joint bodies set up by the partner countries and regions with the Community;
- (d) international organisations, including regional organisations, UN bodies, departments and missions, international and regional financial institutions and development banks;
- (e) Community institutions and bodies, but only for the purposes of implementing the support measures referred to in Article 3(4);
- (f) EU agencies;

- (g) the following entities and bodies of the Member States, partner countries and regions and any other third country complying with the rules on access to the Community's external assistance set out in Regulation (EC) No 1905/2006, insofar as they help to achieve the objectives of this Regulation:
- (i) public or parastatal bodies, local authorities and consortia or representative associations thereof;
 - (ii) companies, firms and other private organisations and businesses;
 - (iii) financial institutions that grant, promote and finance private investment in partner countries and regions;
 - (iv) non-State actors operating on an independent and accountable basis;
 - (v) natural persons.

2. An appropriate balance shall be applied in the allocation of resources between the bodies listed in paragraph 1(d) of this Article and other eligible entities.

Article 5

Types of financing

Community financing may take the following forms:

- (a) projects and programmes;
- (b) budget support, especially sectoral budget support, if the partner country's management of public spending is sufficiently transparent, reliable and effective, and if the conditions for budget support set out in the relevant geographical financing instrument have been met;
- (c) contributions to international or regional organisations and international funds managed by such organisations;
- (d) contributions to national funds set up by partner countries and regions to attract joint financing from a number of donors, or contributions to funds set up by one or more donors for the purpose of the joint implementation of projects;
- (e) co-financing with entities eligible for funding as defined in Article 4;

- (f) funds made available to the European Investment Bank (EIB) or other financial intermediaries on the basis of Commission programmes for the purpose of providing loans (in particular to support investment in and development of the private sector), risk capital (in the form of subordinated or conditional loans) or other temporary minority holdings in business capital, and contributions to guarantee funds in accordance with Article 32 of Regulation (EC) No 1905/2006, to the extent that the financial risk of the Community is limited to these funds.

Article 6

Financing and Management procedures

1. The measures financed under this Regulation shall be implemented in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁾, taking into account where appropriate the crisis-related nature of the measures to be adopted.

2. In the event of co-financing and in other duly justified cases, the Commission may entrust tasks of public authority, and in particular budget implementation tasks, to the bodies referred to in Article 54(2)(c) of Regulation (EC, Euratom) No 1605/2002.

3. In the case of decentralised management, the Commission may decide to use the procurement or grant procedures of the beneficiary partner country or region after verifying that they respect the relevant criteria set out in Regulation (EC, Euratom) No 1605/2002, provided that the conditions set out in Regulation (EC) No 1905/2006 are met.

4. Community assistance shall in principle not be used for paying taxes, duties or charges in eligible countries.

5. Participation in the appropriate contractual procedures shall be open to all natural and legal persons who are eligible pursuant to the geographical development instrument applicable to the country in which the action takes place, as well as to all natural and legal persons who are eligible pursuant to the rules of the implementing international organisation, care being taken to ensure that equal treatment is afforded to all donors. The same rules shall apply in respect of supplies and materials. Experts may be of any nationality.

⁽¹⁾ OJ L 248, 16.9.2002, p. 1.

*Article 7***Budget commitments**

Budget commitments shall be made on the basis of decisions taken by the Commission.

*Article 8***Protecting the Community's financial interests**

1. Any financial agreement resulting from the implementation of this Regulation shall contain provisions ensuring the protection of the Community's financial interests, in particular with respect to irregularities, fraud, corruption and any other illegal activity, in accordance with Regulation (EC, Euratom) No 2988/95, Regulation (Euratom, EC) No 2185/96 and Regulation (EC) No 1073/1999.

2. Agreements shall expressly entitle the Commission and the Court of Auditors to perform audits, including document audits or on-the-spot audits of any contractor or subcontractor who has received Community funds. They shall also expressly authorise the Commission to carry out on-the-spot checks and inspections as provided for in Regulation (Euratom, EC) No 2185/96.

3. All contracts resulting from the implementation of assistance shall ensure the rights of the Commission and the Court of Auditors under paragraph 2 of this Article during and after the performance of the contracts.

*Article 9***Visibility of the European Union**

Contracts concluded by virtue of this Regulation shall include specific provisions that ensure the appropriate visibility of the European Union in all activities undertaken on the basis of those contracts.

*Article 10***Evaluation**

1. The Commission shall monitor and review activities implemented under this Regulation, where appropriate by means of independent external evaluations, in order to ascertain whether the objectives have been met and enable it to formulate recommendations with a view to improving relevant future development cooperation operations. Proposals by the European Parliament or the Council for independent external evaluations shall be taken into due account.

2. The Commission shall send its evaluation reports to the European Parliament and to the committee referred to in Article 13 for information. Member States may request to discuss specific evaluations in that committee.

3. The Commission shall associate all relevant stakeholders, including non-State actors and local authorities, in the evaluation phase of the Community assistance provided under this Regulation.

*Article 11***Reporting**

The Commission shall provide the European Parliament and the Council with a report on the implementation of the measures, including, as far as possible, on the main outcomes and impacts of the assistance provided under this Regulation, no later than 31 December 2012. In December 2009 the Commission shall provide the European Parliament and the Council with an initial interim report on the measures undertaken. The reports mentioned in this Article shall pay particular attention to the requirements of the Paris Declaration on Aid Effectiveness and the Accra Agenda for Action.

*Article 12***Financial provisions**

The total financial reference amount for the implementation of this Regulation over the period 2008-2010 shall be EUR 1 billion.

*Article 13***Committee**

1. The Commission shall be assisted by the Committee set up by Article 35(1) of Regulation (EC) No 1905/2006.

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

3. The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at 10 working days for measures adopted up to 30 April 2009 and 30 days for measures adopted subsequently.

*Article 14***Entry into force**

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

It shall apply until 31 December 2010.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

ANNEX

Indicative criteria to select target countries and allocate financial resources:

- Poverty levels and real needs of populations
- Food price developments and potential social and economic impact:
 - Reliance on food imports
 - Social vulnerability and political stability
 - Macroeconomic effects of food price developments
- Capacity of country to respond and implement appropriate response measures:
 - Agricultural production capacity
 - Resilience to external shocks.

Indicative financial allocations to countries shall be based on the target country selection criteria and take into account the population size of the target country.

Account will also be taken of other sources of financing available to the target country, at short term, from the donor community, to respond to the food price developments.

REGULATION (EC) No 1338/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
on Community statistics on public health and health and safety at work
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 285(1) 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) Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) ⁽³⁾, stated that the statistical element of the information system on public health was to be developed in collaboration with Member States using, as necessary, the Community Statistical Programme to promote synergy and avoid duplication. Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-2013) ⁽⁴⁾ indicated that its objective of generating and disseminating health information and knowledge would be pursued by actions to develop further a sustainable health monitoring system with mechanisms for collection of comparable data and information, with appropriate indicators, and to develop, with the Community Statistical Programme, the statistical element of this system.

(2) Community information on public health has been developed systematically through the Community public health

programmes. Building on this work, a list of European Community Health Indicators (ECHI) has now emerged providing an overview of health status, determinants of health and health systems. In order to make available the minimum statistical data set needed for the calculation of ECHI, Community statistics on public health should be consistent, when relevant and possible, with the developments and achievements resulting from Community action in the field of public health.

