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⁽¹⁾ Text with EEA relevance.

I

(Acts whose publication is obligatory)

REGULATION (EC) No 1923/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 December 2006
amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
(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 152(4)(b) 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) Regulation (EC) No 999/2001 ⁽³⁾ is intended to provide a single legal framework for transmissible spongiform encephalopathies (TSEs) in the Community.

⁽¹⁾ OJ C 234, 22.9.2005, p. 26.

⁽²⁾ Opinion of the European Parliament of 17 May 2006 (not yet published in the Official Journal), Council common position of 24 November 2006 (not yet published in the Official Journal) and Position of the European Parliament of 12 December 2006 (not yet published in the Official Journal).

⁽³⁾ OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1041/2006 (OJ L 187, 8.7.2006, p. 10).

(2) Regulation (EC) No 932/2005 of the European Parliament and of the Council of 8 June 2005 amending Regulation (EC) No 999/2001 as regards the extension of the period for transitional measures ⁽⁴⁾ prolonged the period of application of the transitional measures provided for in Regulation (EC) No 999/2001 until 1 July 2007 at the latest.

(3) During the General Session of the World Organisation for Animal Health in May 2003, a Resolution was adopted to simplify the current international criteria for the classification of countries according to their Bovine Spongiform Encephalopathy (BSE) risk. A proposal was adopted at the General Session in May 2005. The Articles of Regulation (EC) No 999/2001 should be adapted to reflect the new internationally agreed categorisation system.

(4) New developments concerning sampling and analysis will require comprehensive amendments to Annex X to Regulation (EC) No 999/2001. It is therefore necessary to make certain technical amendments to the existing definition of 'rapid tests' in Regulation (EC) No 999/2001 in order to facilitate amendment of the structure of that Annex at a later stage.

(5) In the interests of clarity of Community legislation, it is appropriate to clarify that the definition of 'mechanically separated meat' provided for in other Community legislation on food safety should be applicable in Regulation (EC) No 999/2001 in the context of TSE eradication measures.

⁽⁴⁾ OJ L 163, 23.6.2005, p. 1.

- (6) Regulation (EC) No 999/2001 establishes a monitoring programme for BSE and scrapie. In its opinion of 6-7 March 2003, the Scientific Steering Committee recommended the introduction of a monitoring programme for TSEs in cervids. Therefore the monitoring system provided for in that Regulation should be extended to other TSEs, with the possibility to adopt further measures to implement that system at a later stage.
- (7) A harmonised breeding programme to select for resistance to TSEs in ovine animals has been put in place as a transitional measure by Commission Decision 2003/100/EC of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep⁽¹⁾. Regulation (EC) No 999/2001 should be amended to provide a permanent legal basis for that programme, as well as the possibility of amending such programmes to take account of the evaluated scientific results and overall consequences of their implementation.
- (8) Regulation (EC) No 999/2001 prohibits the feeding of certain processed animal proteins to certain animals, with the possibility to provide for derogations. New developments concerning prohibitions on animal feeding may require amendments to be made to Annex IV to that Regulation. It is necessary to make certain technical amendments to the existing wording of the corresponding Article in order to facilitate amendment of the structure of that Annex at a later stage.
- (9) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽²⁾ establishes rules for the disposal of specified risk materials and animals infected by TSEs. Rules on transit through the Community of products of animal origin have now been adopted. Accordingly, in the interests of consistency of Community legislation, the existing rules in Regulation (EC) No 999/2001 on the disposal of such materials and animals should be replaced by a reference to Regulation (EC) No 1774/2002, and the reference to rules on transit in Regulation (EC) No 999/2001 should be deleted.
- (10) New developments concerning specified risk materials will also require comprehensive amendments to Annex V to Regulation (EC) No 999/2001. It is necessary to make certain technical amendments to the existing wording of the corresponding provisions of that Regulation in order to facilitate amendment of the structure of that Annex at a later stage.
- (11) Although stunning by injection of gas in the cranial cavity is prohibited within the Community, injection of gas may also occur after stunning. It is therefore necessary to amend the relevant provisions on slaughter methods in Regulation (EC) No 999/2001 with a view to prohibiting gas injection into the cranial cavity after stunning.
- (12) Commission Regulation (EC) No 1915/2003 amending Regulation (EC) No 999/2001⁽³⁾ sets out new provisions on eradication of scrapie in ovine and caprine animals. Accordingly, it is necessary to prohibit the movement of ovine and caprine animals from holdings where scrapie is officially suspected.
- (13) Based on evolving scientific knowledge, Regulation (EC) No 999/2001 should allow the extension to other species of the scope of the rules concerning the placing on the market and export of bovine, ovine and caprine animals, their semen, embryos and ova.
- (14) The opinion of the Scientific Steering Committee of 26 June 1998 indicates that certain restrictions regarding sourcing of raw material for the manufacture of dicalcium phosphate should be observed. Accordingly, dicalcium phosphate should be removed from the list of products which are not subject to restrictions on placing on the market under Regulation (EC) No 999/2001. The absence of restrictions applicable to milk and dairy products should be clarified.
- (15) Based on evolving scientific knowledge and risk classification, and notwithstanding the possibility to adopt safeguard measures, Regulation (EC) No 999/2001 should permit the adoption in accordance with the comitology procedure of more specific requirements for the placing on the market and export of products of animal origin originating from Member States or third countries with a controlled or undetermined risk of TSE.
- (16) The measures necessary for the implementation of Regulation (EC) No 999/2001 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⁾.

⁽¹⁾ OJ L 41, 14.2.2003, p. 41.

⁽²⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).

⁽³⁾ OJ L 283, 31.10.2003, p. 29.

⁽⁴⁾ OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11.)

(17) In particular, the Commission should be empowered to adopt decisions approving the rapid tests, adapting the age of the animals, introducing the tolerance level, allowing feeding of young animals of ruminant species with proteins derived from fish and extending certain provisions to other animal species; to establish rules providing for exemptions from the requirement to remove and destroy specific risk material; to establish criteria to demonstrate improvement of the epidemiological situation and criteria for granting exemptions from certain restrictions as well as production processes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 999/2001 and/or to supplement that Regulation by the addition of new non-essential elements, those measures should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(18) Regulation (EC) No 999/2001 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 999/2001 is hereby amended as follows:

1) the following recital shall be inserted:

'(8a) The feeding to non-ruminants of certain processed animal proteins originating from non-ruminants should be allowed taking into account the prohibition on intra-species recycling as laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (*) and the control aspects in particular linked to the differentiation of processed animal proteins specific to certain species as laid down in the Communication on the TSE Road map adopted by the Commission on 15 July 2005.

(*) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).';

2) the following recitals shall be inserted:

'(11a) In its resolution of 28 October 2004 (**), the European Parliament expressed concerns about feeding animal proteins to ruminants as they do not form part of the natural nutrition of adult cattle. In the wake of the BSE crisis and the foot-and-mouth disease crisis it has increasingly become accepted that the best way to ensure human and animal health is to keep and nourish

animals in a way that respects the particularities of each species. Pursuant to the precautionary principle and in keeping with the natural diet and living conditions of ruminants, it is therefore necessary to maintain the prohibition on the feeding of animal proteins to ruminants in forms not normally constituting part of their natural diet.

(11b) Mechanically separated meat is obtained by removing meat from bones in such a way that the muscle fibre structure is destroyed or modified. It can contain parts of the bones and the periosteum (bone skin). Thus, mechanically separated meat is not comparable with regular meat. Consequently its use for human consumption should be reviewed.

(**) OJ C 174 E, 14.7.2005, p. 178.;

3) in Article 3, paragraph 1 shall be amended as follows:

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

'(l) rapid tests: the screening methods listed in Annex X, for which the results are known within 24 hours;';

(b) the following points shall be added:

'(n) mechanically separated meat or "MSM": the product obtained by removing meat from flesh-bearing bones after boning, using mechanical means resulting in the loss or modification of the muscle fibre structure;

(o) passive surveillance: the reporting of all animals suspected of being infected by a TSE and, where TSE cannot be excluded by clinical investigation, the laboratory testing of such animals;

(p) active surveillance: the testing of animals not reported as suspected of being infected by a TSE, such as emergency slaughtered animals, animals with observations at ante mortem inspection, fallen stock, healthy slaughtered animals and animals culled in connection with a TSE case, in particular in order to determine the evolution and prevalence of TSE in a country or region thereof.;

4) Article 5 is hereby amended as follows:

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

'1. The BSE status of Member States or third countries or regions thereof (hereinafter referred to as "countries or regions") shall be determined by classification into one of the following three categories:

— negligible BSE risk as defined in Annex II,

— controlled BSE risk as defined in Annex II,

— undetermined BSE risk as defined in Annex II.

The BSE status of countries or regions may be determined only on the basis of the criteria set out in Annex II, Chapter A. These criteria shall include the outcome of a risk analysis on the basis of all the potential factors for the appearance of bovine spongiform encephalopathy as defined in Annex II, Chapter B, and their development over time, as well as comprehensive active and passive surveillance measures taking into account the risk category of the country or region.

Member States, and third countries wishing to be retained on the list of third countries approved for the export to the Community of the live animals or of the products covered by this Regulation, shall submit to the Commission an application for their BSE status to be determined, accompanied by the relevant information on the criteria set out in Annex II, Chapter A, and on the potential risk factors specified in Annex II, Chapter B, and their development over time.;

(b) paragraph 4 shall be replaced by the following:

'4. Member States and third countries which have not submitted an application in accordance with the third subparagraph of paragraph 1 shall, with respect to the dispatch from their territory of live animals and products of animal origin, comply with the import requirements applicable to countries with an undetermined BSE risk, until they have submitted such an application and a final decision has been taken on their BSE status.;

5) Article 6 is hereby amended as follows:

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

'1. Each Member State shall carry out an annual monitoring programme for TSEs based on active and passive surveillance in accordance with Annex III. If available for the animal species, that programme shall include a screening procedure using rapid tests.

Rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24 (3) and listed in Annex X.;

(b) the following paragraphs shall be inserted:

'1a. The annual monitoring programme referred to in paragraph 1 shall cover as a minimum the following subpopulations:

- (a) all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;
- (b) all bovine animals above 30 months of age slaughtered normally for human consumption;
- (c) all bovine animals above 24 months of age not slaughtered for human consumption, which have died or been killed on the farm, during transport or in an abattoir (fallen stock).

Member States may decide to derogate from the provision under point (c) in remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this possibility shall inform the Commission and submit a list of the areas concerned together with a justification for the derogation. The derogation shall not cover more than 10 % of the bovine population in a Member State.

1b. After consultation of the appropriate scientific committee, the age laid down in paragraph 1a(a) and (c) may be adapted according to scientific progress in accordance with the procedure referred to in Article 24 (3).

