COMMISSION OF THE EUROPEAN COMMUNITIES



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2008/0030 (COD)

Proposal for a

# **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

amending Regulation (EC) No 999/2001 as regards the implementing powers conferred on the Commission

(presented by the Commission)

## EXPLANATORY MEMORANDUM

#### 1. CONTEXT OF THE PROPOSAL

#### **1.1** Reform of the comitology procedures

Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>1</sup> was amended by Council Decision 2006/512/EC of 17 July 2006<sup>2</sup>.

Article 5a of the amended Decision 1999/468/EC introduced a new regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

### 1.2. Priority alignment and general alignment

In a joint statement<sup>3</sup>, the Parliament, the Council and the Commission listed a number of basic instruments that should be adapted to the amended Decision as a matter of urgency in order to incorporate the new regulatory procedure with scrutiny (priority alignment). For the regulatory procedure with scrutiny to be applicable to the other instruments adopted under the codecision procedure and already in force at the time when Decision 2006/512/EC took effect, the joint statement also calls for the adaptation of these instruments, in accordance with the applicable procedures (general alignment).

The Commission has undertaken to examine all these instruments, with a view to submitting, by the end of 2007, legislative proposals to adapt them, if necessary, to the new regulatory procedure with scrutiny<sup>4</sup>.

### 1.3. Method

As mentioned in the Commission's Communication to the European Parliament and the Council of (...), the Commission has carefully examined all the instruments adopted by codecision in order to identify those which permit the Commission to adopt measures of general scope designed to amend non-essential elements of the basic instrument in question. The Commission has identified more than 200 instruments that should be adapted.

<sup>&</sup>lt;sup>1</sup> OJ L 184, 17.7.1999, p. 23.

<sup>&</sup>lt;sup>2</sup> OJ L 200, 22.7.2006, p. 11.

<sup>&</sup>lt;sup>3</sup> OJ C 255, 21.10.2006, p. 1.

<sup>&</sup>lt;sup>4</sup> PE 376.314v01-00 - A6-0236/2006 (Commission declaration annexed to the Parliament's report)

Some of these instruments come under the Commission's codification programme. This is the case for Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. Adaptation to the new procedure should take place, depending on how far the codification process has progressed, either by recasting the codified proposal or, as in the present case, by legislative amendment.

#### 2. LEGAL ASPECTS OF THE PROPOSAL

The purpose of adaptation is to incorporate the regulatory procedure with scrutiny, as provided for in Article 5a of amended Decision 1999/468/EC.

Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies is intended to provide a single legal framework for transmissible spongiform encephalopathies (TSEs) in the Community.

Regulation (EC) No 1923/2006 of the European Parliament and of the Council amending Regulation (EC) No 999/2001 introduced the regulatory procedure with scrutiny only for certain implementing measures which were concerned by the amendments. Therefore, Regulation (EC) No 999/2001 should be adapted for the remaining implementing powers.

Since the basic instrument is a Regulation, it must be adapted by means of an equivalent instrument.

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# **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

#### amending Regulation (EC) No 999/2001 as regards the implementing powers conferred on the Commission

## (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<sup>5</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>6</sup>,

Having consulted the Committee of the Regions<sup>7</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>8</sup>,

Whereas:

- (1) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>9</sup> provides that certain measures are to 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) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.
- (3) In accordance with the joint statement of the European Parliament, the Council and the Commission on Decision 2006/512/EC, for this new procedure to be applicable to instruments adopted in accordance with the procedure laid down in Article 251 of the

<sup>&</sup>lt;sup>5</sup> OJ C xxx, xx.xxxxx, p. xx.

OJ C xxx, xx.xx.xxx, p. xx.

<sup>&</sup>lt;sup>7</sup> OJ C xxx, xx.xx.xxx, p. xx.

<sup>&</sup>lt;sup>8</sup> OJ C , , p. .

OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 727/2007 (OJ L 165, 27.6.2007, p. 8).

Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

- (4) As regards Regulation (EC) No 999/2001, Regulation (EC) No 1923/2006 of the European Parliament and of the Council introduced the regulatory procedure with scrutiny only for certain implementing measures which were concerned by the amendments. Therefore, Regulation (EC) No 999/2001 should be adapted for the remaining implementing powers.
- (5) Power should be conferred on the Commission in particular for the approval of rapid tests, the extension of certain provisions to other products of animal origin, the adoption of implementing rules including the method to confirm BSE in ovine and caprine animals, the modification of the Annexes and the adoption of transitional measures.
- (6) Since these measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 999/2001, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (7) Regulation (EC) No 999/2001 should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

#### Article 1

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

- (1) Article 5, paragraph 3, third subparagraph is amended as follows:
  - " The rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24(3) and entered on a list set out in Annex X, Chapter C, point 4."
- (2) Article 16, paragraph 7 is amended as follows:
  - "7. In accordance with the procedure referred to in Article 24(3), the provisions of paragraphs 1 to 6 may be extended to other products of animal origin. Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2)."
- (3) Article 20, paragraph 2 is amended as follows:
  - "2. Where necessary to ensure the uniform application of this Article, implementing rules, including the method to confirm BSE in ovine and caprine animals, shall be adopted in accordance with the procedure referred to in Article 24(3)."
- (4) The first paragraph of Article 23 is amended as follows:

"After consultation of the appropriate scientific committee on any question which could have an impact on public health, the annexes shall be amended or supplemented and any appropriate transitional measures shall be adopted in accordance with the procedure referred to in Article 24(3)."

- (5) Article 23a is amended as follows:
  - (a) Point (a) is replaced by the following:
    - "(a) approval of the rapid tests referred to in Article 5(3) third subparagraph, Article 6(1) and Article 8(2),"
  - (b) The following points are added:
    - "(k) extension to other products of animal origin of the provisions of paragraphs 1 to 6 of Article 16,
    - (1) adoption of implementing rules referred to in Article 20(2), including the method to confirm BSE in ovine and caprine animals,
    - (m) amendment or addition to the annexes and adoption of any appropriate transitional measures referred to in Article 23."

# 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,

For the European Parliament The President For the Council The President