(3) Council Resolution of 3 June 2002 on a new Community strategy on health and safety at work (2002-2006) ⁽⁵⁾ called on the Commission and the Member States to step up work in hand on harmonisation of statistics on accidents at work and occupational illnesses, so as to have available comparable data from which to make an objective assessment of the impact and effectiveness of the measures taken under the new Community strategy, as well as emphasised, in a specific section, the need to take into account the increase in the proportion of women on the labour market and to respond to their specific needs in relation to policies on health and safety at work. In addition, in its Resolution of 25 June 2007 on a new Community strategy on health and safety at work (2007-2012) ⁽⁶⁾ the Council called on the Commission to cooperate with the legislative authorities in establishing an appropriate European statistical system in the area of occupational safety and health, which takes account of the different national systems and avoids imposing additional administrative burdens. Finally, in its Recommendation of 19 September 2003 concerning the European schedule of occupational diseases ⁽⁷⁾, the Commission recommended that the Member States progressively make their statistics on occupational diseases compatible with the European schedule, in accordance with the work being done on the system of harmonising European statistics on occupational diseases.

(4) The Barcelona European Council of 15 and 16 March 2002 recognised three guiding principles for the reform of health care systems: accessibility for all, high-quality care and long-term financial sustainability. The Commission Communication of 20 April 2004 entitled 'Modernising social

⁽¹⁾ OJ C 44, 16.2.2008, p. 103.

⁽²⁾ Opinion of the European Parliament of 13 November 2007 (OJ C 282 E, 6.11.2008, p. 109), Council Common Position of 2 October 2008 (OJ C 280 E, 4.11.2008, p. 1) and Position of the European Parliament of 19 November 2008 (not yet published in the Official Journal).

⁽³⁾ OJ L 271, 9.10.2002, p. 1.

⁽⁴⁾ OJ L 301, 20.11.2007, p. 3.

⁽⁵⁾ OJ C 161, 5.7.2002, p. 1.

⁽⁶⁾ OJ C 145, 30.6.2007, p. 1.

⁽⁷⁾ OJ L 238, 25.9.2003, p. 28.

protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the “open method of coordination”, proposed starting work to identify possible indicators for joint objectives for developing care systems on the basis of activities undertaken in the context of the Community action programme for health, of Eurostat’s health statistics and of cooperation with international organisations. In establishing such indicators, specific attention should be devoted to the use and comparability of self-assessed health as reported in surveys.

- (5) Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme ⁽¹⁾ includes an action on environment and health and quality of life as a key environmental priority, calling for the definition and development of indicators of health and environment. In addition, the Council Conclusions on Structural Indicators of 8 December 2003 requested that indicators on biodiversity and health be included, under the title ‘environment’, in the structural indicators database used for the annual Spring Report to the European Council; health and safety at work indicators are also included in this database, under the title ‘employment’. The set of sustainable development indicators adopted by the Commission in 2005 also contains a theme on public health indicators.
- (6) The Environment and Health Action Plan 2004-2010 recognises the need to improve the quality, comparability and accessibility of data on health status for diseases and disorders linked to the environment, using the Community Statistical Programme.
- (7) Council Resolution of 15 July 2003 on promoting the employment and social integration of people with disabilities ⁽²⁾ called on the Member States and the Commission to collect statistical material on the situation of people with disabilities, including on the development of services and benefits for this group. In addition, the Commission in its Communication of 30 October 2003 entitled ‘Equal opportunities for people with disabilities: A European Action Plan’, decided to develop context indicators, which are comparable across Member States, in order to assess the effectiveness of disability policies. It indicated that

maximum use should be made of sources and structures of the European Statistical System, in particular through development of harmonised survey modules, to acquire the internationally comparable statistical information needed for monitoring progress.

- (8) In order to ensure relevance and comparability of the data and avoid duplication of work, the statistical activities of the Commission (Eurostat) in the area of public health and health and safety at work should be carried out in cooperation with the United Nations and its special organisations, such as the World Health Organisation (WHO) and the International Labour Organisation (ILO), as well as the Organisation for Economic Cooperation and Development (OECD), when relevant and possible.
- (9) The Commission (Eurostat) already collects on a regular basis statistical data on public health and health and safety at work from the Member States, which provide such data on a voluntary basis. It also collects data on those areas through other sources. Those activities are developed in close collaboration with Member States. In the area of public health statistics in particular, development and implementation are steered and organised according to a partnership structure between the Commission (Eurostat) and Member States. However, greater accuracy and reliability, coherence and comparability, coverage, timeliness and punctuality of the existing statistical data collections are still needed and it is also necessary to ensure that further collections agreed and developed with the Member States are implemented in order to achieve the minimum statistical data set necessary at Community level in the areas of public health and health and safety at work.
- (10) The production of specific Community statistics is governed by the rules set out in Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics ⁽³⁾.
- (11) This Regulation ensures full respect for the right to the protection of personal data as provided for in Article 8 of the Charter of Fundamental Rights of the European Union ⁽⁴⁾.
- (12) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽⁵⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the

⁽¹⁾ OJ L 242, 10.9.2002, p. 1.

⁽²⁾ OJ C 175, 24.7.2003, p. 1.

⁽³⁾ OJ L 52, 22.2.1997, p. 1.

⁽⁴⁾ OJ C 303, 14.12.2007, p. 1.

⁽⁵⁾ OJ L 281, 23.11.1995, p. 31.

- Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ⁽¹⁾ apply in the context of this Regulation. The statistical requirements to which Community action in the field of public health, national strategies for the development of high-quality, accessible and sustainable health care and Community strategy on health and safety at work gives rise, as well as requirements arising in connection with structural indicators, sustainable development indicators and ECHI and other sets of indicators which it is necessary to develop for the purpose of monitoring Community and national political actions and strategies in the areas of public health and health and safety at work, constitute a substantial public interest.
- (13) The transmission of data subject to statistical confidentiality is governed by the rules set out in Regulation (EC) No 322/97 and in Council Regulation (Euratom, EEC) No 1588/90 of 11 June 1990 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities ⁽²⁾. Measures which are taken in accordance with those Regulations ensure the physical and logical protection of confidential data and ensure that no unlawful disclosure and non-statistical use occur when Community statistics are produced and disseminated.
- (14) In the production and dissemination of Community statistics under this Regulation, the national and Community statistical authorities should take account of the principles set out in the European Statistics Code of Practice, which was adopted by the Statistical Programme Committee on 24 February 2005.
- (15) Since the objective of this Regulation, namely the establishment of a common framework for the systematic production of Community statistics on public health and health and safety at work, cannot be sufficiently achieved by the Member States 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 that objective.
- (16) Recognising that the organisation and management of health care systems are matters of national competence and that the implementation of Community legislation on workplaces and labour conditions is primarily the responsibility of Member States, this Regulation ensures full respect for Member States' competence for public health and health and safety at work.
- (17) It is important that gender and age be included in the breakdown variables as this allows the impact of gender and age differences on health and safety at work to be taken into account.
- (18) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽³⁾.
- (19) In particular, the Commission should be empowered to adopt the implementing measures covering characteristics of certain subjects and their breakdown, the reference periods, intervals and time limits for data provision as well as provision of metadata. 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.
- (20) Complementary financing for the collection of data in the fields of public health and health and safety at work are to be provided respectively within the frameworks of the second programme of Community action in the field of health (2008-13) and of the Community Programme for Employment and Social Solidarity — Progress ⁽⁴⁾. Within those frameworks, financial resources should be used to help Member States in further building up national capacities to implement improvements and new tools for statistical data collection in the fields of public health and health and safety at work.
- (21) The European Data Protection Supervisor has been consulted.

⁽¹⁾ OJ L 8, 12.1.2001, p. 1.

⁽²⁾ OJ L 151, 15.6.1990, p. 1.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁴⁾ Decision No 1672/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Community Programme for Employment and Social Solidarity — Progress (OJ L 315, 15.11.2006, p. 1).

