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(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
