ANNEX

1. In Annex VII to Regulation (EC) No 999/2001, point 6 is replaced by the following:

6. During a transitional period until 1 January 2007 at the latest and by way of derogation from the restriction set out in point 4(b), where it is difficult to obtain replacement ovine animals of a known genotype, Member States may decide to allow non-pregnant ewes of an unknown genotype to be introduced onto the holdings to which the measures referred to in point 2(b)(i) and (ii) apply.

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

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

— microplate based immunoassay (ELISA) which detects Proteinase Kresistant 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 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 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 TSE 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 TeSeE test),

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

— 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 chemiluminiscent 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 on which the test must 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 Community Reference Laboratory.

Changes to rapid tests and to test protocols may only be made after prior notification to the Community Reference Laboratory and provided that the Community 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 (EC) No 253/2006, ANNEX.