- (22) The Statistical Programme Committee has been consulted in accordance with Article 3(1) of Decision 89/382/EEC, Euratom ⁽¹⁾,

Article 3

Definitions

HAVE ADOPTED THIS REGULATION:

For the purpose of this Regulation:

Article 1

Subject matter

1. This Regulation establishes a common framework for the systematic production of Community statistics on public health and health and safety at work. The statistics shall be produced in compliance with standards on impartiality, reliability, objectivity, cost-effectiveness and statistical confidentiality.

2. The statistics shall include, in the form of a harmonised and common data set, information required for Community action in the field of public health, for supporting national strategies for the development of high-quality, universally accessible and sustainable health care as well as for Community action in the field of health and safety at work.

3. The statistics shall provide data for structural indicators, sustainable development indicators and European Community Health Indicators (ECHI), as well as for the other sets of indicators which it is necessary to develop for the purpose of monitoring Community actions in the fields of public health and health and safety at work.

Article 2

Scope

Member States shall supply to the Commission (Eurostat) statistics on the following domains:

- health status and health determinants, as defined in Annex I,
- health care, as defined in Annex II,
- causes of death, as defined in Annex III,
- accidents at work, as defined in Annex IV,
- occupational diseases and other work-related health problems and illnesses, as defined in Annex V.

⁽¹⁾ Council Decision 89/382/EEC, Euratom of 19 June 1989 establishing a Committee on the Statistical Programmes of the European Communities (O) L 181, 28.6.1989, p. 47).

(a) 'Community statistics' shall have the meaning assigned to it by the first indent of Article 2 of Regulation (EC) No 322/97;

(b) 'production of statistics' shall have the meaning assigned to it by the second indent of Article 2 of Regulation (EC) No 322/97;

(c) 'public health' shall mean all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality;

(d) 'health and safety at work' shall mean all elements related to the prevention and protection of the health and safety of workers at work in their current or past activities, in particular accidents at work, occupational diseases and other work-related health problems and illnesses;

(e) 'microdata' shall mean individual statistical records;

(f) 'transmission of confidential data' shall mean transmission between national authorities and the Community authority of confidential data which do not permit direct identification, in accordance with Article 14 of Regulation (EC) No 322/97 and with Regulation (Euratom, EEC) No 1588/90;

(g) 'personal data' shall mean any information relating to an identified or identifiable natural person, in accordance with the Article 2(a) of Directive 95/46/EC.

Article 4

Sources

Member States shall compile data concerning public health and health and safety at work from sources which shall, depending on the domains and subjects and on the characteristics of the national systems, consist of either household or similar surveys or survey modules, or national administrative or reporting sources.

*Article 5***Methodology**

1. The methods used for the implementation of the data collections shall take into consideration, including in the case of preparatory activities, national experience and expertise, and national specificities, capacities and existing data collections, in the framework of the collaborative networks and other European Statistical System (ESS) structures with Member States set up by the Commission (Eurostat). The methodologies for regular data collections which result from projects with a statistical dimension carried out under other Community programmes such as the public health or the research programmes shall also be taken into consideration.

2. The statistical methodologies and data collections to be developed for the compilation of statistics on public health and health and safety at work at Community level shall take into consideration the need for coordination, whenever relevant, with the activities of international organisations in the field, with a view to ensuring international comparability of statistics and consistency of data collections as well as avoiding duplication of effort and of deliveries of data by Member States.

*Article 6***Pilot studies and cost-benefit analyses**

1. Whenever data are required in addition to those already collected and to those for which methodologies already exist, or when insufficient quality of data is identified in the domains referred to in Article 2, the Commission (Eurostat) shall institute pilot studies to be completed on a voluntary basis by the Member States. The purpose of such pilot studies shall be to test the concepts and methods and to assess the feasibility of the related data collections, including statistical quality, comparability and cost effectiveness, in accordance with the principles set up by the European Statistics Code of Practice.

2. Whenever preparation of an implementing measure is envisaged in accordance with the regulatory procedure with scrutiny referred to in Article 10(2), a cost-benefit analysis, taking into account the benefits of the availability of the data in relation to the cost of the data collection and the burden on Member States, shall be carried out.

3. The Commission (Eurostat) shall prepare a report evaluating the findings of the pilot studies and/or cost benefit analysis, including the effects and implications of national specificities, in cooperation with Member States, in the framework of the collaborative networks and other ESS structures.

*Article 7***Transmission, treatment and dissemination of data**

1. When necessary for the production of Community statistics, Member States shall transmit the confidential microdata or, depending on the domain and subject concerned, the aggregated data, in accordance with the provisions on transmission of data subject to confidentiality set out in Regulation (EC) No 322/97 and in Regulation (Euratom, EEC) No 1588/90. Those provisions shall apply to the treatment of the data by the Commission (Eurostat), in so far as the data are considered confidential within the meaning of Article 13 of Regulation (EC) No 322/97. Member States shall ensure that the transmitted data do not permit the direct identification of the statistical units (individuals) and that personal data are protected in compliance with the principles laid down in Directive 95/46/EC.

2. Member States shall transmit the data and metadata required by this Regulation in electronic form, in accordance with an interchange standard agreed between the Commission (Eurostat) and the Member States. The data shall be provided in accordance with the time limits set out, at the intervals provided for, and in respect of the reference periods indicated in the Annexes or in the implementing measures adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

3. The Commission (Eurostat) shall take the necessary steps to improve the dissemination, accessibility and documentation of the statistical information, in accordance with the principles of comparability, reliability and statistical confidentiality laid down in Regulation (EC) No 322/97 and with Regulation (EC) No 45/2001.

*Article 8***Quality assessment**

1. For the purpose of this Regulation, the following quality assessment dimensions shall apply to the data to be transmitted:

- (a) 'relevance' shall refer to the degree to which statistics meet the current and potential needs of users;
- (b) 'accuracy' shall refer to the closeness of estimates to the unknown true values;
- (c) 'timeliness' shall refer to the time lag between the availability of the information and the event or phenomenon it describes;
- (d) 'punctuality' shall refer to the time lag between the date of the release of the data and the target date when it should have been delivered;

- (e) 'accessibility' and 'clarity' shall refer to the conditions and modalities by which users can obtain, use and interpret data;
- (f) 'comparability' shall refer to the measurement of the impact of differences in applied statistical concepts and measurement tools and procedures when statistics are compared between geographical areas, sectoral domains or over time;
- (g) 'coherence' shall refer to the adequacy of the data to be reliably combined in different ways and for various uses.

2. Every five years each Member State shall provide the Commission (Eurostat) with a report on the quality of the data transmitted. The Commission (Eurostat) shall assess the quality of data transmitted and publish the reports.

Article 9

Implementing measures

1. The implementing measures shall cover:
 - (a) the characteristics, namely variables, definitions and classifications of the subjects, covered in Annexes I to V;
 - (b) the breakdown of characteristics;
 - (c) the reference periods, intervals and time limits for data provision;
 - (d) the provision of metadata.

These measures shall take account of, in particular, the provisions of Article 5, Article 6(2) and (3) and Article 7(1), as well as the availability, suitability and the legal context of existing Community data sources after examination of all sources related to the respective domains and subjects.

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

These measures 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 10(2).

2. If necessary, derogations and transition periods for Member States, both to be based upon objective grounds, shall be adopted in accordance with the regulatory procedure referred to in Article 10(3).

Article 10

Committee

1. The Commission shall be assisted by the Statistical Programme Committee set up by Decision 89/382/EEC, Euratom.

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

3. 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.

Article 11

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*.

ANNEX I

Domain: Health status and health determinants(a) *Aims*

The aim of this domain is the provision of statistics on health status and determinants.

