***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 260/2005. (See end of Document for details)*

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

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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.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 260/2005.