At the request of a Member State which can demonstrate the improvement of the epidemiological situation of the country, according to certain criteria to be laid down in accordance with the procedure referred to in Article 24(3), the annual monitoring programmes for that particular Member State may be revised.

The Member State concerned shall provide proof of its capability to determine the effectiveness of the measures in place and ensure protection of human and animal health based on a comprehensive risk analysis. In particular, the Member State shall demonstrate:

- (a) a clearly declining or consistently low BSE prevalence, based on up-to-date testing results;
 - (b) that it has implemented and enforced for at least six years a full BSE testing scheme (Community legislation on traceability and identification of live animals and BSE surveillance);
 - (c) that it has implemented and enforced for at least six years Community legislation on total feed ban for farmed animals.;
- (c) the following paragraph shall be added:

'5. Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).;

6) the following Article shall be inserted:

'Article 6a

Breeding Programmes

1. Member States may introduce breeding programmes to select for resistance to TSEs in their ovine populations. Those programmes shall include a framework to recognise the TSE-resistant status of certain flocks and may be extended to include other animal species based on scientific evidence corroborating the resistance to TSE of particular genotypes of those species.

2. Specific rules for the programmes provided for in paragraph 1 of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).

3. Member States which introduce breeding programmes shall submit regular reports to the Commission in order to enable the programmes to be scientifically evaluated, in particular with regard to their impact on the incidence of TSEs but also on genetic diversity and variability and on the maintenance of old or rare ovine breeds or of those that are well-adapted to a particular region. The scientific results and overall consequences of the breeding programmes shall be evaluated regularly, and where necessary, those programmes shall be amended accordingly;

7) Article 7 is hereby amended as follows:

(a) paragraphs 1 to 4 shall be replaced by the following:

‘1. The feeding to ruminants of protein derived from animals shall be prohibited.

2. The prohibition provided for in paragraph 1 shall be extended to animals other than ruminants and restricted, as regards the feeding of those animals with products of animal origin, in accordance with Annex IV.

3. Paragraphs 1 and 2 shall apply without prejudice to the provisions laid down in Annex IV setting out the derogations from the prohibition contained in those paragraphs.

The Commission may decide in accordance with the procedure referred to in Article 24(3), based on a scientific assessment of the dietary needs of young ruminants and subject to the rules adopted for the implementation of this Article provided for in paragraph 5 of this Article, and following an assessment of the control aspects of this derogation, to allow the feeding of young animals of ruminant species with proteins derived from fish.

4. Member States, or regions thereof, with an undetermined BSE risk shall not be permitted to export or store feed intended for farmed animals which contains protein derived from mammals or feed intended for mammals, except feed for dogs, cats and fur animals, which contains processed protein derived from mammals.

Third countries, or regions thereof, with an undetermined BSE risk shall not be permitted to export to the Community feed intended for farmed animals which contains protein derived from mammals or feed intended for mammals, except feed for dogs, cats and fur animals, which contains processed protein derived from mammals.

At the request of a Member State or third country a decision in accordance with the procedure referred to in Article 24(2) may be taken, following detailed criteria to be laid down in accordance with the procedure referred to in Article 24(3), to grant individual exemptions from the restrictions in this paragraph. Any exemption shall take account of the provisions provided for in paragraph 3 of this Article.’;

(b) the following paragraph shall be inserted:

‘4a. Based on a favourable risk assessment taking into account at least the amount and possible source of contamination and the final destination of the consignment, a decision may be taken in accordance with the procedure referred to in Article 24(3) to introduce a tolerance level for insignificant amounts of animal proteins in feedingstuffs caused through adventitious and technically unavoidable contamination.’;

(c) paragraph 5 shall be replaced by the following:

‘5. Rules for the implementation of this Article, in particular rules on the prevention of cross-contamination and on the methods of sampling and analysis required to check compliance with this Article, shall be adopted in accordance with the procedure referred to in Article 24(2). Those rules shall be based on a report of the Commission covering sourcing, processing, control and traceability of feedingstuffs of animal origin.’;

8) in Article 8, paragraphs 1 to 5 shall be replaced by the following:

‘1. The specified risk material shall be removed and disposed of in accordance with Annex V to this Regulation and with Regulation (EC) No 1774/2002. It shall not be imported into the Community. The list of specified risk material referred to in Annex V shall include at least the brain, spinal cord, eyes and tonsils of bovine animals aged over 12 months and the vertebral column of bovine animals above an age to be determined in accordance with the procedure referred to in Article 24(3). Taking into account the different risk categories laid down in the first subparagraph of Article 5(1) and the requirements of Article 6(1a) and (1b) (b), the list of specified risk material in Annex V shall be amended accordingly.

2. Paragraph 1 of this Article shall not apply to tissues from animals which have undergone an alternative test approved for that distinct purpose in accordance with the procedure referred to in Article 24(3) provided that this test is listed in Annex X, is applied under the conditions provided for in Annex V and the test results are negative.

The Member States which authorise the use of an alternative test pursuant to this paragraph shall inform the other Member States and the Commission.

3. In Member States, or regions thereof, with a controlled or undetermined BSE risk, the laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity in connection with stunning, shall not be used on bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

4. The data relating to age set out in Annex V may be adjusted. Such adjustments shall be based on the latest proven scientific findings concerning the statistical probability of the occurrence of a TSE in the relevant age groups of the Community’s bovine, ovine and caprine population.

5. Rules providing for exemptions from paragraphs 1 to 4 of this Article may be adopted in accordance with the procedure referred to in Article 24(3), with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for third countries or regions thereof with a controlled BSE risk, with regard to the date of the effective enforcement of the ban of mammalian protein in feed for ruminants with a view to limiting the requirements to remove and destroy specified risk material to animals born before that date in the countries or regions concerned.;

9) in Article 9, paragraphs 1 and 2 shall be replaced by the following:

‘1. The products of animal origin listed in Annex VI shall be produced using production processes approved in accordance with the procedure referred to in Article 24(3).

2. Bones of bovine, ovine and caprine animals from countries or regions with a controlled or undetermined BSE risk shall not be used for the production of mechanically separated meat (MSM). Before 1 July 2008, the Member States shall submit a report to the Commission on the use and the production method of MSM in their territory. This report shall include a statement as to whether the Member State intends to continue with the production of MSM.

The Commission shall thereupon present a communication to the European Parliament and the Council on the future necessity and use of MSM in the Community, including the information policy towards consumers.;

10) Article 12 is hereby amended as follows:

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

‘1. Any animal suspected of being infected by a TSE shall be either placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control.

If a TSE is officially suspected in a bovine animal at a holding in a Member State, all other bovine animals at that holding shall be placed under an official movement restriction until the results of the examination are available. If a TSE is officially suspected in an ovine or caprine animal at a holding in a Member State, all other ovine and caprine animals at that holding shall be placed under an official movement restriction until the results are available.

However, if there is evidence that the holding where the animal was present when the TSE was suspected is unlikely to be the holding where the animal could have been exposed to the TSE, the competent authority may decide that only the animal suspected of being infected shall be placed under an official movement restriction.

If considered necessary, the competent authority may also decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

In accordance with the procedure referred to in Article 24(2) and by way of derogation from the official movement restrictions provided for in this paragraph, a Member State may be exempted from implementing such restrictions if it applies measures offering equivalent safeguards based on an appropriate assessment of the possible risks for human and animal health.;

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

‘3. All parts of the body of the suspect animal shall be either retained under official control until a negative diagnosis has been made, or disposed of in accordance with Regulation (EC) No 1774/2002.;

11) in Article 13, paragraph 1 is hereby amended as follows:

(a) point (a) of the first subparagraph shall be replaced by the following:

‘(a) all parts of the body of the animal shall be disposed of in accordance with Regulation (EC) No 1774/2002 except for material retained for records in accordance with Annex III, Chapter B, of this Regulation.;

(b) point (c) of the first subparagraph shall be replaced by the following:

‘(c) all animals and products thereof at risk, as listed in Annex VII, point 2, of this Regulation, identified by the inquiry referred to in point (b) of this paragraph shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002.;

(c) after the first subparagraph, the following subparagraph shall be inserted:

‘At the request of a Member State and based on a favourable risk assessment taking particularly into account the control measures in that Member State, a decision may be taken in accordance with the procedure referred to in Article 24(2) to allow the use of bovine animals referred to in this paragraph until the end of their productive lives.;

12) in Article 15, paragraph 3 shall be replaced by the following:

‘3. In accordance with the procedure referred to in Article 24(3), the provisions of paragraphs 1 and 2 may be extended to other animal species.

4. Rules for implementing this Article may be adopted in accordance with the procedure referred to in Article 24(2).;

13) Article 16 is hereby amended as follows:

(a) in paragraph 1, point (b) shall be replaced by the following:

'(b) milk and dairy products, hides and skins, and gelatine and collagen derived from hides and skins.;

(b) paragraphs 2 and 3 shall be replaced by the following:

'2. Products of animal origin imported from a third country with a controlled or undetermined BSE risk shall come from healthy bovine, ovine and caprine animals which have not been subjected to a laceration of the central nervous tissue or gas injection into the cranial cavity as referred to in Article 8(3).

3. Food products of animal origin containing material obtained from bovine animals originating in a country or region with an undetermined BSE risk shall not be placed on the market unless they come from animals which:

(a) were born eight years after the date from which the prohibition on the feeding to ruminants of animal protein derived from mammals was effectively enforced; and

(b) were born, raised and have stayed in herds with a certified history of freedom from BSE for at least seven years.

Furthermore, food products of ruminant origin shall not be dispatched from a Member State or a region thereof with an undetermined BSE risk to another Member State or be imported from a third country with an undetermined BSE risk.

This prohibition shall not apply to products of animal origin listed in Annex VIII, Chapter C, and fulfilling the requirements of Annex VIII, Chapter C.

They must be accompanied by an animal health certificate issued by an official veterinarian certifying that they have been produced in conformity with this Regulation.;

14) the following Article shall be inserted:

'Article 23a

The following measures which are designed to amend non-essential elements of this Regulation, including by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(3):

(a) approval of the rapid tests referred to in Article 6(1) and Article 8(2),

(b) adaptation of the age referred to in Article 6(1b),

(c) criteria to demonstrate improvement of the epidemiological situation referred to in Article 6(1b),

(d) decision to allow feeding of young animals of ruminant species with proteins derived from fish as referred to in Article 7(3),

(e) criteria for granting exemptions from the restrictions referred to in Article 7(4),

(f) decision to introduce a tolerance level as referred to in Article 7(4a),

(g) decision on age as referred to in Article 8(1),

(h) rules providing for exemptions from the requirement to remove and destroy specified risk material as referred to in Article 8(5),

(i) approval of production processes referred to in Article 9(1),

(j) decision to extend certain provisions to other animal species as referred to in Article 15(3).'

