COMMISSION REGULATION (EC) No 253/2006

of 14 February 2006

amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rapid tests and measures for the eradication of TSEs in ovine and caprine animals

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 ([1]), and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the eradication of transmissible spongiform encephalopathies (TSEs) after confirmation of TSEs in a flock of ovine or caprine animals and sets out a list of rapid tests approved for TSE monitoring.

(2) In accordance with Regulation (EC) No 999/2001, as amended by Commission Regulation (EC) No 260/2003 ([2]), since 1 October 2003 certain measures have applied following the confirmed presence of a TSE in ovine or caprine flocks. At the time, two types of TSE potentially present in ovine or caprine animals, namely scrapie and bovine spongiform encephalopathy (BSE), could not be routinely discriminated in ovine or caprine animals. Strict measures were therefore introduced on the grounds that every TSE case in ovine or caprine animals could be BSE.

(3) In accordance with Regulation (EC) No 999/2001, as amended by Commission Regulation (EC) No 36/2005 ([3]), since January 2005 discriminatory testing has been mandatory in all confirmed TSE cases in ovine and caprine animals. Following the stepping-up of surveillance in ovine and caprine animals in 2005 in accordance with Regulation (EC) No 999/2001, as amended by Commission Regulation (EC) No 214/2005 ([4]), preliminary results indicate that BSE can be ruled out in all positive TSE cases to date. Measures for the eradication of TSEs in ovine and caprine animals will be reconsidered in the framework of the TSE road map. Discussion on the subject will, however, not be finalised before the end of 2005.

(4) In order to prevent stricter measures to eradicate TSEs in ovine animals becoming applicable despite ongoing discussion on their possible review, transitional measures currently applying until 1 January 2006 on the restocking of flocks culled in connection with TSE eradication should be extended.

(5) In its report of 2 September 2005, the European Food Safety Authority (EFSA) recommended the approval of a new BSE rapid post-mortem test. That test should be included in the list of rapid tests for monitoring BSE.

(6) Until now, no formal evaluation of tests specifically for the purpose of testing ovine or caprine animals has been completed. Five rapid tests currently listed in Annex X to Regulation (EC) No 999/2001 were provisionally approved, pending evaluation, for the monitoring programme in ovine and caprine animals on the basis of data provided by the test manufacturers.

(7) In its reports of 17 May and 26 September 2005 on the evaluation of rapid post-mortem tests intended for ovine and caprine animals, the EFSA recommended the approval of eight new rapid post-mortem tests, including the five provisionally approved rapid tests. These tests should be included in the list of rapid tests for monitoring TSEs in ovine and caprine animals.

(8) Changes to rapid tests and to test protocols may only be made with the approval of the Community Reference Laboratory (CRL) for TSEs. The CRL has approved changes to the BSE rapid post-mortem test called 'Inpro CDI'. The CRL has also accepted the change of name to 'Beckman Coulter InPro CDI kit'.

(9) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1974/2005 (OJ L 317, 3.12.2005, p. 4).
([2]) OJ L 37, 13.2.2003, p. 7.
([3]) OJ L 10, 13.1.2005, p. 9.
([4]) OJ L 37, 10.2.2005, p. 9.

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VII and X to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following 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, 14 February 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

1. In Annex VII to Regulation (EC) No 999/2001, point 6 is replaced by the following:

'6. During a transitional period until 1 January 2007 at the latest and by way of derogation from the restriction set out in point 4(b), where it is difficult to obtain replacement ovine animals of a known genotype, Member States may decide to allow non-pregnant ewes of an unknown genotype to be introduced onto the holdings to which the measures referred to in point 2(b)(i) and (ii) apply.'

2. In Annex X to Regulation (EC) No 999/2001, Chapter C, point 4 is replaced by the following:

'4. ***Rapid tests***

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

— immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K resistant fragment PrP^{Res} (Prionics-Check Western test),

— chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test & Enfer TSE Kit version 2.0, automated sample preparation),

— sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad TeSeE test),

— microplate based immunoassay (ELISA) which detects Proteinase Kresistant PrP^{Res} with monoclonal antibodies (Prionics-Check LIA test),

— conformation-dependent immunoassay, BSE antigen test kit (Beckman Coulter InPro CDI kit),

— chemiluminescent ELISA for qualitative determination of PrP^{Sc} (CediTect BSE test),

— immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA),

— microplate based chemiluminiscent immunoassay for the detection of PrP^{Sc} in bovine tissues (Institut Pourquier Speed'it BSE),

— lateral flow immunoassay using two different monoclonal antibodies to detect Proteinase K resistant PrP fractions (Prionics Check PrioSTRIP),

— two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP^{Sc} (Roboscreen Beta Prion BSE EIA Test Kit),

— sandwich ELISA for the detection of Proteinase K resistant PrP^{Sc} (Roche Applied Science PrionScreen),

— antigen-capture ELISA using two different monocloncal antibodies to detect Proteinase K resistant PrP fractions (Fujirebio FRELISA BSE post-mortem rapid BSE Test).

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), the following methods shall be used as rapid tests for the monitoring of TSE ovine and caprine animals:

— conformation-dependent immunoassay, BSE antigen test kit (Beckman Coulter InPro CDI kit),

— sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad TeSeE test),

— sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad TeSeE Sheep/Goat test),

— chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer TSE Kit version 2.0),

— immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

— microplate based chemiluminiscent immunoassay for the detection of PrP^{Sc} in ovine tissues (POURQUIER'S-LIA Scrapie),

— immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K resistant fragment PrP^{Res} (Prionics-Check Western Small Ruminant test),

— microplate based chemiluminescent immunoassay for the detection of Proteinase K resistant PrP^{Sc} (Prionics Check LIA Small Ruminants).

In the case of all tests, sample tissue on which the test must be applied must comply with the manufacturer's instructions for use.

The producer of the rapid tests must have put in place a quality assurance system, approved by the Community Reference Laboratory (CRL) that ensures that the test performance does not change. The producer must provide the test protocol to the Community Reference Laboratory.

Changes to rapid tests and to test protocols may only be made after prior notification to the Community Reference Laboratory and provided that the Community Reference Laboratory finds that the change does not alter the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.'