[F1 ANNEX I

SPECIFIC DEFINITIONS

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

[F2 1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council[(1)], Commission Regulation (EU) No 142/2011[(2)], Regulation (EC) No 178/2002 of the European Parliament and of the Council[(3)], Regulation (EC) No 767/2009 of the European Parliament and of the Council[(4)] and Council Directive 2006/88/EC[(5)] shall apply:

(a) the definition of 'farmed animal' in Article 3(6) of Regulation (EC) No 1069/2009;

(b) the following definitions in Annex I to Regulation (EU) No 142/2011:

- (i) 'fur animals' in point 1;
- (ii) 'blood products' in point 4;
- (iii) 'processed animal protein' in point 5;
- (iv) 'fishmeal' in point 7;
- (v) 'collagen' in point 11;
- (vi) 'gelatine' in point 12;
- (vii) 'hydrolysed proteins' in point 14;
- (viii) 'canned petfood' in point 16;
- (ix) 'petfood' in point 19;
- (x) 'processed petfood' in point 20;

(c) the definition of 'feed' in Article 3(4) of Regulation (EC) No 178/2002;

(d) Regulation (EC) No 767/2009:

- (i) 'feed materials' in Article 3(2)(g);
- (ii) 'compound feed' in Article 3(2)(h);
- (iii) 'complete feed' in Article 3(2)(i);

(e) Directive 2006/88/EC:

- (i) 'aquaculture animal' in Article 3(1)(b);
- (ii) 'aquatic animal' in Article 3(1)(e).]

Textual Amendments

F2 Substituted by Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F3 2. For the purpose of this Regulation, the following definitions shall also apply:

(a) 'BSE indigenous case' means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;

(b) 'cohort' means a group of bovine animals which includes both:

(i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and

(ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;

(c) 'index case' means the first animal on a holding, or in an epidemiologically defined group, in which a TSE infection is confirmed;

(d) 'TSE in small ruminants' means a transmissible spongiform encephalopathy case detected in an ovine or caprine animal following a confirmatory test for abnormal PrP protein;

(e) 'scrapie case' means a transmissible spongiform encephalopathy confirmed case in an ovine or caprine animal where a diagnosis of BSE has been excluded in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants[6];

(f) 'classical scrapie case' means a scrapie confirmed case classified as classical in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(g) 'atypical scrapie case' means a scrapie confirmed case which is distinguishable from classical scrapie in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(h) 'Prion protein genotype' in ovine animals means a combination of two alleles as described in point 1 of Annex I to Commission Decision 2002/1003/EC[7];

(i) 'BSE case' means a case of BSE confirmed in a national reference laboratory according to the methods and protocols in point 3.1.(a) and (b) of Chapter C of Annex X;

(j) 'classical BSE case' means a BSE case classified as such in accordance with the criteria laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates[8];

(k) 'atypical BSE case' means a BSE case which cannot be classified as a classical BSE case in accordance with the criteria laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates;

(l) 'ovine and caprine animals over 18 months of age' means ovine and caprine animals:

(i) whose age is confirmed by the registers or movement documents referred to in point 1(b), (c) and (d) of Article 3 of Council Regulation (EC) No 21/2004[9], or

(ii) which have more than two permanent incisors erupted through the gum.**]]**

Textual Amendments

F3 Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F4ANNEX II

DETERMINATION OF BSE STATUS

Textual Amendments

F4 Substituted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

CHAPTER A

Criteria

The BSE status of Member States or third countries or regions thereof (hereinafter referred to as countries or regions), shall be determined on the basis of the criteria set out in points (a) to (e).

In the country or region:

(a) a risk analysis in accordance with the provisions of Chapter B, identifying all the potential factors for BSE occurrence and their historic perspective in the country or region, is carried out;

(b) a system of continuous surveillance and monitoring of BSE relating in particular to the risks described in Chapter B and complying with the minimal surveillance requirements laid down in Chapter D is in place;

(c) an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of bovine animals, to encourage reporting

of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Chapter D of this Annex is in place;

(d) an obligation to notify and investigate all bovine animals showing clinical signs consistent with BSE is in force;

(e) the examination of brain or other tissues collected within the framework of the surveillance and monitoring system referred to in point (b) is carried out in an approved laboratory.