15) Article 24 shall be replaced by the following:

'Article 24

Committees

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. However, the Standing Committee on Zootechnics shall also be consulted by the Commission with regard to Article 6a.

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 time-limits referred to in Article 5(6) of that Decision shall be three months and, in the case of safeguard measures referred to in Article 4(2) of this Regulation, 15 days.

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.;

16) the following Article shall be inserted:

'Article 24a

Decisions to be adopted in accordance with one of the procedures referred to in Article 24 shall be based on an appropriate assessment of the possible risks for human and animal health and shall, taking into account existing scientific evidence, maintain, or if scientifically justified increase, the level of protection of human and animal health ensured in the Community.'

Article 2

This Regulation shall enter into force on the twentieth 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 Brussels, 18 December 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

J.-E. ENESTAM

REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on nutrition and health claims made on foods

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) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market must be safe and adequately labelled.
- (2) Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.
- (3) General labelling provisions are contained 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⁾. Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. This Regulation should complement the general principles in Directive 2000/13/EC and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including, *inter alia*, generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications. This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.

(5) Non-beneficial nutrition claims are not covered by the scope of this Regulation; Member States intending to introduce national schemes relating to non-beneficial nutrition claims should notify such schemes to the Commission and to other Member States in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ⁽⁴⁾.

(6) At international level the Codex Alimentarius has adopted General Guidelines on claims in 1991 and Guidelines for the use of nutrition claims in 1997. An amendment to the latter has been adopted by the Codex Alimentarius Commission in 2004. That amendment concerns the inclusion of health claims in the 1997 Guidelines. Due consideration is given to the definitions and conditions set in the Codex Guidelines.

(7) The possibility of using the claim 'low fat' for spreadable fats provided for in Council Regulation (EC) No 2991/94 of 5 December 1994 laying down standards for spreadable fats ⁽⁵⁾ should be adapted to the provisions of this Regulation as soon as possible. In the meantime, Regulation (EC) No 2991/94 applies for the products it covers.

⁽¹⁾ OJ C 110, 30.4.2004, p. 18.

⁽²⁾ Opinion of the European Parliament of 26 May 2005 (OJ C 117 E, 18.5.2006, p. 187), Council common position of 8 December 2005 (OJ C 80 E, 4.4.2006, p. 43) and Position of the European Parliament of 16 May 2006 (not yet published in the Official Journal). Council Decision of 12 October 2006.

⁽³⁾ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

⁽⁴⁾ OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.

⁽⁵⁾ OJ L 316, 9.12.1994, p. 2.

- (8) There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.
- (9) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added. This may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To address this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances, for example the alcohol content of the product or the nutrient profile of the product, are appropriate criteria for determining whether the product can bear claims. The use of such criteria at national level, whilst justified for the purpose of allowing consumers to make informed nutritional choices, is likely to result in barriers to intra-Community trade and should therefore be harmonised at Community level.
- (10) The application of nutrient profiles as a criterion would aim to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. Nutrient profiles as provided for in this Regulation would be intended for the sole purpose of governing the circumstances in which claims may be made. They should be based on generally accepted scientific data relative to the relationship between diet and health. However, profiles should also allow for product innovation and should take into account the variability of dietary habits and traditions, and the fact that individual products may have an important role in the context of an overall diet.
- (11) The establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and mono-unsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutrient profiles, the different categories of foods and the place and role of these foods in the overall diet should be taken into account. Exemptions from the requirement to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical tasks and the adoption of the relevant measures should be entrusted to the Commission, taking into account the advice of the European Food Safety Authority.
- (12) Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements⁽¹⁾ presented in a liquid form and containing more than 1,2 % by volume of alcohol are not considered as beverages under this Regulation.
- (13) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.
- (14) In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body. In addition, and where appropriate, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed.

⁽¹⁾ OJ L 183, 12.7.2002, p. 51.

- (15) It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 concerning misleading and comparative advertising ⁽¹⁾, the Court of Justice of the European Communities has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.
- (16) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them.
- (17) A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice.
- (18) Given the positive image conferred on foods bearing nutrition and health claims and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.
- (19) General nutritional labelling provisions are contained in Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs ⁽²⁾. According to that Directive, where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling should be compulsory. Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given should be that of Group 2 as defined in Article 4(1) of Directive 90/496/EEC. In order to achieve a high level of consumer protection, this obligation to provide the information of Group 2 should apply, *mutatis mutandis*, where any health claim is made, with the exception of generic advertising.
- (20) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. Any claim considered to have the same meaning for consumers as a nutrition claim included in the aforementioned list should be subject to the same conditions of use indicated therein. For example, claims related to the addition of vitamins and minerals such as 'with ...', 'restored ...', 'added ...', or 'enriched ...' should be subject to the conditions set for the claim 'source of ...'. The list should be regularly updated in order to take into account scientific and technological developments. Furthermore, for comparative claims it is necessary that the products being compared be clearly identified to the final consumer.
- (21) Conditions for claims such as 'lactose-free' or 'gluten-free', addressed to a group of consumers with specific disorders, should be dealt with in 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⁾. In addition, that Directive provides the possibility that foodstuffs for normal consumption can indicate their suitability for use by these groups of consumers if they fulfil the conditions for such statement. Until the conditions for such statements are set at Community level, Member States may maintain or adopt relevant national measures.
- (22) Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments.

⁽¹⁾ OJ L 250, 19.9.1984, p. 17. Directive as last amended by Directive 2005/29/EC of the European Parliament and of the Council (OJ L 149, 11.6.2005, p. 22).

⁽²⁾ OJ L 276, 6.10.1990, p. 40. Directive as last amended by Commission Directive 2003/120/EC (OJ L 333, 20.12.2003, p. 51).

⁽³⁾ OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

- (23) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate, when using psychological and behavioural claims, to require scientific substantiation.
- (24) In the light of Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction ⁽¹⁾ which prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, it is considered appropriate to extend this restriction to all foods.
- (25) Health claims other than those referring to the reduction of disease risk, based on generally accepted scientific data, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a Community list of such permitted claims after consulting the European Food Safety Authority.
- (26) In order to keep up with scientific and technological developments, the list referred to above should be revised promptly whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (27) A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet. Furthermore, diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.
- (28) In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the European Food Safety Authority and in the subsequent authorisation procedure.
- (29) In some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. Other legitimate factors relevant to the matter under consideration should therefore be taken into account.
- (30) For the sake of transparency and in order to avoid multiple applications in respect of claims which have already been assessed, a public register containing the lists of such claims should be established and updated by the Commission.
- (31) In order to stimulate research and development within the agri-food industry, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application pursuant to this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials.
- (32) Given the particular nature of foods bearing claims, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (33) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation.
- (34) Since the objective of this Regulation, namely to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection, 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.
- (35) 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 ⁽²⁾,

⁽¹⁾ OJ L 55, 6.3.1996, p. 22.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS REGULATION:

- (c) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽²⁾.

CHAPTER I

Article 2

SUBJECT MATTER, SCOPE AND DEFINITIONS

Definitions

Article 1

Subject matter and scope

1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

2. This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer, including foods which are placed on the market unpacked or supplied in bulk.

It shall also apply in respect of foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

3. A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.

4. This Regulation shall apply without prejudice to the following Community provisions:

- (a) Directive 89/398/EEC and Directives adopted on the basis thereof;
- (b) Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters ⁽¹⁾;

⁽¹⁾ OJ L 229, 30.8.1980, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

1. For the purposes of this Regulation:

- (a) the definitions of 'food', 'food business operator', 'placing on the market' and 'final consumer', set out in Articles 2, 3(3), 3(8) and 3(18) of 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 ⁽³⁾, shall apply;
- (b) the definition of 'food supplement' set out in Directive 2002/46/EC shall apply;
- (c) the definitions of 'nutrition labelling', 'protein', 'carbohydrate', 'sugars', 'fat', 'saturates', 'mono-unsaturates', 'poly-unsaturates' and 'fibre' set out in Directive 90/496/EEC shall apply;
- (d) the definition of 'labelling' set out in Article 1(3)(a) of Directive 2000/13/EC shall apply.

2. The following definitions shall also apply:

1. 'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
2. 'nutrient' means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances which belong to or are components of one of those categories;
3. 'other substance' means a substance other than a nutrient that has a nutritional or physiological effect;

⁽²⁾ OJ L 330, 5.12.1998, p. 32. Directive as amended by Regulation (EC) No 1882/2003.

⁽³⁾ OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

4. 'nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- (a) the energy (calorific value) it
 - (i) provides,
 - (ii) provides at a reduced or increased rate, or
 - (iii) does not provide; and/or
- (b) the nutrients or other substances it
 - (i) contains,
 - (ii) contains in reduced or increased proportions, or
 - (iii) does not contain;

5. 'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

6. 'reduction of disease risk claim' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

7. 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002.

CHAPTER II

GENERAL PRINCIPLES

Article 3

General principles for all claims

Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market in the Community only if they comply with the provisions of this Regulation.

Without prejudice to Directives 2000/13/EC and 84/450/EEC, the use of nutrition and health claims shall not:

- (a) be false, ambiguous or misleading;
- (b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;

(c) encourage or condone excess consumption of a food;

(d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. Derogations in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet, including the conditions for their application, may be adopted in accordance with the procedure referred to in Article 24(2), taking into account the special conditions present in Member States;

(e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

Article 4

Conditions for the use of nutrition and health claims

1. By 19 January 2009, the Commission shall, in accordance with the procedure referred to in Article 24(2), establish specific nutrient profiles and the conditions, including exemptions, which shall be respected for the use of nutrition and health claims on foods and/or categories of foods.

These nutrient profiles established for food and/or certain categories of food, and the conditions for the use of nutrition or health claims with respect to the nutrient profiles, shall be laid down taking into account in particular:

- (a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;
- (b) the role and importance of the food (or of categories of foods) in the diet of the population in general or, as appropriate, of certain risk groups including children;
- (c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

The nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health.

In setting the nutrient profiles, the Commission shall request the Authority to provide, within 12 months, relevant scientific advice, focusing in particular on:

- (i) whether profiles should be set for food in general and/or categories of food;
- (ii) the choice and balance of nutrients to be taken into account;
- (iii) the choice of reference quantity/basis for profiles;
- (iv) the approach to the calculation of the profiles, and
- (v) testing of a proposed system.

In setting the nutrient profiles, the Commission shall carry out consultations with interested parties, in particular food business operators and consumer groups.

Nutrient profiles and their conditions of use shall be updated to take into account relevant scientific developments in accordance with the procedure referred to in Article 24(2).

2. By way of derogation from paragraph 1, nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium shall be allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided they comply with the conditions laid down in this Regulation.