(b) *Scope*

This domain covers the statistics on health status and health determinants that are based on self-assessment and compiled from population surveys such as the European Health Interview Survey (EHIS), as well as other statistics compiled from administrative sources such as those on morbidity or accidents and injuries. Persons living in institutions as well as children aged 0-14 years shall be included, when appropriate and at the relevant ad hoc intervals, subject to successful prior pilot studies.

(c) *Reference periods, intervals and time limits for data provision*

Statistics shall be provided every five years from the EHIS; a different frequency may be needed for other data collections, such as those on morbidity or accidents and injuries, as well as for some specific survey modules; the measures relating to the first reference year, the interval and the time limit for provision of the data shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(d) *Subjects covered*

The harmonised and common data set to be provided shall cover the following list of subjects:

- health status, including health perceptions, physical and mental functioning, limitations and disability,
- diagnosis-specific morbidity,
- protection against possible pandemics and transmissible diseases,
- accidents and injuries, including those related to consumer safety, and, whenever possible, alcohol- and drug-related harm,
- lifestyle, such as physical activity, diet, smoking, alcohol consumption and drug-use, and environmental, social and occupational factors,
- access and use of preventive and curative health care facilities, as well as of long-term care services (population survey),
- background demographic and socio-economic information on the individuals.

Not all subjects are necessarily to be covered at the time of each data provision. The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

The implementation of Health Examination Surveys shall be optional in the framework of this Regulation. The average length of the interview per household shall not exceed one hour for the EHIS and 20 minutes for the other survey modules.

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning characteristics of surveys and other sources used, population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX II

Domain: Health care(a) *Aims*

The aim of this domain is the provision of statistics on health care.

(b) *Scope*

This domain covers the sum of activities performed either by institutions or individuals pursuing, through the application of medical, paramedical and nursing knowledge and technology, the goal of health, including long-term care, as well as related administration and management activities.

The data shall be compiled mainly from administrative sources.

(c) *Reference periods, intervals and time limits for data provision*

Statistics shall be provided annually. The measures relating to the first reference year, the interval and the time limit for provision of the data shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(d) *Subjects covered*

The harmonised and common data set to be provided shall cover the following list of subjects:

- health care facilities,
- health care human resources,
- health care utilisation, individual and collective services,
- health care expenditure and financing.

Not all subjects are necessarily to be covered at the time of each data provision. The data set shall be established following the relevant international classifications and taking into consideration the circumstances and practices in Member States.

The mobility of patients, namely their use of health care facilities in a country other than their country of residence, and of health professionals, such as those practising their profession outside the country where they obtained their first licence, shall be considered in the data collections. The quality of health care shall also be considered in the data collection.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning characteristics of sources and compilations used, population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX III

Domain: Causes of death(a) *Aims*

The aim of this domain is the provision of statistics on the causes of death.

(b) *Scope*

This domain covers the causes of death statistics as derived from national medical death certificates taking into account WHO recommendations. The statistics to be compiled refer to the underlying cause which is defined by WHO as 'the disease or injury which initiated the train of morbid events leading directly to death, or the circumstances of the accident or violence which produced the fatal injury'. The statistics shall be compiled for all deaths and stillbirths occurring in each Member State, distinguishing residents and non-residents. Whenever possible, data on causes of death for residents dying abroad shall be included in the statistics of their country of residence.

(c) *Reference periods, intervals and time limits for data provision*

Statistics shall be provided annually. The measures relating to the first reference year shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2). The data shall be submitted no later than 24 months after the end of the reference year. Provisional or estimated data can be provided earlier. In the case of public-health incidents, additional special data collections may be established, either for all deaths or for specific causes of death.

(d) *Subjects covered*

The harmonised and common data set to be provided shall cover the following list of subjects:

- characteristics of the deceased,
- region,
- characteristics of the death, including the underlying cause of death.

The causes of death data set shall be established in the framework of the WHO International Classification of Diseases and shall follow the Eurostat rules and the UN and WHO recommendations for population statistics. The provision of data relating to the characteristics of stillbirths shall be on a voluntary basis. Provision of data relating to neonatal deaths (deaths up to the age of 28 days) shall recognise national differences in practice regarding the recording of multiple causes of death.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX IV

Domain: Accidents at work(a) *Aims*

The aim of this domain is the provision of statistics on accidents at work.

(b) *Scope*

An accident at work is defined as 'a discrete occurrence in the course of work which leads to physical or mental harm'. The data shall be collected, for the entire workforce, for fatal accidents at work and accidents at work resulting in more than three days of absence from work, using administrative sources complemented with relevant additional sources whenever necessary and feasible for specific groups of workers or specific national situations. A limited subset of basic data on accidents with less than four days of absence may be collected, when available and on an optional basis, in the framework of the collaboration with the ILO.

(c) *Reference periods, intervals and time limits for data provision*

Statistics shall be provided annually. The measures relating to the first reference year shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2). The data shall be submitted no later than 18 months after the end of the reference year.

(d) *Subjects covered*

The harmonised and common microdata set to be provided shall cover the following list of subjects:

- characteristics of the injured person,
- characteristics of the injury, including severity (days lost),
- characteristics of the enterprise including economic activity,
- characteristics of the workplace,
- characteristics of the accident, including the sequence of events characterising the causes and circumstances of the accident.

The accidents-at-work data set shall be established in the framework of the specifications laid down by the European Statistics on Accidents at Work (ESAW) methodology, taking into consideration the circumstances and practices in Member States.

The provision of data relating to the nationality of the injured person, the size of the enterprise and the time of the accident shall be on a voluntary basis. Concerning the ESAW-methodology Phase III subjects, namely the workplace and the sequence of events characterising the causes and circumstances of the accident, a minimum of three variables shall be provided. Member States should also supply more data conforming to the ESAW Phase III specifications on a voluntary basis.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning population covered, the declaration rates for accidents at work and, when relevant, sampling characteristics, as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX V

Domain: Occupational diseases and other work-related health problems and illnesses(a) *Aims*

The aim of this domain is the provision of statistics on recognised cases of occupational disease and other work-related health problems and illnesses.

(b) *Scope*

- A case of occupational disease is defined as a case recognised by the national authorities responsible for recognition of occupational diseases. The data shall be collected for incident occupational diseases and deaths due to occupational disease.
- Work-related health problems and illnesses are those health problems and illnesses which can be caused, worsened or jointly caused by working conditions. This includes physical and psychosocial health problems. A case of work-related health problem and illness does not necessarily refer to recognition by an authority and the related data shall be collected from existing population surveys such as the European Health Interview Survey (EHIS) or other social surveys.

(c) *Reference periods, intervals and time limits for data provision*

For occupational diseases, statistics shall be provided annually and submitted no later than 15 months after the end of the reference year. The measures relating to the reference periods, the intervals and the time limits for provision of the other data collections shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(d) *Subjects covered*

The harmonised and common data set to be provided for occupational diseases shall cover the following list of subjects:

- characteristics of the diseased person, including gender and age,
- characteristics of the disease, including severity,
- characteristics of the enterprise and workplace, including economic activity,
- characteristics of the causative agent or factor.

The occupational diseases data set shall be established in the framework of the specifications laid down by the European Occupational Diseases Statistics (EODS) methodology, taking into consideration the circumstances and practices in Member States.

The harmonised and common data set to be provided for work-related health problems shall cover the following list of subjects:

- characteristics of the person suffering the health problem, including gender, age and employment status,
- characteristics of the work-related health problem, including severity,
- characteristics of the enterprise and workplace, including size and economic activity,
- characteristics of the agent or factor that caused the health problem or made it worse.