CHAPTER B

Risk analysis

[F5 1. Structure of the risk analysis

The risk analyses shall comprise an entry assessment and an exposure assessment.

Textual Amendments

F5 Substituted by Commission Regulation (EU) No 1148/2014 of 28 October 2014 amending Annexes II, VII, VIII, IX and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

2. Entry assessment (external challenge)

2.1. The entry assessment shall consist of assessing the likelihood that the BSE agent has either been introduced into the country or region via commodities potentially contaminated with a BSE agent, or is already present in the country or region.

The following risk factors shall be taken into account:

(a) the presence or absence of the BSE agent in the country or region and, if the agent is present, its prevalence based on the outcome of surveillance activities;

(b) the production of meat-and-bone meal or greaves from the BSE indigenous ruminant population;

(c) imported meat-and-bone meal or greaves;

(d) imported bovine and ovine and caprine animals;

(e) imported animal feed and feed ingredients;

(f) imported products of ruminant origin for human consumption, which may have contained tissues listed in point 1 of Annex V and may have been fed to bovine animals;

(g) imported products of ruminant origin for *in vivo* use in bovine animals.

2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the bovine animals population) relevant to the risk factors listed in point 2.1 should be taken into ac-count in carrying out the entry assessment.]

3. Exposure assessment

The exposure assessment shall consist of assessing the likelihood of exposure of bovine animals to the BSE agent, through a consideration of the following:

(a) recycling and amplification of the BSE agent through consumption by bovine animals of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;

(b) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

(c) the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;

(d) the level of surveillance for BSE conducted on the bovine animals population to that time and the results of that surveillance.

CHAPTER C

Definition of categories

I. COUNTRY OR REGION WITH A NEGLIGIBLE BSE RISK

A country or region:

(1) where a risk analysis in accordance with Chapter B has been conducted in order to identify the historical and existing risk factors;

(2) which has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

(3) which has demonstrated that Type B surveillance, in accordance with Chapter D, is in place, and the relevant points target, in accordance with Table 2 thereof, has been met; and

(4) which is:

  (a) either in the following situation:

    (i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed;

    (ii) the criteria in points (c), (d) and (e) of Chapter A of this Annex have been complied with for at least seven years; and

    (iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

  (b) or in the following situation:

    (i) there has been one or more BSE indigenous cases in the country or region but every BSE indigenous case was born more than 11 years ago;

(ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for at least seven years;

(iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed:

— all BSE cases,

— all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

— if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

II. COUNTRY OR REGION WITH A CONTROLLED BSE RISK

A country or region

(1) where a risk analysis based on the information laid down in Chapter B has been conducted in order to identify the historical and existing risk factors;

(2) which has demonstrated that appropriate measures are been taken to manage all identified risks, but those measures have not been taken for the relevant period of time;

(3) which has demonstrated that Type A surveillance, in accordance with Chapter D, is in place and the relevant points target, in accordance with Table 2, has been met. Type B surveillance may replace Type A surveillance once the relevant points target is met; and

(4) which is:

(a) either in the following situation:

(i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for a period shorter than seven years; and/or

(iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for eight years;

(b) or in the following situation:

(i) in the country or region there has been a BSE indigenous case, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(ii) the criteria in points (c) to (e) of Chapter A of this Annex have been complied with for a period shorter than seven years; and/or

(iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for at least eight years;

(iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed: and

— all BSE cases, and

— all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

— if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

III. COUNTRY OR REGION WITH UNDETERMINED BSE RISK

A country or region for which the determination of BSE status has not been concluded, or which does not meet the conditions to be fulfilled by the country or region to be classified in one of the other categories.