3. Beverages containing more than 1,2 % by volume of alcohol shall not bear:

- (a) health claims;
- (b) nutrition claims, other than those which refer to a reduction in the alcohol or energy content.

4. In the absence of specific Community rules regarding nutrition claims referring to the reduction or absence of alcohol or energy in beverages which normally contain alcohol, relevant national rules may apply in compliance with the provisions of the Treaty.

5. Foods or categories of foods other than those referred to in paragraph 3, for which nutrition or health claims are to be restricted or prohibited, may be determined in accordance with the procedure referred to in Article 24(2) and in the light of scientific evidence.

Article 5

General conditions

1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

(a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific data;

(b) the nutrient or other substance for which the claim is made:

(i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data; or

(ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;

(c) where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data;

(e) compliance with the specific conditions set out in Chapter III or Chapter IV as the case may be.

2. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

3. Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.

Article 6

Scientific substantiation for claims

1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.
2. A food business operator making a nutrition or health claim shall justify the use of the claim.
3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation.

Article 7

Nutrition information

The obligation and the modalities for providing information pursuant to Directive 90/496/EEC where a nutrition claim is made shall apply, *mutatis mutandis*, where a health claim is made, with the exception of generic advertising. However, the information to be provided shall consist of information in Group 2 as defined in Article 4(1) of Directive 90/496/EEC.

In addition and as the case may be, the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in the same field of vision of the nutrition information and be expressed in accordance with Article 6 of Directive 90/496/EEC.

In the case of food supplements, the nutrition information shall be provided in accordance with Article 8 of Directive 2002/46/EC.

CHAPTER III

NUTRITION CLAIMS

Article 8

Specific conditions

1. Nutrition claims shall only be permitted if they are listed in the Annex and are in conformity with the conditions set out in this Regulation.

2. Amendments to the Annex shall be adopted in accordance with the procedure referred to in Article 24(2) and, where appropriate, after consulting the Authority.

Article 9

Comparative claims

1. Without prejudice to Directive 84/450/EEC, a comparison may only be made between foods of the same category, taking into consideration a range of foods of that category. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food.
2. Comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands.

CHAPTER IV

HEALTH CLAIMS

Article 10

Specific conditions

1. Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.
2. Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:
 - (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
 - (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
 - (c) where appropriate, a statement addressed to persons who should avoid using the food; and
 - (d) an appropriate warning for products that are likely to present a health risk if consumed to excess.

3. Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.

4. Where appropriate, guidelines on the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2) and, if necessary, in consultation with interested parties, in particular food business operators and consumer groups.

Article 11

National medical associations and health-related charities

In the absence of specific Community rules concerning recommendations of or endorsements by national medical associations and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty.

Article 12

Restrictions on the use of certain health claims

The following health claims shall not be allowed:

- (a) claims which suggest that health could be affected by not consuming the food;
- (b) claims which make reference to the rate or amount of weight loss;
- (c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.

Article 13

Health claims other than those referring to the reduction of disease risk

1. Health claims describing or referring to:
 - (a) the role of a nutrient or other substance in growth, development and the functions of the body, or

(b) psychological and behavioural functions; or

(c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

which are included in the list provided for in paragraph 3 may be made without undergoing the authorisation procedure laid down in Articles 15 to 18, if they are:

- (i) based on generally accepted scientific data; and
- (ii) well understood by the average consumer.

2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification.

3. After consulting the Authority, the Commission shall adopt, in accordance with the procedure referred to in Article 24(2), a Community list of permitted claims as referred to in paragraph 1, and all necessary conditions for the use of these claims by 31 January 2010 at the latest.

4. Any changes to the list referred to in paragraph 3, based on generally accepted scientific data, shall be adopted in accordance with the procedure referred to in Article 24(2), after consulting the Authority, on the Commission's own initiative or following a request by a Member State.

5. Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific data and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Articles 15 to 18.

Article 14

Reduction of disease risk claims

1. Notwithstanding Article 2(1)(b) of Directive 2000/13/EC, reduction of disease risk claims may be made where they have been authorised in accordance with the procedure laid down in Articles 15 to 18 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims.

2. In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Article 15

Application for authorisation

1. When reference is made to this Article, an application for authorisation shall be submitted in accordance with the following paragraphs.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority shall:

(i) acknowledge receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) inform without delay the Authority; and

(iii) make the application and any supplementary information supplied by the applicant available to the Authority;

(b) the Authority shall:

(i) inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) make the summary of the application referred to in paragraph 3(g) available to the public.

3. The application shall include the following:

(a) the name and address of the applicant;

(b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;

(c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;

(d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

(e) a copy of other scientific studies which are relevant to that health claim;

(f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

(g) a summary of the application.

4. The Commission, having first consulted the Authority, shall establish in accordance with the procedure referred to in Article 24(2) implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application.

5. The Commission, in close cooperation with the Authority, shall make available appropriate technical guidance and tools to assist food business operators, in particular SMEs, in the preparation and presentation of the application for scientific assessment.

Article 16

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to respect a time limit of six months from the date of receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

3. In order to prepare its opinion, the Authority shall:

(a) verify that the proposed wording of the health claim is substantiated by scientific data;

(b) consider whether the wording of the health claim complies with the criteria laid down in this Regulation;

(c) give advice on whether the proposed wording of the health claim is understandable and meaningful to the average consumer.

4. In the event of an opinion in favour of authorising the health claim, the opinion shall include the following particulars:

- (a) the name and address of the applicant;
- (b) the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics;
- (c) the recommended wording of the proposed health claim, including, as the case may be, the specific conditions of use;
- (d) where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising.

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based.

6. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public.

The applicant or members of the public may make comments to the Commission within 30 days from such publication.

Article 17

Community authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 22(2) a draft decision on the lists of permitted health claims, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft Decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision to amend the lists of permitted health claims shall include the particulars referred to in Article 16(4).

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 24(2).

4. The Commission shall, without delay, inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. Health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with the provisions of Article 20.

6. The granting of authorisation shall not lessen the general civil and criminal liability of any food business operator in respect of the food concerned.

Article 18

Modification, suspension and revocation of authorisations

1. The applicant/user of a claim included in one of the lists provided for in Articles 13 and 14 may apply for a modification of the relevant list. The procedure laid down in Articles 15 to 17 shall apply, *mutatis mutandis*.

2. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether a health claim included in the lists provided for in Articles 13 and 14 still meets the conditions laid down in this Regulation.

It shall forthwith transmit its opinion to the Commission, the Member States and, where relevant, to the original applicant of the claim in question. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public.

The applicant/user or a member of the public may make comments to the Commission within 30 days of such publication.

The Commission shall examine the opinion of the Authority and any comments received as soon as possible. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure laid down in Article 17.

CHAPTER V

GENERAL AND FINAL PROVISIONS

Article 19

Community Register

1. The Commission shall establish and maintain a Community Register of nutrition and health claims made on food, hereinafter referred to as 'the Register'.
2. The Register shall include the following:
 - (a) the nutrition claims and the conditions applying to them as set out in the Annex;
 - (b) restrictions adopted in accordance with Article 4(5);
 - (c) the authorised health claims and the conditions applying to them provided for in Articles 13(3), 14(1), 18(2), 20, 23(2) and 27(6) and the national measures referred to in Article 22(3);
 - (d) a list of rejected health claims and the reasons for their rejection.

Health claims authorised on the basis of proprietary data shall be recorded in a separate Annex to the Register together with the following information:

1. the date the Commission authorised the health claim and the name of the original applicant that was granted authorisation;
 2. the fact that the Commission authorised the health claim on the basis of proprietary data;
 3. the fact that the health claim is restricted for use unless a subsequent applicant obtains authorisation for the claim without reference to the proprietary data of the original applicant.
3. The Register shall be made available to the public.

Article 20

Data protection

1. The scientific data and other information in the application required under Article 15(2) may not be used for the benefit of a subsequent applicant for a period of seven years from the date of authorisation, unless the subsequent applicant

has agreed with the prior applicant that such data and information may be used, where:

- (a) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and
- (b) the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and
- (c) the health claim could not have been authorised without the submission of the proprietary data by the prior applicant.

2. Until the end of the seven-year period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether a claim could be or could have been included in the list provided for in Article 14 or, where appropriate, Article 13 without the submission of data designated as proprietary by the prior applicant.

Article 21

National provisions

Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in or advertising of foods which comply with this Regulation by the application of non-harmonised national provisions governing claims made on certain foods or on foods in general.

Article 22

Notification procedure

1. If a Member State considers it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the envisaged measures and give the reasons justifying them.

2. The Commission shall consult the Standing Committee on the Food Chain and Animal Health instituted by Article 58(1) of Regulation (EC) No 178/2002 (hereinafter referred to as the Committee) if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.

3. The Member State concerned may take the envisaged measures six months after the notification referred to in paragraph 1, provided that the Commission's opinion is not negative.

Article 25

Monitoring

If the Commission's opinion is negative, it shall determine, in accordance with the procedure referred to in Article 24(2) and before the expiry of the period referred to in the first subparagraph of this paragraph, whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measure.

To facilitate efficient monitoring of foods bearing nutrition or health claims, Member States may require the manufacturer or the person placing such foods on the market in their territory to notify the competent authority of that placing on the market by forwarding to it a model of the label used for the product.

Article 23

Safeguard measures

1. Where a Member State has serious grounds for considering that a claim does not comply with this Regulation, or that the scientific substantiation provided for in Article 6 is insufficient, that Member State may temporarily suspend the use of that claim within its territory.

Article 26

Evaluation

It shall inform the other Member States and the Commission and give reasons for the suspension.

By 19 January 2013 at the latest, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, in particular on the evolution of the market in foods in respect of which nutrition or health claims are made and on the consumers' understanding of claims, together with a proposal for amendments if necessary.

2. In accordance with the procedure referred to in Article 24 (2), a decision shall be taken, where appropriate after obtaining an opinion from the Authority.

Article 27

Transitional measures

The Commission may initiate this procedure on its own initiative.

3. The Member State referred to in paragraph 1 may maintain the suspension until the decision referred to in paragraph 2 has been notified to it.

1. Foods placed on the market or labelled prior to the date of application of this Regulation which do not comply with this Regulation may be marketed until their expiry date, but not later than 31 July 2009. With regard to the provisions in Article 4(1), foods may be marketed until 12 months following adoption of the relevant nutrient profiles and their conditions of use.

Article 24

Committee procedure

1. The Commission shall be assisted by the Committee.

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

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

2. Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.

3. The Committee shall adopt its rules of procedure.

3. Nutrition claims which have been used in a Member State before 1 January 2005 in compliance with national provisions applicable to them and which are not included in the Annex, may continue to be used until 19 January 2010 under the responsibility of food business operators and without prejudice to the adoption of safeguard measures as referred to in Article 23.

