ANNEX

Annexes III and X to Regulation (EC) No 999/2001 are amended as follows:

1. in Part I of Chapter A of Annex III, points 6.3 and 6.4 are replaced by the following:

   6.3. All parts of the body of an animal tested for BSE including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council.

   6.4. All parts of the body of an animal found positive or inconclusive to the rapid test including the hide shall be disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(III).;

2. in Annex X, Chapter C is amended as follows:

   (a) In Point 3.1, points (a) and (b) are replaced by the following:

      (a) Suspect cases

      Samples from bovine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

      (i) the immunohistochemical (IHC) method;

      (ii) SAF-immunoblot or OIE approved alternative;

      (iii) the demonstration of characteristic fibrils by electron microscopy;

      (iv) the histopathological examination;

      (v) the combination of rapid tests as laid down in the third subparagraph.

      In case the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

      Rapid tests may be used for both primary screening of suspect cases and, if inconclusive or positive, for subsequent confirmation, according to the guidelines from the Community reference laboratory and provided that:

      (i) the confirmation is carried out in a national reference laboratory for TSEs; and

      (ii) one of the two rapid tests is a Western blot; and

      (iii) the second rapid test used:
      — includes a negative tissue control and a bovine BSE sample as positive tissue control,
      — is of a different type than the test used for the primary screening; and

(iv) if a rapid Western blot is used as the first test, the result of that test must be documented and submitted to the national reference laboratory for TSEs; and

(v) where the result of the primary screening is not confirmed by the subsequent rapid test, the sample must be subjected to an examination by one of the other confirmatory methods; in case the histopathological examination is used for that purpose but proves to be inconclusive or negative, the tissues must be submitted to a further examination by one of the other confirmatory methods and protocols.

If the result of one of the confirmatory examinations referred to in points (i) to (v) of the first subparagraph is positive, the animals shall be regarded a positive BSE cases.

(b) BSE monitoring

Samples from bovine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part I shall be examined by a rapid test.

When the result of the rapid test is inconclusive or positive, the sample shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) SAF-immunoblot or OIE approved alternative;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) the histopathological examination;

(v) the combination of rapid tests as laid down in the fourth subparagraph.

In case the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for both primary screening and, if inconclusive or positive, for subsequent confirmation, according to the guidelines from the Community reference laboratory and provided that:

(i) the confirmation is carried out in a national reference laboratory for TSEs; and

(ii) one of the two rapid tests is a Western blot; and

(iii) the second rapid test used:

— includes a negative tissue control and a bovine BSE sample as positive tissue control,

— is of a different type than the test used for the primary screening; and

(iv) if a rapid Western blot is used as the first test, the result of that test must be documented and submitted to the national reference laboratory for TSEs; and

(v) where the result of the primary screening is not confirmed by the subsequent rapid test, the sample must be subjected to an examination by one of the other confirmatory methods; in case the histopathological examination is used for that purpose but proves to be inconclusive or negative, the tissues must be submitted to a further examination by one of the other confirmatory methods and protocols.

An animal shall be regarded a positive BSE case if the result of the rapid test is inconclusive or positive, and at least one of the confirmatory examinations referred to in points (i) to (v) of the first subparagraph is positive.;

(b) in Point 3.2, point (a) is replaced by the following:

(a) Suspect cases

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) SAF-immunoblot or OIE approved alternative;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) the histopathological examination.

In case the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for primary screening of suspect cases. Such tests may not be used for subsequent confirmation.

Where the result of the rapid test used for primary screening of suspect cases is positive or inconclusive, the sample shall be subjected to an examination by one of the confirmatory examinations referred to in points (i) to (iv) of the first subparagraph. In case the histopathological examination is used for that purpose but proves to be inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

If the result of one of the confirmatory examinations referred to in point (i) to (iv) of the first subparagraph is positive, the animals shall be regarded positive TSE cases and further examination as referred to in point (c) shall be performed.;

(c) in point 3.2, the heading of point (c) is replaced by the following:
(c)Further examination of positive TSE cases;

. . . . . .

(d) in point 3.2, point (c)(i) is replaced by the following:

(i) Primary molecular testing with a discriminatory immuno-blotting

Samples from clinical suspect cases and from animals tested in accordance with Annex III, Chapter A, Part II, points 2 and 3 which are regarded as positive TSE cases but which are not atypical scrapie cases, following the examinations referred to in points (a) or (b), or which display characteristics which are deemed by the testing laboratory to merit investigation, shall be forwarded for further examination by a primary molecular typing method to:

— Agence Française de Sécurité Sanitaire des Aliments, Laboratoire de pathologie bovine, 31 avenue Tony Garnier, BP 7033, F-69342, Lyon Cedex, France,

— Veterinary Laboratories Agency, Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB, United Kingdom, or

— to a laboratory, appointed by the competent authority, which has participated successfully in proficiency testing organised by the Community reference laboratory for the use of a molecular typing method.;

(e) in point 3.2(c)(ii), the word ‘scrapie’ is replaced by ‘TSE’;

(f) 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:

— 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 with the TeSeE SAP Detection kit carried out following denaturation and concentration steps with the TeSeE Purification kit (Bio-Rad TeSeE 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),

— 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), 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 with the TeSeE SAP Detection kit carried out following denaturation and concentration steps with the TeSeE Purification kit (Bio-Rad TeSeE 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 chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer TSE Kit version 2.0),

— the microplate-based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),

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

— the microplate-based chemiluminescent immunoassay for the detection of Proteinase K-resistant PrP^{Sc} (Prionics Check LIA Small Ruminants).

In all 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 Community reference laboratory and ensures that the test performance does not change. Producers must provide the Community reference laboratory with the test protocols.

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 162/2009.