

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 PrP^{Res} (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 PrP^{Sc} (Enfer TSE Version 3),
- the sandwich immunoassay for PrP^{Res} 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 PrP^{Res} 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 PrP^{Res} detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),
- the sandwich immunoassay for PrP^{Res} 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 legislation: There are currently no known outstanding effects for the
Commission Regulation (EU) No 1064/2012, ANNEX. (See end of Document for details)

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.'

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 1064/2012, ANNEX.