4. Nutrition claims in the form of pictorial, graphic or symbolic representation, complying with the general principles of this Regulation, which are not included in the Annex and are used according to specific conditions and criteria elaborated by national provisions or rules, shall be subject to the following:

- (a) Member States shall communicate to the Commission, by 31 January 2008 at the latest, such nutrition claims and the national provisions or rules applicable, accompanied by scientific data in support of such provisions or rules;
- (b) the Commission shall, in accordance with the procedure referred to in Article 24(2), adopt a Decision concerning the use of such claims.

Nutrition claims not authorised under this procedure may continue to be used for twelve months following the adoption of the Decision.

5. Health claims as referred to in Article 13(1)(a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 23.

6. Health claims other than those referred to in Article 13(1)(a) and 14, which have been used in compliance with national provisions before the date of entry into force of this Regulation, shall be subject to the following:

- (a) health claims which have been the subject of evaluation and authorisation in a Member State shall be authorised as follows:

- (i) Member States shall communicate to the Commission, by 31 January 2008 at the latest, such claims accompanied by a report evaluating the scientific data in support of the claim;

- (ii) after consulting the Authority, the Commission shall, in accordance with the procedure referred to in Article 24(2), adopt a Decision concerning the health claims authorised in this way.

Health claims not authorised under this procedure may continue to be used for six months following the adoption of the Decision;

- (b) health claims which have not been the subject of evaluation and authorisation in a Member State: such claims may continue to be used provided an application is made pursuant to this Regulation before 19 January 2008, health claims not authorised under this procedure may continue to be used for six months after a decision is taken pursuant to Article 17(3).

Article 28

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 1 July 2007.

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

Done at Brussels, 20 December 2006.

For the European Parliament
The President
J. BORRELL FONTELLES

For the Council
The President
J. KORKEAOJA

ANNEX

Nutrition claims and conditions applying to them

LOW ENERGY

A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.

ENERGY-REDUCED

A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

ENERGY-FREE

A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.

LOW-FAT

A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).

FAT-FREE

A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.

LOW-SATURATED FAT

A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

SATURATED FAT-FREE

A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.

LOW SUGAR

A claim that a food is low in sugar, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 5g of sugar per 100 g for solids or 2,5 g of sugar per 100 ml for liquids.

SUGAR-FREE

A claim that a food is sugar-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of sugar per 100 g or 100 ml.

WITH NO ADDED SUGAR

A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.

LOW SODIUM/SALT

A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.

VERY LOW SODIUM/SALT

A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters.

SODIUM-FREE or SALT-FREE

A claim that a food is sodium-free or salt-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,005 g of sodium, or the equivalent value for salt, per 100 g.

SOURCE OF FIBRE

A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.

HIGH FIBRE

A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.

SOURCE OF PROTEIN

A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.

HIGH PROTEIN

A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20 % of the energy value of the food is provided by protein.

SOURCE OF (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)

A claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 7 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ⁽¹⁾.

⁽¹⁾ See page 26 of this Official Journal.

HIGH (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)

A claim that a food is high in vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of 'source of (NAME OF VITAMIN/S) and/or (NAME OF MINERAL/S)'.

CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)

A claim that a food contains a nutrient or another substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular Article 5. For vitamins and minerals the conditions of the claim 'source of' shall apply.

INCREASED (NAME OF THE NUTRIENT)

A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 30 % compared to a similar product.

REDUCED (NAME OF THE NUTRIENT)

A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 % compared to a similar product, except for micronutrients where a 10 % difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.

LIGHT/LITE

A claim stating that a product is 'light' or 'lite', and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.

NATURALLY/NATURAL

Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/ natural' may be used as a prefix to the claim.

REGULATION (EC) No 1925/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on the addition of vitamins and minerals and of certain other substances to foods

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Community provisions, relevant national rules may apply without prejudice to the provisions of the Treaty.

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) There is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts. Their addition to foods is regulated in Member States by differing national rules that impede the free movement of these products, create unequal conditions of competition and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules harmonising national provisions relating to the addition of vitamins and minerals and of certain other substances to foods.
- (2) This Regulation aims to regulate the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers. In the absence of specific Community rules regarding prohibition or restriction of use of substances or ingredients containing substances other than vitamins or minerals under this Regulation or under other specific

- (3) Some Member States require the mandatory addition of some vitamins and minerals to certain ordinary foods, for reasons dictated by public health considerations. These reasons may be pertinent at national or even regional level, but would not currently justify harmonisation of the mandatory addition of nutrients across the Community. However, if and when this became appropriate, such provisions could be adopted at Community level. Meanwhile, it would be useful for information on such national measures to be compiled.

- (4) Vitamins and minerals may be added to foods voluntarily by food manufacturers or must be added as nutritional substances as provided for by specific Community legislation. They may also be added for technological purposes as additives, colourings, flavourings or other such uses including authorised oenological practices and processes provided for by relevant Community legislation. This Regulation should apply without prejudice to the specific Community rules concerning the addition of vitamins and minerals to or their use in specific products or groups of products or their addition for purposes other than those covered by this Regulation.

- (5) Given that detailed rules on food supplements containing vitamins and minerals have been adopted by Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽³⁾, provisions of this Regulation regarding vitamins and minerals should not apply to food supplements.

- (6) Vitamins and minerals are added to foods by manufacturers for a number of purposes including to restore their content where this has been reduced during manufacturing, storage or handling procedures or to provide a similar nutritional value to foods for which they are intended as alternatives.

⁽¹⁾ OJ C 112, 30.4.2004, p. 44.

⁽²⁾ Opinion of the European Parliament of 26 May 2005 (OJ C 117 E, 18.5.2006, p. 206), Council Common Position of 8 December 2005 (OJ C 80 E, 4.4.2006, p. 27) and Position of the European Parliament of 16 May 2006 (not yet published in the Official Journal), Council Decision of 12 October 2006.

⁽³⁾ OJ L 183, 12.7.2002, p. 51. Directive as amended by Commission Directive 2006/37/EC (OJ L 94, 1.4.2006, p. 32).

- (7) An adequate and varied diet can, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities such as those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is being achieved neither for all vitamins and minerals nor by all groups of the population across the Community. Foods to which vitamins and minerals have been added appear to make an appreciable contribution to the intake of these nutrients and as such may be considered to make a positive contribution to overall intakes.
- (8) Some nutrient deficiencies, although not very frequent, can be demonstrated to exist at present in the Community. Changes in the socio-economic situation prevailing in the Community and the life styles of different groups of the population have led to different nutritional requirements and to changing dietary habits. This in turn has led to changes in the energy and nutrient requirements of various groups of the population and to intakes of certain vitamins and minerals for these groups that would be below those recommended in different Member States. In addition, progress in scientific knowledge indicates that intakes of some nutrients for maintaining optimal health and well-being could be higher than those currently recommended.
- (9) Only vitamins and minerals normally found in and consumed as part of the diet and considered essential nutrients should be allowed to be added to foods although this does not mean that their addition thereto is necessary. Controversy as to the identity of these essential nutrients that could potentially arise should be avoided. It is therefore appropriate to establish a positive list of these vitamins and minerals.
- (10) The chemical substances used as sources of vitamins and minerals which may be added to foods should be safe and also be bio-available i.e. available to be used by the body. For this reason a positive list of these substances should also be established. Such substances that have been approved by the Scientific Committee on Food in an Opinion expressed on 12 May 1999, on the basis of the above criteria of safety and bio-availability, and can be used in the manufacture of foods intended for infants and young children, other foods for particular nutritional uses or food supplements should appear in this positive list. Although sodium chloride (common salt) does not appear among the substances in this list, it may continue to be used as an ingredient in the preparation of food.
- (11) In order to keep up with scientific and technological developments, it is important to revise the above lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (12) Foods to which vitamins and minerals are added are in most cases promoted by manufacturers and may be perceived by consumers as products having a nutritional, physiological or other health advantage over similar or other products without such nutrients added. This may induce consumer choices that may be otherwise undesirable. To counter this potential undesirable effect, it is considered appropriate to impose some restrictions on the products to which vitamins and minerals can be added, in addition to those that would result naturally from technological considerations or become necessary for safety reasons when maximum limits of vitamins and minerals in such products are set. The content in the product of certain substances, such as alcohol, would, in this context, be an appropriate criterion for not allowing vitamins and minerals to be added to it. Any derogation from banning the addition of vitamins and minerals to alcoholic beverages should be limited to protecting traditional wine recipes, with the relevant products being notified to the Commission. No claims about any nutritional or health benefits of the additions should be made. Moreover, in order to avoid any confusion for the consumer as to the natural nutritional value of fresh foods, the addition of vitamins and minerals thereto should not be allowed.
- (13) This Regulation is not intended to cover the use of vitamins and minerals in trace quantities as authenticity markers used with the objective of combating fraud.
- (14) Excessive intakes of vitamins and minerals may result in adverse health effects and it is therefore necessary to set maximum amounts for them when they are added to foods, as the case may be. These amounts must ensure that the normal use of the products, under the instructions for use provided by the manufacturer and in the context of a diversified diet, will be safe for the consumer. Therefore those amounts should be total maximum safe levels for the vitamins and minerals present in the food naturally and/or added to the food for whatever purpose, including for technological uses.

- (15) For that reason those maximum amounts and any other conditions restricting their addition to foods, where necessary, should be adopted taking into account their upper safe levels established by scientific risk assessment based on generally acceptable scientific data and their potential intake from other foods. Due account should also be taken of the population reference intakes of vitamins and minerals. Where it is necessary, for certain vitamins and minerals, to establish restrictions regarding the foods to which they can be added (e.g. the addition of iodine to salt), priority should be given to the purposes of restoring their content where this has been reduced during manufacturing, storage or handling procedures and of providing a similar nutritional value to foods for which those foods are intended as alternatives.
- (16) Vitamins and minerals added to foods should result in a minimum amount being present in the food. Otherwise the presence of too small and insignificant amounts in these fortified foods would not offer any benefit to consumers and would be misleading. The same principle underlies the requirement that these nutrients should be present in a significant amount in the food in order to be allowed to be declared in nutrition labelling. Therefore it would be appropriate that the minimum amounts of vitamins and minerals in foods to which those vitamins and minerals have been added should be the same as those significant amounts that should be present for those nutrients to be declared in nutrition labelling unless otherwise provided for by appropriate derogations.
- (17) The adoption of maximum amounts and any conditions of use based on the application of the principles and criteria stipulated in this Regulation and the adoption of minimum amounts would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (18) General labelling provisions and definitions are contained 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⁾. This Regulation should therefore be confined to the necessary additional provisions. Those additional provisions should also apply without prejudice to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽²⁾.
- (19) Given the nutritional importance of products to which vitamins and minerals have been added and their potential impact on dietary habits and overall nutrient intakes, the consumer should be able to evaluate the global nutritional quality of those products. Therefore, by derogation from Article 2 of Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs ⁽³⁾, nutrition labelling should be compulsory.
- (20) A normal and varied diet contains many ingredients, which in turn contain many substances. The intake of these substances or ingredients resulting from their normal and traditional use in current diets would not cause concern and does not need to be regulated. Some substances other than vitamins and minerals or ingredients containing them are added to foods as extracts or concentrates and may result in intakes that are significantly higher than those that could be ingested through eating an adequate and varied diet. The safety of such practices is in some cases seriously contested and the benefits are unclear; therefore they should be regulated. It is appropriate, in such cases, that food business operators, responsible for the safety of the foods they place on the market, assume the burden of proof in relation to their safety.
- (21) Given the particular nature of foods to which vitamins and minerals are added, means additional to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (22) Since the objective of this Regulation, namely to ensure the effective functioning of the internal market as regards the addition of vitamins and minerals and certain other substances to foods whilst providing a high level of consumer protection, 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.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

⁽²⁾ See page 9 of this Official Journal.