Not all subjects are necessarily to be covered at the time of each data provision.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

REGULATION (EC) No 1339/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 2008
establishing a European Training Foundation
(recast)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 150 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having consulted the Committee of the Regions,

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

Whereas:

- (1) The European Council meeting at Strasbourg on 8 and 9 December 1989 called upon the Council to adopt, at the beginning of 1990, the necessary decisions for the establishment of a European Training Foundation for Central and Eastern Europe, acting on a proposal from the Commission. To this end on 7 May 1990 the Council adopted Regulation (EEC) No 1360/90.
- (2) Council Regulation (EEC) No 1360/90 of 7 May 1990 establishing a European Training Foundation ⁽³⁾ has been substantially amended several times. Since further amendments are to be made, it should be recast in the interests of clarity.
- (3) On 18 December 1989 the Council adopted Regulation (EEC) No 3906/89 on economic aid to the Republic of Hungary and the Polish People's Republic ⁽⁴⁾ which provided for aid in areas including training to support the process of economic and social reform in Hungary and Poland.
- (4) The Council subsequently extended such aid to other countries of Central and Eastern Europe under relevant legal acts.
- (5) On 27 July 1994 the Council adopted Regulation (EC) No 2063/94 ⁽⁵⁾ amending Regulation (EEC) No 1360/90, with a view to including in the activities of the European Training Foundation the States receiving assistance under Regulation (Euratom, EEC) No 2053/93 of 19 July 1993 concerning the provision of technical assistance to economic reform and recovery in the independent States of the former Soviet Union and Mongolia ⁽⁶⁾ (the TACIS Programme).
- (6) On 17 July 1998 the Council adopted Regulation (EC) No 1572/98 ⁽⁷⁾ amending Regulation (EEC) No 1360/90 with a view to including in the activities of the European Training Foundation the Mediterranean non-member countries and territories which are beneficiaries of the financial and technical measures to accompany the reform of their economic and social structures pursuant to Council Regulation (EC) No 1488/96 of 23 July 1996 on financial and technical measures to accompany (MEDA) the reform of economic and social structures in the framework of the Euro-Mediterranean partnership ⁽⁸⁾.
- (7) On 5 December 2000 the Council adopted Regulation (EC) No 2666/2000 on assistance for Albania, Bosnia and Herzegovina, Croatia, the Federal Republic of Yugoslavia and the Former Yugoslav Republic of Macedonia ⁽⁹⁾ amending Regulation (EEC) No 1360/90 with a view to including in the activities of the European Training Foundation the Western Balkan States covered by Regulation (EC) No 2666/2000.
- (8) External assistance programmes relating to the countries covered by the activities of the European Training Foundation are to be replaced by new external relations policy instruments, mainly the instrument established by Council Regulation (EC) No 1085/2006 of 17 July 2006 establishing an Instrument for Pre-Accession Assistance (IPA) ⁽¹⁰⁾ and the instrument established by Regulation (EC) No 1638/2006 of the European Parliament and of the Council of 24 October 2006 laying down general provisions establishing a European Neighbourhood and Partnership Instrument ⁽¹¹⁾.

⁽¹⁾ Opinion of 22 October 2008 (not yet published in the Official Journal).

⁽²⁾ Opinion of the European Parliament of 22 May 2008 (not yet published in the Official Journal), Council Common Position of 18 November 2008 (OJ C 310 E, 5.12.2008, p. 1) and Position of the European Parliament of 16 December 2008 (not yet published in the Official Journal).

⁽³⁾ OJ L 131, 23.5.1990, p. 1.

⁽⁴⁾ OJ L 375, 23.12.1989, p. 11.

⁽⁵⁾ OJ L 216, 20.8.1994, p. 9.

⁽⁶⁾ OJ L 187, 29.7.1993, p. 1.

⁽⁷⁾ OJ L 206, 23.7.1998, p. 1.

⁽⁸⁾ OJ L 189, 30.7.1996, p. 1. Regulation repealed by Regulation (EC) No 1638/2006.

⁽⁹⁾ OJ L 306, 7.12.2000, p. 1.

⁽¹⁰⁾ OJ L 210, 31.7.2006, p. 82.

⁽¹¹⁾ OJ L 310, 9.11.2006, p. 1.

- (9) By supporting human capital development in the context of its external relations policy, the European Union contributes to economic development in these countries by providing the skills necessary to foster productivity and employment and supports social cohesion by promoting civic participation.
- (10) In the context of the efforts of these countries to reform their economic and social structures, the development of human capital is essential for attaining long-term stability and prosperity and in particular for achieving socio-economic equilibrium.
- (11) The European Training Foundation could make an important contribution, in the context of EU external relations policies, to improving human capital development, in particular education and training in a lifelong learning perspective.
- (12) In order to make its contribution, the European Training Foundation will need to call upon the experience gained within the EU in relation to education and training in a lifelong learning perspective and upon those of its institutions which are involved in this activity.
- (13) There exist in the Community and in third countries, including the countries covered by the activities of the European Training Foundation, regional and/or national, public and/or private facilities which can be called upon to collaborate in the effective provision of aid in the area of human capital development, in particular education and training in a lifelong learning perspective.
- (14) The status and structure of the European Training Foundation should facilitate a flexible response to the specific and differing requirements of the individual countries to be assisted, and enable it to carry out its functions in close cooperation with existing national and international bodies.
- (15) The European Training Foundation should be endowed with legal personality, while maintaining a close corporate relationship with the Commission and respecting the overall political and operational responsibilities of the Community and its institutions.
- (16) The European Training Foundation should have close links with the European Centre for the Development of Vocational Training (Cedefop), with the Trans-European Mobility Scheme for University Studies (Tempus) and any other schemes instituted by the Council to provide aid in the area of training to the countries covered by its activities.
- (17) The European Training Foundation should be open to the participation of countries which are not Member States of the Community and which share the commitment of the Community and the Member States to the provision of aid to the countries covered by the activities of the European Training Foundation in the field of human capital development, in particular education and training in a lifelong learning perspective, under arrangements to be laid down in agreements between the Community and themselves.
- (18) All Member States, the European Parliament and the Commission should be represented on a Governing Board in order to oversee effectively the functions of the Foundation.
- (19) In order to guarantee the full autonomy and independence of the Foundation, it should be granted an autonomous budget the revenues of which come primarily from a Community contribution. The Community budgetary procedure should be applicable as far as the Community contribution and any other subsidies chargeable to the general budget of the European Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors.
- (20) The Foundation is a body set up by the Communities within the meaning of Article 185(1) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁾ (hereinafter referred to as the 'Financial Regulation') and should adopt its financial rules accordingly.
- (21) Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 ⁽²⁾ (hereinafter referred to as the 'Framework Financial Regulation') should apply to the Foundation.
- (22) In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) ⁽³⁾ should apply without restriction to the Foundation.
- (23) 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 ⁽⁴⁾ should apply to the Foundation.

⁽¹⁾ OJ L 248, 16.9.2002, p. 1.

⁽²⁾ OJ L 357, 31.12.2002, p. 72.

⁽³⁾ OJ L 136, 31.5.1999, p. 1.

⁽⁴⁾ OJ L 145, 31.5.2001, p. 43.

- (24) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ⁽¹⁾ should apply to the processing of personal data by the Foundation.
- (25) Pursuant to a Decision of 29 October 1993, taken by common agreement between the representatives of the Governments of the Member States, meeting at Head of State and Government level, on the location of the seats of certain bodies and departments of the European Communities and of Europol ⁽²⁾, the Foundation is to have its seat in Turin, Italy.
- (26) Since the objective of this Regulation, namely assisting third countries in the field of human capital development, cannot be sufficiently achieved by the Member States 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 that objective.
- (27) This Regulation respects the fundamental rights recognised by the Charter of Fundamental Rights of the European Union, in particular Article 43 thereof,

HAVE ADOPTED THIS REGULATION:

Article 1

Objective and scope

1. The European Training Foundation (hereinafter referred to as the 'Foundation') is hereby established. The objective of the Foundation shall be to contribute, in the context of EU external relations policies, to improving human capital development, in the following countries:

- (a) the countries eligible for support under Regulation (EC) No 1085/2006 and subsequent related legal acts;
- (b) the countries eligible for support under Regulation (EC) No 1638/2006 and subsequent related legal acts;
- (c) other countries designated by decision of the Governing Board on the basis of a proposal supported by two-thirds of its members and a Commission opinion, and covered by a Community instrument or international agreement that includes an element of human capital development, and as far as available resources allow.