CHAPTER D

Minimal surveillance requirements

1. Surveillance types

For the purpose of this Annex, the following definitions shall apply:

(a) *Type A surveillance*

The application of Type A surveillance will allow the detection of BSE at a design prevalence[10] of at least one case per 100 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %;

(b) *Type B surveillance*

The application of Type B surveillance will allow the detection of BSE at a design prevalence of at least one case per 50 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %.

Type B surveillance may be carried out by countries or region of negligible BSE risk status to confirm the conclusions of the risk analysis, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through

surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries or regions of controlled BSE risk status, following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

For the purpose of this Annex, the following four sub-populations of bovine animals have been identified for surveillance purposes:

(a) bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

(b) bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter);

(c) bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock);

(d) bovine animals over 36 months of age at routine slaughter.

2. Surveillance strategy

2.1. The surveillance strategy shall be designed to ensure that samples are representative of the herd of the country or region, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made shall be fully documented, and the documentation retained for seven years.

2.2. In order to implement the surveillance strategy for BSE, a country shall use documented records or reliable estimates of the age distribution of the adult bovine animals population and the number of bovine animals tested for BSE stratified by age and by sub-population within the country or region.

3. Points values and point targets

Surveillance samples must meet the point targets set out in Table 2, on the basis of ‘point values’ fixed in Table 1. All clinical suspects shall be investigated, regardless of the number of points accumulated. A country shall sample at least three out of the four sub-populations. The total points for samples collected shall be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points. The total points accumulation shall be periodically compared to the target number of points for a country or region.

TABLE 1

Surveillance point values for samples collected from animals in the given sub-population and age category

Surveillance sub-population			
Routine slaughter[a]	**Fallen stock[b]**	**Casualty slaughter[c]**	**Clinical suspect[d]**
Age ≥ 1 year and < 2 years			
0,01	0,2	0,4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0,1	0,2	0,4	260
Age ≥ 4 years and < 7 years (middle adult)			
0,2	0,9	1,6	750
Age ≥ 7 years and < 9 years (older adult)			
0,1	0,4	0,7	220
Age ≥ 9 years (aged)			
0,0	0,1	0,2	45

a Bovine animals over 36 months of age at routine slaughter.

b Bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock).

c Bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter).

d Bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects).

I[F5]TABLE 2

Points targets for different adult bovine animals population sizes in a country or region

Points targets for country or region		
Adult bovine animals population size(24 months and older)	**Type A surveillance**	**Type B surveillance**
> 1 000 000	300 000	150 000
900 0011 000 000	214 600	107 300
800 001900 000	190 700	95 350
700 001800 000	166 900	83 450
600 001700 000	143 000	71 500
500 001600 000	119 200	59 600
400 001500 000	95 400	47 700
300 001400 000	71 500	35 750
200 001300 000	47 700	23 850
100 001200 000	22 100	11 500
90 001100 000	19 900	9 950
80 00190 000	17 700	8 850

70 00180 000	15 500	7 750
60 00170 000	13 000	6 650
50 00160 000	11 000	5 500
40 00150 000	8 800	4 400
30 00140 000	6 600	3 300
20 00130 000	4 400	2 200
10 00120 000	2 100	1 050
9 00110 000	1 900	950
8 0019 000	1 600	800
7 0018 000	1 400	700
6 0017 000	1 200	600
5 0016 000	1 000	500
4 0015 000	800	400
3 0014 000	600	300
2 0013 000	400	200
1 0012 000	200	100**]**

4. Specific targeting

Within each of the sub-populations above in a country or region, a country may target bovine animals identifiable as imported from countries or regions where BSE has been detected and bovine animals which have consumed potentially contaminated feedstuffs from countries or regions where BSE has been detected.

5. BSE surveillance model

A country may choose to use the full BSurvE model or an alternative method based on the BSurvE model to estimate its BSE presence/prevalence.