⁽³⁾ OJ L 276, 6.10.1990, p. 40. Directive as last amended by Commission Directive 2003/120/EC (OJ L 333, 20.12.2003, p. 51).

(23) 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⁾,

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 ⁽²⁾;

(2) 'other substance' means a substance other than a vitamin or a mineral that has a nutritional or physiological effect.

HAVE ADOPTED THIS REGULATION:

CHAPTER II

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to the addition of vitamins and minerals and of certain other substances to foods, with the purpose of ensuring the effective functioning of the internal market, whilst providing a high level of consumer protection.

2. The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC.

3. This Regulation shall apply without prejudice to specific provisions laid down in Community legislation concerning:

- (a) foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended;
- (b) novel foods and novel food ingredients;
- (c) genetically modified food;
- (d) food additives and flavourings;
- (e) authorised oenological practices and processes.

Article 2

Definitions

For the purposes of this Regulation:

(1) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002 of the European

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

ADDITION OF VITAMINS AND MINERALS

Article 3

Requirements for the addition of vitamins and minerals

1. Only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods, subject to the rules laid down in this Regulation.

2. Vitamins and minerals in a form that is bio-available to the human body may be added to foods, whether or not they are usually contained therein, in order to take into account, in particular:

- (a) a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; or
- (b) the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or
- (c) evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

3. Modifications to the lists referred to in paragraph 1 of this Article shall be adopted in accordance with the procedure referred to in Article 14(2), taking account of the opinion of the Authority.

Prior to making these modifications, the Commission shall carry out consultations with interested parties, in particular food business operators and consumer groups.

⁽²⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

Article 4

Restrictions on the addition of vitamins and minerals

Vitamins and minerals may not be added to:

- (a) unprocessed foodstuffs, including, but not limited to, fruit, vegetables, meat, poultry and fish;
- (b) beverages containing more than 1,2 % by volume of alcohol, except and by way of derogation from Article 3(2), to products:
 - (i) referred to in Article 44(6) and (13) of Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ⁽¹⁾; and
 - (ii) which were marketed prior to the adoption of this Regulation; and
 - (iii) which have been notified to the Commission by a Member State in accordance with Article 11,

and provided that no nutrition or health claim is made.

Additional foods or categories of foods to which particular vitamins and minerals may not be added may be determined in accordance with the procedure referred to in Article 14(2) in the light of scientific evidence and taking into account their nutritional value.

Article 5

Purity criteria

1. The purity criteria for vitamin formulations and mineral substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 14(2), except where they apply pursuant to paragraph 2 of this Article.
2. Purity criteria for vitamin formulations and mineral substances listed in Annex II, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Regulation, shall apply.
3. For those vitamin formulations and mineral substances listed in Annex II for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.

⁽¹⁾ OJ L 179, 14.7.1999, p. 1. Regulation as last amended by Regulation (EC) No 2165/2005 (OJ L 345, 28.12.2005, p. 1).

Article 6

Conditions for the addition of vitamins and minerals

1. When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts that shall be set in accordance with the procedure referred to in Article 14(2). The Commission may, to this end, submit proposals for the maximum amounts by 19 January 2009. For concentrated and dehydrated products, the maximum amounts set shall be those present in the foods when prepared for consumption according to the manufacturer's instructions.

2. Any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods shall be adopted in accordance with the procedure referred to in Article 14(2).

3. The maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 shall be set taking into account:

- (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers; and

- (b) intakes of vitamins and minerals from other dietary sources.

4. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set, due account shall also be taken of reference intakes of vitamins and minerals for the population.

5. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following shall also be taken into account, as necessary:

- (a) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;

- (b) the nutrient profile of the product established as provided for by Regulation (EC) No 1924/2006.

6. The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC. The minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 14(2).

Article 7

Labelling, presentation and advertising

1. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients. Where appropriate, a derogation concerning a specific nutrient may be adopted in accordance with the procedure referred to in Article 14(2).

2. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not mislead or deceive the consumer as to the nutritional merit of a food that may result from the addition of these nutrients.

3. Nutrition labelling of products to which vitamins and minerals have been added and which are covered by this Regulation shall be compulsory. The information to be provided shall consist of that specified in Article 4(1), Group 2 of Directive 90/496/EEC and of the total amounts present of the vitamins and minerals when added to the food.

4. The labelling of products to which vitamins and minerals have been added may bear a statement indicating such addition under the conditions laid down in Regulation (EC) No 1924/2006.

5. This Article shall apply without prejudice to other provisions of food law applicable to specified categories of foods.

6. Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 14(2).

CHAPTER III

ADDITION OF CERTAIN OTHER SUBSTANCES

Article 8

Substances prohibited, restricted or under Community scrutiny

1. The procedure provided for in this Article shall be followed where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

2. On its own initiative or on the basis of information provided by Member States, the Commission may take a decision, following in each case an assessment of available information by the Authority and in accordance with the procedure referred to in Article 14(2), to include, if necessary, the substance or ingredient in Annex III. In particular:

(a) if a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall:

(i) be placed in Annex III, Part A, and its addition to foods or its use in the manufacture of foods shall be prohibited; or

(ii) be placed in Annex III, Part B, and its addition to foods or its use in the manufacture of foods shall only be allowed under the conditions specified therein;

(b) if the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C.

3. Community provisions applicable to specified foods may provide for restrictions or prohibitions on the use of certain substances in addition to those laid down in this Regulation.

4. Food business operators, or any other interested parties, may at any time submit for evaluation to the Authority a file containing the scientific data demonstrating the safety of a substance listed in Annex III, Part C, under the conditions of its use in a food or in a category of foods and explaining the purpose of that use. The Authority shall inform without delay the Member States and the Commission of the submission and shall make the file available to them.

5. Within four years from the date a substance has been listed in Annex III, Part C, a decision shall be taken, in accordance with the procedure referred to in Article 14(2) and taking into account the opinion of the Authority on any files submitted for evaluation as mentioned in paragraph 4 of this Article, to generally allow the use of a substance listed in Annex III, Part C, or to list it in Annex III, Part A or B, as appropriate.

6. The Commission shall establish, in accordance with the procedure referred to in Article 14(2), implementing rules for the application of this Article, including rules concerning the submission referred to in paragraph 4 of this Article.

- (f) the substances for which dossiers have been submitted as provided for in Article 17(1)(b);
- (g) information about the substances referred to in Annex III and the reasons for their inclusion therein;
- (h) information about the substances listed in Annex III, Part C, whose use is generally allowed as referred to in Article 8(5).

3. The Register shall be made available to the public.

Article 10

Free movement of goods

Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in foods which comply with this Regulation and Community acts adopted for its implementation by the application of non-harmonised national provisions governing the addition of vitamins and minerals to foods.

Article 11

National provisions

1. By 19 July 2007, Member States shall inform the Commission of existing national provisions on the mandatory addition of vitamins and minerals and of products covered by the derogation provided for in Article 4(b).

2. If a Member State, in the absence of Community provisions, considers it necessary to adopt new legislation:

- (a) on the mandatory addition of vitamins and minerals to specified foods or categories of foods; or
- (b) on the prohibition or restriction on the use of certain other substances in the manufacture of specified foods,

it shall notify the Commission in accordance with the procedure laid down in Article 12.

Article 12

Notification procedure

1. If a Member State considers it necessary to adopt new legislation, it shall notify the Commission and the other Member States of the envisaged measures and give the reasons justifying them.

2. The Commission shall consult the Committee referred to in Article 14(1), if it considers such consultation to be useful or if a Member State so requests, and shall give an opinion on the envisaged measures.

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 9

Community Register

1. The Commission shall establish and maintain a Community Register on the addition of vitamins and minerals and of certain other substances to foods, hereinafter referred to as 'the Register'.

2. The Register shall include the following:

- (a) the vitamins and minerals which may be added to foods as listed in Annex I;
- (b) the vitamin formulations and mineral substances which may be added to foods as listed in Annex II;
- (c) the maximum and minimum amounts of vitamins and minerals which may be added to foods and any associated conditions set in accordance with Article 6;
- (d) the information regarding national provisions on the mandatory addition of vitamins and minerals referred to in Article 11;
- (e) any restrictions on the addition of vitamins and minerals as set out in Article 4;

3. The Member State concerned may take the envisaged measures only six months after the notification referred to in paragraph 1, and provided that the Commission's opinion is not negative.

If the Commission's opinion is negative, it shall determine, in accordance with the procedure referred to in Article 14(2) and before the expiry of the period referred to in the first subparagraph of this paragraph, whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measures.

Article 13

Safeguard measures

1. Where a Member State has serious grounds for considering that a product endangers human health despite complying with this Regulation, that Member State may temporarily suspend or restrict application of the provisions in question within its territory.

It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. In accordance with the procedure referred to in Article 14(2), a decision shall be taken, where appropriate after obtaining an opinion from the Authority.

The Commission may initiate this procedure on its own initiative.

3. The Member State referred to in paragraph 1 may maintain the suspension or restriction until the decision referred to in paragraph 2 has been notified to it.

Article 14

Committee procedure

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

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

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

3. The Committee shall adopt its Rules of Procedure.

Article 15

Monitoring

To facilitate efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, Parts B and C, Member States may require the manufacturer or the person placing such foods on the market in their territory to notify the competent authority of that placing on the market by providing a model of the label used for the product. In such cases, information on the withdrawal of the product from the market may also be required.

Article 16

Evaluation

By 1 July 2013, the Commission shall submit to the European Parliament and the Council a report on the effects of implementing this Regulation, in particular concerning the evolution of the market in foods to which vitamins and minerals have been added, their consumption, nutrient intakes for the population and changes in dietary habits, and the addition of certain other substances, accompanied by any proposals for amendment of this Regulation which the Commission deems necessary. In this context Member States shall provide the necessary relevant information to the Commission by 1 July 2012. Rules for implementing this Article shall be specified in accordance with the procedure referred to in Article 14(2).