⁽¹⁾ OJ L 8, 12.1.2001, p. 1.

⁽²⁾ OJ C 323, 30.11.1993, p. 1.

The countries referred to in points (a), (b) and (c) shall be designated as the 'partner countries'.

2. For the purpose of this Regulation, 'human capital development' shall be defined as work which contributes to the lifelong development of individuals' skills and competences through the improvement of vocational education and training systems.

3. In order to achieve its objective, the Foundation may provide assistance to partner countries in:

- (a) facilitating adaptation to industrial changes, in particular through vocational training and retraining,
- (b) improving initial and continuing vocational training in order to facilitate vocational integration and reintegration into the labour market,
- (c) facilitating access to vocational training and encouraging the mobility of instructors and trainees and particularly young people,
- (d) stimulating cooperation on training between educational establishments and firms,
- (e) developing exchanges of information about and experience in issues common to the training systems of the Member States,
- (f) increasing the adaptability of workers, particularly through increased participation in education and training in a lifelong learning perspective,
- (g) designing, introducing and implementing reforms in education and training systems, in order to develop employability and labour market relevance.

Article 2

Functions

For the purpose of achieving the objective set out in Article 1(1), the Foundation, within the limits of the powers conferred on the Governing Board and following the general guidelines established at Community level, shall have the following functions:

- (a) to provide information, policy analyses and advice on human capital development issues in the partner countries;
- (b) to promote knowledge and analysis of skills needs in national and local labour markets;

- (c) to support relevant stakeholders in partner countries in building capacity in human capital development;
- (d) to facilitate the exchange of information and experience among donors engaged in human capital development reform in partner countries;
- (e) to support the delivery of Community assistance to partner countries in the field of human capital development;
- (f) to disseminate information and encourage networking and the exchange of experience and good practice between the EU and partner countries and amongst partner countries in human capital development issues;
- (g) to contribute, at the Commission's request, to the analysis of the overall effectiveness of training assistance to the partner countries;
- (h) to undertake such other tasks as may be agreed between the Governing Board and the Commission, within the general framework of this Regulation.

Article 3

General provisions

1. The Foundation shall have legal personality and shall enjoy in each of the Member States the most extensive legal capacity accorded to legal persons under its laws. The Foundation may, in particular, acquire or dispose of movable and immovable property and may be a party to legal proceedings. The Foundation shall be non-profit making.
2. The Foundation shall have its seat in Turin, Italy.
3. The Foundation shall cooperate with the other relevant Community bodies, with the support of the Commission. The Foundation shall cooperate, in particular, with the European Centre for the Development of Vocational Training (Cedefop) in the framework of a joint annual work programme annexed to the annual work programme of each of the two agencies with the objective of promoting synergy and complementarity between their activities.
4. Representatives of the social partners at European level which are already active in the work of Community institutions, and international organisations active in the training field, may, where appropriate, be invited to participate in the work of the Foundation.
5. The Foundation shall be subject to the administrative review of the European Ombudsman, pursuant to the conditions set out in Article 195 of the Treaty.

6. The Foundation may establish co-operation agreements with other relevant bodies active in the human capital development field in the EU and worldwide. The Governing Board shall adopt such agreements on the basis of a draft submitted by the Director after the Commission has delivered its opinion. The working arrangements contained therein must comply with Community law.

Article 4

Transparency

1. The Foundation shall act with a high level of transparency and comply, in particular, with paragraphs 2 to 4.
 2. The Foundation shall make public within six months of setting up its Governing Board:
 - (a) the rules of procedure of the Foundation and those of the Governing Board;
 - (b) the annual activity report of the Foundation.
 3. In appropriate cases, the Governing Board may authorise representatives of interested parties to attend meetings of the Foundation's bodies in the capacity of observers.
 4. Regulation (EC) No 1049/2001 shall apply to documents held by the Foundation.
- The Governing Board shall adopt practical arrangements for applying that Regulation.

Article 5

Confidentiality

1. Without prejudice to Article 4(4), the Foundation shall not divulge to third parties confidential information it has received for which confidential treatment has been requested and is justified.
2. The members of the Governing Board and the Director shall be subject to the obligation of professional secrecy referred to in Article 287 of the Treaty.
3. The information gathered by the Foundation in accordance with its establishing act shall be subject to Regulation (EC) No 45/2001.

*Article 6***Remedies**

Decisions taken by the Foundation pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice of the European Communities under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

*Article 7***Governing Board**

1. The Foundation shall have a Governing Board consisting of one representative of each Member State, three representatives of the Commission, as well as three non-voting experts appointed by the European Parliament.

In addition, three representatives of the partner countries may attend meetings of the Governing Board as observers.

Representatives may be replaced by alternates appointed at the same time.

2. The Member States and the Commission shall each appoint their own representatives and their alternates on the Governing Board.

The representatives of the partner countries shall be appointed by the Commission from a list of candidates proposed by those countries on the basis of their experience and expertise in the Foundation's areas of work.

The Member States, the European Parliament and the Commission shall endeavour to achieve a balanced representation of men and women on the Governing Board.

3. The term of office of representatives shall be five years. It shall be renewable once.

4. The Governing Board shall be chaired by one of the representatives of the Commission. The term of office of the Chairperson shall expire when his or her membership of the Governing Board ceases.

5. The Governing Board shall adopt its rules of procedure.

*Article 8***Voting rules and tasks of the Chairperson**

1. The representatives of the Member States on the Governing Board shall each have one vote. The representatives of the Commission shall have one shared vote.

Decisions of the Governing Board shall require a two-thirds majority of its members entitled to vote, except in the cases referred to in paragraphs 2 and 3.

2. The Governing Board shall determine, by a unanimous decision of its members entitled to vote, rules governing the languages of the Foundation, taking into account the need to ensure access to, and participation in, the work of the Foundation by all interested parties.

3. The Chairperson shall convene the Governing Board at least once a year. Further meetings may be convened at the request of a simple majority of the members of the Governing Board entitled to vote.

The Chairperson shall be responsible for informing the Governing Board of other Community activities relevant to its work and the Commission's expectations concerning the Foundation's activities in the forthcoming year.

*Article 9***Powers of the Governing Board**

The Governing Board shall have the following functions and powers:

- (a) to appoint and, where necessary, dismiss the Director in accordance with Article 10(5);
- (b) to exercise disciplinary authority over the Director;
- (c) to adopt the Foundation's annual work programme on the basis of a draft submitted by the Director after the Commission has delivered its opinion, in accordance with Article 12;
- (d) to draw up an annual estimate of expenditure and revenue for the Foundation and forward it to the Commission;
- (e) to adopt the Foundation's draft establishment plan and the definitive budget following completion of the annual budget procedure, in accordance with Article 16;
- (f) to adopt the Foundation's annual activity report, in accordance with the procedure laid down in Article 13 and send it to the Community institutions and the Member States;
- (g) to adopt the Foundation's rules of procedure on the basis of a draft submitted by the Director after the Commission has delivered its opinion;
- (h) to adopt the financial rules applicable to the Foundation on the basis of a draft submitted by the Director after the Commission has delivered its opinion, in accordance with Article 19;
- (i) to adopt the procedures for applying Regulation (EC) No 1049/2001, in accordance with Article 4 of this Regulation.