6. Maintenance surveillance

Once the points target has been achieved, and in order to continue to designate the status of a country or region as controlled BSE risk or negligible risk, surveillance can be reduced to Type B surveillance (provided all other indicators remain positive). However, to continue to comply with the requirements laid down in this Chapter, ongoing annual surveillance must continue to include at least three of the four prescribed sub-populations. In addition all bovine animals clinically suspected of being infected with BSE shall be investigated regardless of the number of points accumulated. The annual surveillance in a country or region following the achievement of the required points target, shall be no less than the amount required for one-seventh of its total Type B surveillancetarget.**]**

[F6ANNEX III

MONITORING SYSTEM

Textual Amendments

F6 Substituted by Commission Regulation (EC) No 2245/2003 of 19 December 2003 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals.

CHAPTER A

I. MONITORING IN BOVINE ANIMALS

1. General

Monitoring in bovine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3(1)(b).

[F32. **Monitoring in animals slaughtered for human consumption**

2.1. All bovine animals over 24 months of age shall be tested for BSE where they have undergone:

— emergency slaughter in accordance with point 1 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004[11], or

— an ante mortem inspection with observations concerning accidents, or serious physiological and functional problems, or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004[12].

2.2. All healthy bovine animals over 30 months of age slaughtered normally for human consumption shall be tested for BSE.**]**

3. Monitoring in animals not slaughtered for human consumption

3.1. All bovine animals over 24 months of age which have died or been killed but which were not:

— killed for destruction pursuant to Commission Regulation (EC) No 716/96[13],

— killed in the framework of an epidemic, such as foot-and-mouth disease,

— slaughtered for human consumption,

shall be tested for BSE.

3.2. Member States may decide to derogate from the provisions of point 3.1 in remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this derogation shall inform the Commission thereof, and submit a list of the derogated areas. The derogation shall not cover more than 10 % of the bovine population in the Member State.

[F74. Monitoring in animals purchased for destruction pursuant to Regulation (EC) No 716/96

All animals born between 1 August 1995 and 1 August 1996 killed for destruction pursuant Regulation (EC) No 716/96 shall be tested for BSE.**]**

Textual Amendments

F7 Substituted by Commission Regulation (EC) No 657/2006 of 10 April 2006 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the United Kingdom and repealing Council Decision 98/256/EC and Decisions 98/351/EC and 1999/514/EC (Text with EEA relevance).

5. Monitoring in other animals

In addition to the testing referred to in points 2 to 4, Member States may on a voluntary basis decide to test other bovine animals on their territory, in particular where those animals originate from countries with indigenous BSE, have consumed potentially contaminated feedingstuffs or were born or derived from BSE infected dams.

6. Measures following testing

6.1. Where an animal slaughtered for human consumption has been selected for testing for BSE, the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC shall not be carried out on the carcase of that animal until a negative result to the rapid test has been obtained.

6.2. Member States may derogate from the provisions of point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.

[F8 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.

Textual Amendments

F8 Substituted by Commission Regulation (EC) No 162/2009 of 26 February 2009 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

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).]

[F9 6.5. Where an animal slaughtered for human consumption is found positive or inconclusive to the rapid test, at least the carcase immediately preceding and the two carcases immediately following the tested positive or inconclusive animal on the same slaughter line shall be destroyed in accordance with point 6.4. By way of derogation, Member States may decide to destroy the aforementioned carcases only if the result of the rapid test is confirmed to be positive or inconclusive by confirmatory examinations referred to in Annex X, Chapter C, point 3.1(b).]

Textual Amendments

F9 Substituted by Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

6.6. Member States may derogate from the provisions of point 6.5 where a system is in place in the slaughterhouse preventing contamination between carcase.

[F10 7. Revision of the annual monitoring programmes concerning BSE (BSE monitoring programmes), as provided for in Article 6(1b)

7.1. Member States' applications

Applications submitted to the Commission by Member States for revision of their annual BSE monitoring programme shall include at least the following:

(a) information on the annual BSE monitoring system in place during the previous six-year period within the territory of the Member State, including detailed documentation proving compliance with the epidemiological criteria set out in point 7.2;

(b) information on the bovine identification and traceability system, as referred to in point (b) of the third subparagraph of Article 6(1b), in place during the previous six-year period within the territory of the Member State, including a detailed description of the functioning of the computerised database as referred to in Article 5 of Regulation (EC) No 1760/2000 of the European Parliament and of the Council[14]