Article 17

Transitional measures

1. By way of derogation from Article 3(1) and until 19 January 2014, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

(a) the substance in question is used for addition to foods marketed in the Community on 19 January 2007; and

(b) the Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 19 January 2010.

2. Until 19 January 2014, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in foods to which vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II are added.

3. Member States may, in compliance with the rules of the Treaty, continue to apply existing national provisions on maximum and minimum amounts of vitamins and minerals listed in Annex I added to foods and on the conditions applic-

able to this addition until the adoption of corresponding Community measures in accordance with Article 6 or under other specific Community provisions.

Article 18

Entry into force

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

It shall apply from 1 July 2007.

Foods placed on the market or labelled prior to 1 July 2007 which do not comply with this Regulation may be marketed until their expiry date, but not later than 31 December 2009.

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

Done at Brussels, 20 December 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

J. KORKEAOJA

ANNEX I

VITAMINS AND MINERALS WHICH MAY BE ADDED TO FOODS

1. **Vitamins**

Vitamin A
Vitamin D
Vitamin E
Vitamin K
Vitamin B1
Vitamin B2
Niacin
Pantothenic acid
Vitamin B6
Folic acid
Vitamin B12
Biotin
Vitamin C

2. **Minerals**

Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium
Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus

ANNEX II

VITAMIN FORMULATIONS AND MINERAL SUBSTANCES WHICH MAY BE ADDED TO FOODS

1. **Vitamin formulations**

VITAMIN A

retinol

retinyl acetate

retinyl palmitate

beta-carotene

VITAMIN D

cholecalciferol

ergocalciferol

VITAMIN E

D-alpha-tocopherol

DL-alpha-tocopherol

D-alpha-tocopheryl acetate

DL-alpha-tocopheryl acetate

D-alpha-tocopheryl acid succinate

VITAMIN K

phyloquinone (phytomenadione)

VITAMIN B1

thiamin hydrochloride

thiamin mononitrate

VITAMIN B2

riboflavin

riboflavin 5'-phosphate, sodium

NIACIN

nicotinic acid

nicotinamide

PANTOTHENIC ACID

D-pantothenate, calcium

D-pantothenate, sodium

dexpanthenol

VITAMIN B6

pyridoxine hydrochloride

pyridoxine 5'-phosphate

pyridoxine dipalmitate

FOLIC ACID

pteroylmonoglutamic acid

VITAMIN B12

cyanocobalamin

hydroxocobalamin

BIOTIN

D-biotin

VITAMIN C

L-ascorbic acid

sodium-L-ascorbate

calcium-L-ascorbate

potassium-L-ascorbate

L-ascorbyl 6-palmitate

2. **Mineral substances**

calcium carbonate

calcium chloride

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium oxide

calcium sulphate

magnesium acetate

magnesium carbonate

magnesium chloride

magnesium salts of citric acid

magnesium gluconate

magnesium glycerophosphate

magnesium salts of orthophosphoric acid

magnesium lactate

magnesium hydroxide

magnesium oxide

magnesium sulphate

ferrous carbonate

ferrous citrate

ferric ammonium citrate

ferrous gluconate

ferrous fumarate

ferric sodium diphosphate

ferrous lactate	manganese sulphate
ferrous sulphate	sodium bicarbonate
ferric diphosphate (ferric pyrophosphate)	sodium carbonate
ferric saccharate	sodium citrate
elemental iron (carbonyl + electrolytic + hydrogen reduced)	sodium gluconate
cupric carbonate	sodium lactate
cupric citrate	sodium hydroxide
cupric gluconate	sodium salts of orthophosphoric acid
cupric sulphate	sodium selenate
copper lysine complex	sodium hydrogen selenite
sodium iodide	sodium selenite
sodium iodate	sodium fluoride
potassium iodide	potassium fluoride
potassium iodate	potassium bicarbonate
zinc acetate	potassium carbonate
zinc chloride	potassium chloride
zinc citrate	potassium citrate
zinc gluconate	potassium gluconate
zinc lactate	potassium glycerophosphate
zinc oxide	potassium lactate
zinc carbonate	potassium hydroxide
zinc sulphate	potassium salts of orthophosphoric acid
manganese carbonate	chromium (III) chloride and its hexahydrate
manganese chloride	chromium (III) sulphate and its hexahydrate
manganese citrate	ammonium molybdate (molybdenum (VI))
manganese gluconate	sodium molybdate (molybdenum (VI))
manganese glycerophosphate	

*ANNEX III***SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY**

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

DECISION No 1926/2006/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 December 2006
establishing a programme of Community action in the field of consumer policy (2007-2013)
(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 153 thereof,

Having regard to the proposal from the Commission,

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

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) The Community can contribute to protecting the health, safety and economic and legal interests of citizens through actions in the field of consumer protection.
- (2) It is therefore appropriate to establish a programme of Community action in the field of consumer policy, replacing Decision No 20/2004/EC of the European Parliament and of the Council of 8 December 2003 establishing a general framework for financing Community actions in support of consumer policy for the years 2004 to 2007 ⁽⁴⁾. That Decision should therefore be repealed.
- (3) Integrating consumer interests in all Community policies, in accordance with Article 153 of the Treaty, should be given high priority, together with the consumer policy objectives set out in this programme.

Coordination with other Community policies and programmes is a key part of ensuring that consumer interests are taken fully into account in other policies. In order to promote synergies and avoid duplication, other Community funds and programmes should provide for financial support for the integration of consumer interests in their respective fields.

- (4) This Decision lays down, for the entire duration of the programme, a financial envelope constituting the prime reference, within the meaning of point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management ⁽⁵⁾, for the budgetary authority during the annual budgetary procedure.

- (5) It is of general European interest that the health and safety aspects of services and non-food products and the economic and legal interests of citizens, as well as consumers' interests in the development of standards for products and services, be represented at Community level. Given the particular nature of the organisations concerned, the renewal of Community support for the functioning of such organisations should not be subject to the principle of gradual decrease of the extent of Community support.

- (6) It is appropriate to ensure a transition between this programme and the programme it replaces, in particular regarding the continuation of multi-annual measures and the evaluation of the previous programme's successes and areas that need more attention. As of 1 January 2014, the technical and administrative assistance appropriations should cover, if necessary, the expenditure related to the management of actions not completed by the end of 2013.

- (7) The measures necessary for the implementation of this Decision 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 ⁽⁶⁾.

⁽¹⁾ OJ C 88, 11.4.2006, p. 1.

⁽²⁾ OJ C 192, 16.8.2006, p. 8.

⁽³⁾ Opinion of the European Parliament of 23 March 2006 (not yet published in the Official Journal), Common Position of the Council of 14 November 2006 (not yet published in the Official Journal) and Position of the European Parliament of 12 December 2006.

⁽⁴⁾ OJ L 5, 9.1.2004, p. 1. Decision as amended by Decision No 786/2004/EC (OJ L 138, 30.4.2004, p. 7).

⁽⁵⁾ OJ C 139, 14.6.2006, p. 1.

⁽⁶⁾ OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision No 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

- (8) Implementation of the programme should take into account the fact that the internal market will not function properly if consumers are less well protected in some Member States than in others. The programme should therefore focus especially on consumer protection and consumer awareness in the Member States which have acceded on or after 1 May 2004, in order to ensure a level playing field for all Member States.
- (9) The Agreement on the European Economic Area (hereinafter referred to as 'the EEA Agreement') provides for cooperation in the field of consumer protection between the European Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the European Economic Area (hereinafter referred to as 'the EFTA/EEA countries'), on the other. Provision should also be made to open the programme to participation by other countries, in particular the neighbouring countries of the European Union and countries which are applying for, are candidates for, or are acceding to, membership of the European Union.
- (10) In the context of the implementation of the programme, cooperation with third countries not participating in the programme should be encouraged, taking into account any relevant agreements between those countries and the Community.
- (11) The value and impact of the measures taken under the programme should be regularly monitored and evaluated, including by independent external evaluators. For the purposes of evaluating consumer policy, measurable objectives should be formulated and indicators developed.
- (12) Since the objectives of this Decision cannot be sufficiently achieved by the Member States due to the cross-border nature of the issues involved, and can therefore by reason of the greater potential of Community action efficiently and effectively to protect the health, safety and economic and legal interests of citizens 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 Decision does not go beyond what is necessary in order to achieve those objectives,

HAVE DECIDED AS FOLLOWS:

Article 1

Establishment of the programme

A programme of Community action in the field of consumer policy covering the period from 31 December 2006 to 31 December 2013, hereinafter referred to as 'the Programme', is hereby established.

Article 2

Aim and objectives

1. The aim of the Programme shall be to complement, support and monitor the policies of the Member States and to contribute to protecting the health, safety and economic and legal interests of consumers, as well as to promoting their rights to information, to education and to organise themselves in order to safeguard their interests.
2. The aim referred to in paragraph 1 shall be pursued through the following objectives:
 - (a) to ensure a high level of consumer protection, notably through improved evidence, better consultation and better representation of consumers' interests;
 - (b) to ensure the effective application of consumer protection rules, in particular through enforcement cooperation, information, education and redress.

These objectives shall be achieved through a combination of actions and instruments drawn from the list set out in Annex I according to the priorities set out in the annual work plan referred to in Article 7(2)(a).

Article 3

Funding

1. The financial envelope for the implementation of the Programme for the period from 31 December 2006 to 31 December 2013 is hereby set at EUR 156 800 000.
2. Annual appropriations shall be authorised by the budgetary authority within the limits of the financial framework.

Article 4

Financial contributions

1. Financial contributions by the Community shall not exceed the following levels:
 - (a) 50 % of the costs of actions jointly financed by the Community and one or more Member States, or by the Community and the competent authorities of the third countries participating pursuant to Article 8; except in the case of actions of exceptional utility, the Community contribution to the costs of which shall not exceed 70 %;

- (b) 85 % of the costs of actions intended to develop integrated European Master Degree courses in consumer issues;
- (c) 50 % of expenditure for the functioning of European consumer organisations;
- (d) 95 % of expenditure for the functioning of European consumer organisations representing consumer interests in the development of standards for products and services at Community level.

2. Financial contributions by the Community may take the form of:

- (a) scholarship grants for individual mobility of teachers and students in the framework of integrated European Master Degree courses in consumer issues. The management of these grants may be entrusted to the Erasmus National Agencies of the Life Long Learning programme;
- (b) travel and subsistence allowances for the exchange of enforcement officials.