*Article 10***Director**

1. The Director of the Foundation shall be appointed by the Governing Board for a period of five years from a list of at least three candidates submitted by the Commission. Before being appointed, the candidate selected by the Governing Board shall be invited to make a statement before the competent committee(s) of the European Parliament and answer questions put by its/their members.

In the course of the last nine months of that five-year period, the Commission shall, on the basis of a prior evaluation by external experts, undertake an evaluation which shall assess, in particular:

- the performance of the Director,
- the Foundation's duties and requirements in the coming years.

The Governing Board, acting on a proposal by the Commission, taking into account the evaluation report and only in those cases where it can be justified by the duties and requirements of the Foundation, may extend the term of office of the Director once for not more than three years.

The Governing Board shall inform the European Parliament of its intention to extend the Director's term of office. In the month before the extension of his/her term of office, the Director may be invited to make a statement before the competent committee(s) of the European Parliament and answer questions put by its/their members.

If the term of office is not extended, the Director shall remain in office until the appointment of his/her successor.

2. The Director shall be appointed on the basis of merit, administrative and management skills and expertise and experience in the field of work of the Foundation.

3. The Director shall be the legal representative of the Foundation.

4. The Director shall have the following functions and powers:

- (a) to prepare, on the basis of general guidelines established by the Commission, the draft annual work programme, the draft estimate of expenditure and revenue of the Foundation, its draft rules of procedure and those of the Governing Board, its draft financial rules, and the work of the Governing Board and of any ad hoc working parties convened by the Governing Board;
- (b) to participate, without the right to vote, in meetings of the Governing Board;
- (c) to implement the decisions of the Governing Board;
- (d) to implement the Foundation's annual work programme and respond to requests for assistance from the Commission;

- (e) to perform the duties of authorising officer, in accordance with Articles 33 to 42 of the Framework Financial Regulation;
- (f) to implement the Foundation's budget;
- (g) to put in place an effective monitoring system to enable the regular evaluations referred to in Article 24 to be carried out and, on this basis, prepare a draft annual activity report;
- (h) to present the annual activity report to the European Parliament;
- (i) to manage all staff-related matters, and in particular exercise the powers provided for in Article 21;
- (j) to define the Foundation's organisational structure and submit it to the Governing Board for approval;
- (k) to represent the Foundation before the European Parliament and the Council in accordance with Article 18.

5. The Director shall be accountable for his/her actions to the Governing Board, which may, on a proposal from the Commission, remove the Director from office before his/her term of office has expired.

*Article 11***Public interest and independence**

The members of the Governing Board and the Director shall act in the public interest and independently of any external influence. To this end they shall make a written declaration of commitment and a written declaration of interests every year.

*Article 12***Annual work programme**

1. The annual work programme shall be consistent with the objective, scope and functions of the Foundation defined in Articles 1 and 2.

2. The annual work programme shall be drafted within the framework of a four-year multiannual work programme in cooperation with the Commission services and with regard to the priorities of external relations with the countries and regions concerned and on the basis of experience acquired in education and training within the Community.

3. The projects and activities set out in the annual work programme shall be accompanied by an estimate of the necessary expenditure and by allocations of staff and budgetary resources.

4. The Director shall submit the draft annual work programme to the Governing Board after the Commission has delivered an opinion on it.

5. The Governing Board shall adopt the draft annual work programme by 30 November of the preceding year at the latest. The final adoption of the annual work programme shall take place at the beginning of the financial year in question.

6. Where necessary, the annual work programme may be adapted during the year using the same procedure, in order to ensure greater effectiveness of Community policies.

Article 13

Annual activity report

1. The Director shall report to the Governing Board on the performance of his/her duties in the form of an annual activity report.

2. The annual activity report shall contain financial and management information indicating the results of operations by reference to the annual work programme and to the objectives set, the risks associated with those operations, the use made of the resources provided and the way the internal control system has functioned.

3. The Governing Board shall draft an analysis and an assessment of the draft annual activity report on the previous financial year.

4. The Governing Board shall adopt the annual activity report and forward it together with its analysis and an assessment to the competent bodies of the European Parliament, the Council, the Commission, the Court of Auditors and the European Economic and Social Committee by 15 June of the following year at the latest. This report shall also be forwarded to the Member States and, for information, to the partner countries.

5. The Director shall present the Foundation's annual activity report to the relevant committees of the European Parliament and preparatory bodies of the Council.

Article 14

Links with other Community actions

The Commission, in cooperation with the Governing Board, shall ensure consistency and complementarity between the work of the Foundation and other actions at Community level, both within the Community and in the provision of assistance to the partner countries.

Article 15

Budget

1. Estimates of all the revenue and expenditure of the Foundation shall be prepared for each financial year and shall be shown in the budget of the Foundation, which shall include an establishment plan. The financial year shall correspond to the calendar year.

2. The revenue and expenditure shown in the budget of the Foundation shall be in balance.

3. The revenue of the Foundation shall comprise, without prejudice to other types of income, a subsidy from the general budget of the European Union, payments made as remuneration for services performed as well as finance from other sources.

4. The budget shall also include details of any funds made available by the partner countries themselves for projects benefiting from financial assistance from the Foundation.

Article 16

Budgetary procedure

1. Each year, on the basis of a draft drawn up by the Director, the Governing Board shall produce an estimate of revenue and expenditure for the Foundation for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Governing Board to the Commission by 31 March at the latest.

2. The Commission shall examine the estimate, having regard to the proposed limits of the overall amount available for external actions, and enter in the preliminary draft general budget of the European Union the resources it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget of the European Union.

3. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter together referred to as the 'budgetary authority') together with the preliminary draft general budget of the European Union.

4. The budgetary authority shall authorise the appropriations for the subsidy to the Foundation.

The budgetary authority shall adopt the establishment plan for the Foundation.

5. The budget of the Foundation shall be adopted by the Governing Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

6. The Governing Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of the Foundation's budget, in particular any projects relating to property, such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Governing Board within a period of six weeks from the date of notification of the project.

Article 17

Budget implementation and control

1. By 1 March at the latest following each financial year, the Foundation's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the Financial Regulation.

2. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Foundation's provisional accounts to the Court of Auditors, together with a report on budgetary and financial management for that financial year. The report on budgetary and financial management for that financial year shall also be forwarded to the European Parliament and the Council.

3. The Director shall implement the budget of the Foundation.

4. On receipt of the Court of Auditors' observations on the Foundation's provisional accounts, pursuant to Article 129 of the Financial Regulation, the Director shall draw up the Foundation's final accounts under his/her own responsibility and forward them to the Governing Board for an opinion.

5. The Governing Board shall deliver an opinion on the Foundation's final accounts.

6. The Director shall, by 1 July at the latest following each financial year, forward these final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Governing Board's opinion.

7. The final accounts shall be published.

8. The Director shall send the Court of Auditors a reply to its observations by 30 September following each financial year at the latest. He/she shall also send that reply to the Governing Board.

9. The Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the Financial Regulation.

10. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Director in respect of the implementation of the budget for year N.

11. The Director shall take all appropriate steps called for by the observations accompanying the decision giving the discharge.

Article 18

European Parliament and Council

Without prejudice to the controls referred to in Article 17 and, in particular the budgetary and discharge procedures, the European Parliament or the Council may ask at any time to hear the Director on any subject relating to the Foundation's activities.

Article 19

Financial Rules

1. The financial rules applicable to the Foundation shall be adopted by the Governing Board after the Commission has been consulted. They may not depart from the Framework Financial Regulation unless specifically required for the Foundation's operation and with the Commission's prior consent.