(c) information on prohibitions concerning animal feeding during the previous six-year period within the territory of the Member State, including a detailed description of the enforcement of the feed ban for farmed animals, as referred to in point (c) of the third subparagraph of Article 6(1b), including the sampling plan and the number and type of infringements found and the follow-up results;

(d) a detailed description of the proposed revised BSE monitoring programme that includes the geographical area in which the programme is to be implemented and a description of subpopulations of bovine animals to be covered by the BSE revised monitoring programme, including indications of the age limits and the sample sizes for testing;

(e) the result of a comprehensive risk analysis showing that the revised BSE monitoring programme will ensure the protection of human and animal health. This risk analysis shall include a birth cohort analysis or other relevant studies aiming to demonstrate that the TSE risk reducing measures, including the feeding prohibitions as referred to in point (c) of the third subparagraph of Article 6(1b), have been implemented in an efficient way.

7.2. Epidemiological criteria

Applications for revision of a BSE monitoring programme may only be accepted if the Member State concerned can demonstrate that, in addition to the requirements laid down in points (a), (b) and (c) of the third subparagraph of Article 6(1b), the following epidemiological criteria are met within its territory:

(a) for a period of at least six consecutive years following the date of implementation of the Community BSE testing scheme as referred to in point (b) of the third subparagraph of Article 6(1b):

either

(i) the average decrease of the annual BSE incidence rate observed within the adult bovine animal population (over 24 months of age) was superior to 20 %, and the total number of BSE affected cattle born after the implementation of the Community total feed ban for farmed animals, as referred to in point (c) of the third subparagraph of Article 6(1b), did not exceed 5 % of the total number of confirmed BSE cases;

or

(ii) the annual observed BSE incidence rate within the adult bovine animal population (over 24 months of age) remained consistently less than 1/100 000;

or

(iii) as a further option for a Member State with an adult bovine animal population (over 24 months of age) of less than 1 000 000 animals, the cumulated number of confirmed BSE cases remained under five;

(b) following the six-year period referred to in point (a), there is no evidence that the BSE epidemiological situation is deteriorating.**]**

Textual Amendments

F10 Inserted by Commission Regulation (EC) No 571/2008 of 19 June 2008 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the criteria for revision of the annual monitoring programmes concerning BSE (Text with EEA relevance).

[F11[F9II. MONITORING IN OVINE AND CAPRINE ANIMALS

1. General

Monitoring in ovine and caprine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b).

[F32. **Monitoring in ovine and caprine animals slaughtered for human consumption**

(a) Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 ovine animals slaughtered for human consumption;

(b) Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;

(c) A Member State may choose to replace a maximum of:

— 50 % of its minimum sample size of ovine and caprine animals slaughtered for human consumption set out in points (a) and (b) by testing dead ovine or caprine animals over

the age of 18 months at the ratio of one to one and in addition to the minimum sample size set out in point 3;

— 10 % of its minimum sample size set out in points (a) and (b) by testing ovine or caprine animals killed in the framework of a disease eradication campaign over the age of 18 months at the ratio of one to one.**]**

3. Monitoring in ovine and caprine animals not slaughtered for human consumption

Member States shall test, in accordance with the sampling rules set out in point 4 and the minimum sample sizes indicated in Table A and Table B, ovine and caprine animals which have died or been killed, but which were not:

— killed in the framework of a disease eradication campaign, or

— slaughtered for human consumption.

TABLE A

Member State population of ewes and ewe lambs put to the ram	**Minimum sample size of dead ovine animals**[a]
> 750 000	10 000
100 000750 000	1 500
40 000100 000	100 % up to 500
< 40 000	100 % up to 100

a Minimum sample sizes are set to take account of the size of the ovine populations in the individual Member States and are intended to provide achievable targets.