3. The criteria for assessing whether actions exhibit exceptional utility within the meaning of paragraph 1(a) shall be established in advance in the annual work plan. Actions of exceptional utility shall benefit, in particular, consumers from Member States which acceded to the European Union on or after 1 May 2004.

4. The renewal of financial contributions set out in paragraphs 1(c) and 1(d) shall be exempted from the principle of gradual decrease.

5. For the purposes of paragraphs 1 and 2, financial contributions by the Community may also be given in the form of flat-rate or lump sum financing where this is suited to the nature of the actions concerned as defined in the annual work plan. In the case of flat-rate or lump sum financing, the percentage limits provided for in paragraph 1 shall not apply, although co-financing is still required.

Article 5

Beneficiaries

The classes of beneficiaries eligible for the financial contributions established in Article 4 are set out in Annex II.

Article 6

Administrative and technical assistance

1. The financial allocation for the Programme may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required directly for the management of the Programme and the achievement of its objectives; in particular, studies, meetings, information and

publication actions, expenses linked to IT networks focusing on information exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the Programme.

2. The financial allocation for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the Programme and the measures adopted under Decision No 20/2004/EC. If necessary, appropriations may be entered in the budget beyond 2013 to cover these expenses, to enable the management of actions not completed by 31 December 2013.

Article 7

Implementation

1. The Commission shall be responsible for the implementation of the Programme.

Actions in pursuit of the aim and objectives set out in Article 2 shall make full use of appropriate available methods of implementation including, in particular, direct or indirect implementation by the Commission on a centralised basis.

2. The procedure referred to in Article 10(2) shall apply to the adoption of:

- (a) the annual work plan for the implementation of the Programme, setting out;
 - priorities and actions to be undertaken, including the allocation of financial resources,
 - selection and award criteria and criteria for the percentage of Community financial contributions,
 - use made of flat rate and lump sum financing, and
 - the planned timing of calls for tenders, joint actions and calls for proposals;
- (b) the arrangements, including selection and award criteria, for the implementation of the actions referred to in Article 4(1) (a).

3. The Commission shall inform the Committee referred to in Article 10 of the actions undertaken in the implementation of the Programme.

Article 8

Participation of third countries

The Programme shall be open to the participation of:

- (a) the EFTA/EEA countries, in accordance with the conditions established in the EEA Agreement;

- (b) third countries, in particular countries to which the European Neighbourhood Policy applies, countries that are applying for, are candidates for, or are acceding to, membership of the European Union, and the western Balkan countries included in the stabilisation and association process, in accordance with the conditions laid down in the respective bilateral or multilateral agreements with those countries establishing the general principles for their participation in Community programmes.

Article 9

Monitoring, evaluation and dissemination of results

1. The Commission, in close cooperation with the Member States, shall monitor the implementation of the actions of the Programme in the light of its objectives. It shall report thereon to the Committee referred to in Article 10, and shall keep the European Parliament and the Council informed thereof.
2. At the request of the Commission, Member States shall submit to it information on the implementation and impact of the Programme.
3. The Commission shall ensure that the Programme is evaluated three years after its start, and following its end. The Commission shall communicate the results of those evaluations, accompanied by its comments, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

The Commission shall make the results of actions undertaken pursuant to this Decision publicly available.

Article 10

Committee procedure

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. The Committee shall adopt its rules of procedure.

Article 11

Repeal

Decision No 20/2004/EC is hereby repealed.

Article 12

Entry into force

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

Done at Brussels, 18 December 2006.

For the European Parliament

The President

J. BORRELL FONTELLES

For the Council

The President

J.-E. ENESTAM

ANNEX I

ACTIONS AND INSTRUMENTS REFERRED TO IN ARTICLE 2

Objective I

To ensure a high level of consumer protection, notably through improved evidence, better consultation and better representation of consumers' interests.

Action 1

The collection, exchange, and analysis of data and information that provide an evidence base for the development of consumer policy and for the integration of consumer interests in other Community policies, including:

- 1.1. Monitoring and assessment of market developments with an impact on the economic and other interests of consumers, including studies, price surveys, surveys of changes in the structure of markets, surveys of consumers and business, collection and analysis of consumer complaints, collection and analysis of data on cross-border business-to-consumer trade and markets.
- 1.2. Development and maintenance of databases.
- 1.3. Collection and analysis of statistical and other relevant evidence, the statistical element of which will be developed using as appropriate the Community Statistical Programme.

Action 2

The collection, exchange, analysis of data and information, and development of assessment tools that provide an evidence base on the safety of consumer goods and services, including consumer exposure to chemicals released from products, risks and injuries in relation to specific consumer products and services, and technical analysis of alert notifications.

Action 3

Support for scientific advice and risk evaluation, including the tasks of the independent scientific committees established by Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment ⁽¹⁾.

Action 4

Preparation of legislative and other regulatory initiatives and promotion of co-regulatory and self-regulatory initiatives, including:

- 4.1. Legal and technical expertise, including studies, in relation to regulation and its impact.
- 4.2. Legal and technical expertise, including studies, in relation to policy development on the safety of products and services and the economic and legal interests of consumers.
- 4.3. Legal and technical expertise, including studies, in relation to assessment of the need for product safety standards and the drafting of standardisation mandates for products and services.
- 4.4. Seminars, conferences, workshops and meetings of stakeholders and experts.

Action 5

Financial contributions to the functioning of European consumer organisations.

Action 6

Financial contributions to the functioning of European consumer organisations representing consumer interests in the development of standards for products and services at Community level.

Action 7

Capacity building for regional, national and European consumer organisations, notably through training and exchange of best practice and expertise for staff members, in particular for consumer organisations in Member States which acceded to the European Union on or after 1 May 2004.

⁽¹⁾ OJ L 66, 4.3.2004, p. 45.

Objective II

To ensure the effective application of consumer protection rules, in particular through enforcement cooperation, information, education and redress.

Action 8

Actions to improve the effective application of Community consumer protection legislation, in particular Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ⁽¹⁾ and Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws ⁽²⁾, including:

- 8.1. Actions to improve the coordination of monitoring and enforcement and to improve cooperation between competent authorities, including the development and maintenance of IT tools (e.g. databases, information and communication systems) and the organisation of seminars, conferences, workshops and meetings of stakeholders and experts on enforcement, exchanges of enforcement officials and training, also for members of the judiciary.
- 8.2. Monitoring and assessment of the safety of non-food products and services, including the reinforcement and extension of the scope and operation of the RAPEX alert system, taking developments in market surveillance information exchange into account, and the further development of the consumer product safety network as provided for in Directive 2001/95/EC.
- 8.3. Joint monitoring and enforcement actions and other actions in the context of administrative and enforcement cooperation.
- 8.4. Actions for administrative and enforcement cooperation with third countries which are not participating in the programme.

Action 9

Legal and technical expertise, including studies, for the monitoring and assessment of the transposition, implementation and enforcement of consumer protection legislation by Member States, notably Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market ⁽³⁾ and Regulation (EC) No 2006/2004. This also includes the development and maintenance of easily and publicly accessible databases covering the implementation of Community consumer protection legislation.

Action 10

Actions on information, advice and redress, including:

- 10.1. Monitoring the functioning of alternative dispute resolution schemes and assessing their impact.
- 10.2. Financial contributions for joint actions with public or non-profit bodies constituting Community networks which provide information and assistance to consumers to help them exercise their rights and obtain access to appropriate dispute resolution (the European Consumer Centres Network).
- 10.3. Actions improving communication with EU citizens on consumer issues, especially in Member States which acceded to the European Union on or after 1 May 2004, including publications on issues of interest for consumer policy, provision of information on-line, and actions providing information about consumer protection measures and consumer rights.

Action 11

Actions on consumer education, including:

- 11.1. Specific actions targeted at young consumers, old consumers and vulnerable groups of consumers who are clearly less able to defend their interests, and the development of interactive tools for consumer education.
- 11.2. Financial contributions to the development of integrated European Master Degree courses in consumer issues, including a scheme of scholarships enabling students to spend up to six months in a different country.

⁽¹⁾ OJ L 11, 15.1.2002, p. 4.

⁽²⁾ OJ L 364, 9.12.2004, p. 1. Regulation as amended by Directive 2005/29/EC (OJ L 149, 11.6.2005, p. 22).

⁽³⁾ OJ L 149, 11.6.2005, p. 22.

ANNEX II

BENEFICIARIES ELIGIBLE FOR THE FINANCIAL CONTRIBUTIONS ESTABLISHED IN ARTICLE 4

1. The financial contributions for actions referred to in Article 4(1)(a) may be awarded to a public body or a non-profit-making body designated through a transparent procedure by the Member State or the competent authority concerned and agreed by the Commission.
2. The financial contributions for actions referred to in Article 4(1)(b) may be awarded to higher education institutions of the Member States or third countries participating pursuant to Article 8, as defined in Article 2 of Decision No 2317/2003/EC of the European Parliament and of the Council of 5 December 2003 establishing a programme for the enhancement of quality in higher education and the promotion of intercultural understanding through cooperation with third countries (Erasmus Mundus) (2004-2008) ⁽¹⁾.
3. The financial contributions for actions referred to in Article 4(2)(a) may be awarded to students and teachers participating in the integrated European Master Degree courses in consumer issues benefiting from co-financing under Article 4(1)(b).
4. The financial contributions for actions referred to in Article 4(2)(b) may be awarded to the consumer protection enforcement officials referred to in Regulation (EC) No 2006/2004 and Directive 2001/95/EC.
5. The financial contributions for actions referred to in Article 4(1)(c) may be awarded to European consumer organisations which:
 - (a) are non-governmental, non-profit making, independent of industry, commercial and business or other conflicting interests, and have as their primary objectives and activities the promotion and protection of the health, safety and economic and legal interests of consumers in the Community;
 - (b) have been mandated to represent the interests of consumers at Community level by national consumer organisations in at least half of the Member States that are representative, in accordance with national rules or practice, of consumers and are active at regional or national level; and
 - (c) have provided to the Commission satisfactory accounts of their membership, internal rules and sources of funding.
6. The financial contributions for actions referred to in Article 4(1)(d) may be awarded to European consumer organisations which:
 - (a) are non-governmental, non-profit-making, independent of industry, commercial and business or other conflicting interests, and have as their primary objectives and activities to represent consumer interests in the standardisation process at Community level;
 - (b) have been mandated in at least two thirds of the Member States to represent the interests of consumers at Community level:
 - by bodies representative, in accordance with national rules or practice, of national consumer organisations in the Member States, or
 - in the absence of the bodies, referred to in the first indent, by national consumer organisations in the Member States that are representative, in accordance with national rules or practice, of consumers and are active at national level;
 - (c) have provided to the Commission satisfactory accounts of their membership, internal rules and sources of funding.

⁽¹⁾ OJ L 345, 31.12.2003, p. 1.