Commission Regulation (EU) No 1064/2012 of 13 November 2012 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the list of rapid tests (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1064/2012

of 13 November 2012

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 and the introductory phrase and point (a) of Article 23a 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) Point 4 of Chapter C of Annex X 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) On 8 May 2012, the European Food Safety Authority (EFSA) published an opinion on the evaluation of new TSE rapid tests submitted in the framework of the Commission call for expression of interest 2007/S204-247339[(2)]. EFSA recommended in this opinion that the test Prionics - Check PrioSTRIP SR (visual reading protocol) be considered suitable for approval as rapid test for detection of TSE in small ruminants' central nervous system.

(4) It is therefore appropriate to amend accordingly the lists of rapid tests approved for the monitoring of TSE in small ruminants, set out in point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001.

(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

In Chapter C of Annex X to Regulation (EC) No 999/2001, point 4 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third 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, 13 November 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX

Point 4 of Chapter C of Annex X 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), only the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

— the immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrPRes (Prionics-Check Western test),

— the 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),

— the microplate-based immunoassay for the detection of PrPSc (Enfer TSE Version 3),

— the sandwich immunoassay for PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),

— the microplate-based immunoassay (ELISA) which detects Proteinase K-resistant PrPRes with monoclonal antibodies (Prionics-Check LIA test),

— the 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 & IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

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

— the 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),

— the sandwich ELISA for the detection of Proteinase K-resistant PrP Sc (Roche Applied Science PrionScreen).

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

— the sandwich immunoassay for PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),

— the sandwich immunoassay for PrPRes detection with the TeSeE Sheep/Goat Detection kit carried out following denaturation and concentration steps with the TeSeE Sheep/Goat Purification kit (Bio-Rad TeSeE Sheep/Goat rapid test),

— the 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),

— the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (rapid test Prionics - Check PrioSTRIP SR, visual reading protocol).

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

Producers of rapid tests must have a quality assurance system in place that has been approved by the European Union Reference Laboratory and ensures that the test performance does not change. Producers must provide the European Union Reference Laboratory with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the European Union Reference Laboratory and provided that the European Union 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.'

(**1**) OJ L 147, 31.5.2001, p. 1.

(**2**) OJ/S S204, 23.10.2007, 247339-2007-EN.

Status:
Point in time view as at 13/11/2012.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 1064/2012.