2. In accordance with Article 133(1) of the Financial Regulation, the Foundation shall apply the accounting rules adopted by the Commission's accounting officer so that the accounts of the Foundation can be consolidated with those of the Commission.

3. Regulation (EC) No 1073/1999 shall apply to the Foundation in its entirety.

4. The Foundation shall respect the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council and the Commission concerning internal investigations by the European Anti-fraud Office (OLAF) ⁽¹⁾. The Governing Board shall adopt the necessary measures to help OLAF carry out such internal investigations.

Article 20

Privileges and immunities

The Protocol on the privileges and immunities of the European Communities shall apply to the Foundation.

Article 21

Staff regulations

1. The staff of the Foundation shall be governed by the rules and regulations applicable to the officials and other servants of the European Communities.

2. The Foundation shall exercise over its staff the powers devolved to the Appointing Authority.

3. The Governing Board shall, in agreement with the Commission, adopt the appropriate implementing rules in accordance with the arrangements provided for in Article 110 of the Staff Regulations of Officials of the European Communities and Article 127 of the Conditions of Employment of Other Servants of the European Communities.

4. The Governing Board may adopt provisions to allow national experts from Member States or partner countries to be employed on secondment to the Foundation.

⁽¹⁾ OJ L 136, 31.5.1999, p. 15.

*Article 22***Liability**

1. The contractual liability of the Foundation shall be governed by the law applicable to the contract in question.

2. In the case of non-contractual liability, the Foundation shall, in accordance with the general principles common to laws of the Member States, make good any damage caused by the Foundation or its servants in the performance of their duties.

The Court of Justice of the European Communities shall have jurisdiction in disputes relating to compensation for any such damage.

3. The personal liability of servants towards the Foundation shall be governed by the relevant provisions applying to the staff of the Foundation.

*Article 23***Participation of third countries**

1. The Foundation shall be open to the participation of countries which are not Member States of the Community and which share the commitment of the Community and the Member States to the provision of aid in the human capital development field to the partner countries defined in Article 1(1), under arrangements to be laid down in agreements between the Community and themselves, following the procedure laid down in Article 300 of the Treaty.

The agreements shall, inter alia, specify the nature and extent of and the detailed rules for the participation of these countries in the work of the Foundation, including provisions on financial contributions and staff. Such agreements may not provide for third countries to be represented on the Governing Board with voting rights or contain provisions not in accordance with the staff regulations referred to in Article 21 of this Regulation.

2. The participation of third countries in ad hoc working parties may be decided upon as necessary by the Governing Board, without an agreement as referred to in paragraph 1.

*Article 24***Evaluation**

1. In accordance with Article 25(4) of the Framework Financial Regulation, the Foundation shall regularly carry out ex ante

and ex post evaluations of its activities where these necessitate significant expenditure. The Governing Board shall be notified of the results of these evaluations.

2. The Commission shall, every four years, in consultation with the Governing Board, conduct an evaluation of the implementation of this Regulation, the results obtained by the Foundation and its working methods in light of the objectives, mandate and functions defined in this Regulation. The evaluation shall be carried out by external experts. The Commission shall present the results of the evaluation to the European Parliament, the Council and the European Economic and Social Committee.

3. The Foundation shall take all appropriate steps to remedy any problems which may come to light in the process of evaluation.

*Article 25***Review**

Following its evaluation, the Commission shall present, where necessary, a proposal for the revision of this Regulation. If the Commission considers that the existence of the Foundation is no longer justified with regard to the objectives assigned to it, it may propose that this Regulation be repealed.

*Article 26***Repeal**

Regulations (EEC) No 1360/90, (EC) No 2063/94, (EC) No 1572/98, (EC) No 1648/2003 and Article 16 of Regulation (EC) No 2666/2000, as listed in Annex I to this Regulation, are repealed.

References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex II to this Regulation.

*Article 27***Entry into force**

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

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

Done at Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

ANNEX I

Repealed Regulation and successive amendments

Council Regulation (EEC) No 1360/90	(OJ L 131, 23.5.1990, p. 1)
Council Regulation (EC) No 2063/94	(OJ L 216, 20.8.1994, p. 9)
Council Regulation (EC) No 1572/98	(OJ L 206, 23.7.1998, p. 1)
Article 16 of the Council Regulation (EC) No 2666/2000	(OJ L 306, 7.12.2000, p. 1)
Council Regulation (EC) No 1648/2003	(OJ L 245, 29.9.2003, p. 22)

ANNEX II

CORRELATION TABLE

Regulation (EEC) No 1360/90	This Regulation
Article 1 first paragraph	Article 1(1) introductory words
Article 1 first to fourth intent	—
Article 1 second sentence	—
—	Article 1(1) points (a) to (c)
—	Article 1(1) second subparagraph
—	Article 1(2) to (3)
Article 2	—
Article 3 first paragraph	Article 2 first paragraph
Article 3 points (a) to (g)	—
—	Article 2 points (a) to (f)
Article 3 point (h)	Article 2 point (g)
Article 4(1)	Article 3(1)
—	Article 3(2)
Article 4(3) first sentence	Article 3(3) first sentence
—	Article 3(3) second sentence
Article 4(2)	—
—	Article 3(4) and (5)
—	Article 4(1) to (3)
Article 4a(1)	Article 4(4) first subparagraph
Article 4a(2)	Article 4(4) second subparagraph
—	Article 5
Article 4a(3)	Article 6
Article 5(1)	Article 7(1)
Article 5(2)	Article 7(2) first and second subparagraphs
—	Article 7(2) third and fourth subparagraphs
Article 5(3)	Article 7(3)
Article 5(4) first subparagraph	Article 7(4) first sentence
—	Article 7(4) second sentence
Article 5(4) second subparagraph	Article 7(5)
Article 5(4) third and fourth subparagraphs	Article 8(1) first subparagraph
—	Article 8(1) second subparagraph
Article 5(4) last subparagraph	Article 8(1) last subparagraph
Article 5(5) and (6)	Article 8(2) and (3)
Article 5(7) to (10)	—
—	Article 9
Article 6	—
Article 7(1) first sentence	Article 10(1) first sentence
Article 7(1) second sentence	—
—	Article 10(1) second sentence and second to fourth sub-paragraphs
—	Article 10(2)

Regulation (EEC) No 1360/90	This Regulation
Article 7(2)	Article 10(5) first sentence
Article 7(3)	Article 10(3)
—	Article 10(4) points (a) to (k)
—	Article 11
—	Article 12
—	Article 13
Article 8	Article 14
Article 9	Article 15
Article 10(1)	Article 16(1)
—	Article 16(2)
Article 10(2)	Article 16(3)
Article 10(3)	—
Article 10(4) to (6)	Article 16(4) to (6)
Article 11(1)	Article 17(3)
Article 11(2) and (3)	Article 17(1) and (2)
Article 11(4) to (10)	Article 17(4) to (10)
—	Article 17(11)
—	Article 18
Article 12	Article 19(1)
—	Article 19(2) to (4)
Article 13	Article 20
Article 14	Article 21(1)
—	Article 21(2) to (4)
Article 15	Article 22
Article 16(1)	Article 23(1) first subparagraph and first sentence of the second subparagraph
—	Article 23(1) last sentence of the second subparagraph
Article 16(2)	Article 23(2)
—	Article 24(1)
Article 17	Article 24(2)
—	Article 24(3)
Article 18	—
—	Article 25
—	Article 26
Article 19	Article 27
—	Annex

NOTE TO THE READER

The institutions have decided to no longer quote in their texts the last amendment to cited acts.

Unless otherwise indicated, references to acts in the texts published here are to the version of those acts currently in force.