Commission Regulation (EC) No 21/2008 of 11 January 2008 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the lists of rapid tests (Text with EEA relevance)

COMMISSION REGULATION (EC) No 21/2008

of 11 January 2008

amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the lists of 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 paragraph Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) Annex X, Chapter C, to Regulation (EC) No 999/2001 sets out a list of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals.

(3) Changes to rapid tests and to test protocols may only be made after prior notification to the Community Reference Laboratory (CRL) for TSEs and provided that the CRL finds that the changes do not alter the sensitivity, specificity or reliability of the tests. On 13 April 2007, the CRL approved changes made to the currently approved TSE rapid *post-mortem* test 'Enfer TSE Kit version 2.0', and therefore recommended that the amended version (Enfer TSE version 3) should also be listed in Annex X, Chapter C, to Regulation (EC) No 999/2001.

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

(5) 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 21/2008. (See end of Document for details)*

Article 2

This Regulation shall enter into force on the third 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, 11 January 2008.

For the Commission

Markos KYPRIANOU

Member of the Commission

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 21/2008. (See end of Document for details)*

ANNEX

In Annex X, Chapter C, to Regulation (EC) No 999/2001, 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),

— microplate based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),

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

— microplate based immunoassay (ELISA) which detects Proteinase K resistant 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 chemiluminescent 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 TSEs in 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 Te-SeE test),

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