

Status: Point in time view as at 15/01/2008.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, Division 4.. (See end of Document for details)

ANNEX X

REFERENCE LABORATORIES, SAMPLING AND LABORATORY ANALYSIS METHODS

[^{F1}CHAPTER C

Sampling and laboratory testing

[^{F24}. 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 monoclonal 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),

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- 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),
- microplate based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),
- 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 chemiluminescent 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 to which the test is to 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 CRL.

Changes to rapid tests and to test protocols may be made only after prior notification to the CRL and provided that the CRL 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.]]

Textual Amendments

- F2** Substituted by [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 \(Text with EEA relevance\).](#)

Textual Amendments

- F1** Substituted by [Commission Regulation \(EC\) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation \(EC\) No 999/2001 of the European Parliament and of the Council as regards epidemiological surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals \(Text with EEA relevance\).](#)

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