COMMISSION REGULATION (EC) No 260/2005

of 16 February 2005

amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rapid tests

(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 subparagraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 sets out a list of rapid tests approved for TSE monitoring.

(2) In its opinion of 16 November 2004, the European Food Safety Authority (EFSA) recommended the inclusion of seven new BSE rapid post mortem tests in the list of rapid tests approved for monitoring of bovine spongiform encephalopathy (BSE).

(3) The rapid tests currently listed in Annex X to Regulation (EC) No 999/2001 have been approved for sheep based on data provided by the test manufacturers showing that their tests may also be used for monitoring of TSE in sheep.

(4) The EFSA is currently evaluating rapid post mortem tests intended for small ruminants. A list of approved rapid tests for use in the surveillance programme for small ruminants is to be established on the basis of the opinion to be published. Accordingly, the currently approved rapid tests should be used for detecting TSE in small ruminants, until the publication of that opinion.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex X to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth 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, 16 February 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1993/2004 (OJ L 344, 20.11.2004, p. 12).

ANNEX

In Annex X, Chapter C, point 4 is replaced by the following:

'4. ***Rapid tests***

For the purposes of carrying out the rapid tests in accordance with Article 5(3) and Article 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 protease-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 protease resistant PrP^{Res} with monoclonal antibodies (Prionics-Check LIA test),

— automated conformation-dependent immunoassay comparing the reactivity of a detection antibody to the protease sensitive and protease resistant forms of PrP^{Sc} (some fraction of the protease resistant PrP^{Sc} is equivalent to PrP^{Res}) and to PrP^{C} (InPro CDI-5 test),

— 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 (PK) resistant PrP^{Sc} (Roche Applied Science PrionScreen).

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

— immuno-blotting test based on a Western blotting procedure for the detection of the protease-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),

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

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

— automated conformation-dependent immunoassay comparing the reactivity of a detection antibody to the protease sensitive and protease resistant forms of PrP^{Sc} (some fraction of the protease resistant PrP^{Sc} is equivalent to PrP^{Res}) and to PrP^{C} (InPro CDI-5 test).

The producer of the rapid tests must have a quality assurance system in place agreed by the Community reference laboratory, which ensures that the test performance does not change. The producer must provide the test protocol to the Community reference laboratory.

Modifications to rapid tests or to test protocols may only be made following advance notification to the Community reference laboratory, and provided that the Community reference laboratory finds that the modification does not reduce the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.'