TABLE B

Member State population of goats which have already kidded and goats mated	**Minimum sample size of dead caprine animals**[a]
> 750 000	10 000
250 000750 000	1 500
40 000250 000	100 % up to 500
< 40 000	100 % up to 100

a Minimum sample sizes are set to take account of the size of the caprine population in the individual Member States and are intended to provide achievable targets.

4. Sampling rules applicable to the animals referred to in points 2 and 3

The animals shall be over 18 months of age or have more than two permanent incisors erupted through the gum.

The age of the animals shall be estimated on the basis of dentition, obvious signs of maturity, or any other reliable information.

The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, age, breed, production type or any other characteristic.

The sampling shall be representative for each region and season. Multiple sampling in the same flock shall be avoided, wherever possible. Member States shall aim their monitoring

programmes to achieve, wherever possible, that in successive sampling years all officially registered holdings with more than 100 animals and where TSE cases have never been detected are subject to TSE testing.

The Member States shall put in place a system to check, on a targeted or other basis, that animals are not being diverted from sampling.

However, Member States may decide to exclude from the sampling remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this derogation shall inform the Commission thereof, and shall submit a list of those remote areas where the derogation applies. The derogation shall not cover more than 10 % of the ovine and caprine population in the Member State concerned.

[F3 5. Monitoring in holdings under TSE control and eradication measures

Animals over 18 months of age which are killed for destruction in accordance with Annex VII, Chapter B, Part 2, point 2.2.1. and point 2.2.2.(b) or (c), shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.(b), based on the selection of a simple random sample, in accordance with the sample size set out in the following table.

Number of animals over 18 months of age killed for destruction in the herd or flock	**Minimum sample size**
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97
180	101
200	105
250	112
300	117
350	121
400	124
450	127
500 or more	150**]**

6. Monitoring in other animals

In addition to the monitoring programmes set out in points 2, 3 and 4, Member States may on a voluntary basis carry out monitoring in other animals, in particular:

— animals used for dairy production,

— animals originating from countries with indigenous TSEs,
— animals which have consumed potentially contaminated feedingstuffs,
— animals born or derived from TSE infected dams.

7. Measures following testing of ovine and caprine animals

7.1. Where an ovine or caprine animal slaughtered for human consumption has been selected for TSE testing in accordance with point 2, its carcase shall not be marked with the health marking provided for in Section I, Chapter III of Annex I to Regulation (EC) No 854/2004 until a negative result to the rapid test has been obtained.

7.2. Member States may derogate from point 7.1. where a system approved by the competent authority is in place in the slaughterhouse ensuring that all parts of an animal can be traced and that no parts of the animals tested bearing the health mark can leave the slaughterhouse until a negative result to the rapid test has been obtained.

7.3. All parts of the body of a tested animal, including the hide, shall be retained under official control until a negative result has been obtained to the rapid test, except for animal by-products directly disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

7.4. Except for the material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, all parts of the body of an animal found positive to the rapid test, including the hide, shall be directly disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

8. Genotyping

8.1. The prion protein genotype for the codons 136, 154 and 171 shall be determined for each positive TSE case in sheep. TSE cases found in sheep of genotypes which encode alanine on both alleles at codon 136, arginine on both alleles at codon 154 and arginine on both alleles at codon 171 shall immediately be reported to the Commission. Where the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall be determined.

8.2. In addition to the animals genotyped in accordance with point 8.1, the prion protein genotype for the codons 136, 141, 154 and 171 of a minimum sample of ovine animals shall be determined. In the case of Member States with an adult sheep population of more than 750 000 animals, this minimum sample shall consist of at least 600 animals. In the case of other Member States the minimum sample shall consist of at least 100 animals. The samples may be chosen from animals slaughtered for human consumption, from animals dead-on-farm or from live animals. The sampling should be representative of the entire ovine population.**]**

Textual Amendments

F11 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 epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (Text with EEA relevance).

III. MONITORING IN OTHER ANIMAL SPECIES

Member States may on a voluntary basis carry out monitoring for TSEs in animal species other than bovine, ovine and caprine animals.**]**

[F11CHAPTER B

REPORTING AND RECORDING REQUIREMENTS

I. REQUIREMENTS ON MEMBER STATES

A. Information to be presented by Member States in their annual report as provided for in Article 6(4)

1. The number of suspected cases placed under official movement restrictions in accordance with Article 12(1), per animal species.

2. The number of suspected cases subject to laboratory examination in accordance with Article 12(2), per animal species, including the results of the rapid and confirmatory tests (number of positives and negatives) and, with regard to bovine animals, an estimation of the age distribution of all tested animals. The age distribution should be grouped whenever possible as follows: 'below 24 months', distribution per 12 months between 24 and 155 months, and 'above 155 months' of age.

3. The number of flocks where suspected cases in ovine and caprine animals have been reported and investigated pursuant to Article 12(1) and (2).

4. The number of bovine animals tested within each subpopulation referred to in Chapter A, Part (I), points 2.1., 2.2., 2.3., 3.1., 4.1., 4.2., 4.3. and 5. The method for the sample selection, the results of the rapid and confirmatory tests and an estimation of the age distribution of the tested animals grouped as set out in point 2 shall be provided.

5. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Part II, points 2, 3 and 5 together with the method for sample selection and the results of the rapid and confirmatory tests.

6. The geographical distribution, including the country of origin if not the same as the reporting country, of positive cases of BSE and scrapie. The year, and where possible the month of birth shall be given for each TSE case in bovine, ovine and caprine animals. TSE cases which have been considered atypical and the reasons why shall be indicated. For scrapie cases, the results of the primary molecular testing with a discriminatory immuno-blotting, referred to in Annex X, Chapter C, point 3.2.(c)(i), shall be reported.

7. In animals other than bovine, ovine and caprine, the number of samples and confirmed TSE cases per species.

8. The genotype, and where possible the breed, of each ovine animal either found positive to TSE or sampled in accordance with Chapter A, Part II, points 8.1. and 8.2.

B. Reporting periods

The compilation of reports containing the information referred to in A and forwarded to the Commission on a monthly basis or, with regard to the information referred to in point 8 on a quarterly basis, may constitute the annual report as required by Article 6(4), provided that the information is updated whenever additional information becomes available.**]**

II. INFORMATION TO BE PRESENTED BY THE COMMISSION IN ITS SUMMARY

The summary shall be presented in a tabled format covering at least the information referred to in part I for each Member State.

III. RECORDS

1. The competent authority shall keep, for seven years, records of:

— the number and types of animals placed under movement restrictions as referred to in Article 12(1),

— the number and outcome of clinical and epidemiological investigations as referred to in Article 12(1),

— the number and outcome of laboratory examinations as referred to in Article 12(2),

— the number, identity and origin of animals sampled in the framework of the monitoring programmes as referred to in Chapter A and, where possible, age, breed and anamnestic information,

— the prion protein genotype of positive TSE cases in sheep.

2. The investigating laboratory shall keep, for seven years, all records of testing, in particular laboratory workbooks and, where appropriate, paraffin blocks and photographs of western blots.**]**

[[F2]ANNEX IV

ANIMAL FEEDING

CHAPTER I

Extensions of the prohibition provided for in Article 7(1)

In accordance with Article 7(2), the prohibition provided for in Article 7(1) shall be extended to the feeding:

(a) to ruminants of dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing these products;

(b) to non-ruminant farmed animals, other than fur animals, of:

(i) processed animal protein;

(ii) collagen and gelatine of ruminant origin;

(iii) blood products;

(iv) hydrolysed protein of animal origin;

(v) dicalcium phosphate and tricalcium phosphate of animal origin;

(vi) feed containing the products listed in (i) to (v).

CHAPTER II

Derogations from the prohibitions provided for in Article 7(1) and in Chapter I

In accordance with the first subparagraph of Article 7(3), the prohibitions provided for in Article 7(1) and in Chapter I shall not apply to the feeding to:

(a) ruminants of:

(i) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(ii) eggs and egg products;

(iii) collagen and gelatine derived from non-ruminants;

(iv) hydrolysed proteins derived from:
— parts of non-ruminants, or
— ruminant hides and skins;

(v) compound feed containing the products listed in points (i) to (iv) above;

(b) non-ruminant farmed animals of the following feed materials and compound feed:

(i) hydrolysed proteins derived from parts of non-ruminants or from ruminant hides and skins;

(ii) fishmeal and compound feed containing fishmeal which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section A of Chapter IV;

(iii) dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing such phosphates which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section B of Chapter IV;

(iv) blood products derived from non-ruminants and compound feed containing such blood products which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section C of Chapter IV;

(c) aquaculture animals of processed animal protein, other than fishmeal, derived from non-ruminants and compound feed containing such processed animal protein which are produced, placed on the market and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Section D of Chapter IV;

(d) unweaned ruminants of milk replacers containing fishmeal and which are produced, placed on the market and used in accordance with specific conditions laid down in Section E of Chapter IV;

(e) farmed animals of feed materials of plant origin and compound feed containing such feed materials contaminated with insignificant amount of bone spicules derived from unauthorised animal species. Member States may only use this derogation if they have carried out a risk assessment beforehand which has confirmed there is a negligible risk for animal health. That risk assessment must take into account at least the following:

(i) the level of the contamination;

(ii) the nature and the source of the contamination;

(iii) the intended use of the contaminated feed.

CHAPTER III

General conditions for the application of certain derogations provided for in Chapter II

SECTION A

Transport of feed materials and compound feed intended to be used for feeding non-ruminant farmed animals

1. The following products intended to be used for feeding non-ruminant farmed animals, shall be transported in vehicles and containers which are not used for the transport of feed intended for ruminants:

(a) bulk processed animal protein, including fishmeal, derived from non-ruminants;

(b) bulk dicalcium and tricalcium phosphate of animal origin;

(c) bulk blood products derived from non-ruminants;

(d) bulk compound feed containing the feed materials listed in (a), (b) and (c).

Records detailing the type of products that were transported shall be kept available to the competent authority for a period of at least two years.

2. By way of derogation from point 1, vehicles and containers which have been previously used for the transport of the products listed in that point, may be subsequently used for the transport of feed intended for ruminants provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

3. Bulk processed animal protein derived from non-ruminants and bulk compound feed containing processed animal protein derived from such animals shall be transported in vehicles and containers which are not used for the transport of feed intended for non-ruminant farmed animals other than aquaculture animals.

4. By way of derogation from point 3, vehicles and containers which have been previously used for the transport of the products referred to in that point may be subsequently used for the transport of feed intended for non-ruminant farmed animals other than aquaculture animals provided that they are cleaned beforehand in order to avoid cross-contamination, in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

SECTION B

Production of compound feed intended to be used for feeding non-ruminant farmed animals

1. Compound feed intended to be used for feeding non-ruminant farmed animals and which contain the following feed materials, shall be produced in establishments which do not produce compound feed for ruminants, and which are authorised by the competent authority:

(a) fishmeal;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) blood products derived from non-ruminants.

2. By way of derogation from point 1, the production of compound feed for ruminants, in establishments which also produce compound feed for non-ruminant farmed animals which contains the products listed in that point, may be authorised by the competent authority, following an on-site inspection by it, subject to compliance with the following conditions:

(a) compound feed intended for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminants are manufactured and kept;

(b) records detailing the purchases and uses of the products listed in point 1 and the sales of compound feed containing those products must be kept available to the competent authority for a period of at least five years;

(c) regular sampling and analysis of the compound feed intended for ruminants must be carried out in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Commission Regulation (EC) No 152/2009[(15)]; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

3. By way of derogation from point 1, a specific authorisation for the production of complete feed from compound feed containing the products listed in that point shall not be required for home compounders subject to their compliance with the following conditions:

(a) they must be registered by the competent authority;

(b) they must keep only non-ruminant animals;

(c) they must produce complete feed for use only in the same holding;

(d) any compound feed containing fishmeal used in the production of the complete feed must contain less than 50 % crude protein;

(e) any compound feed containing dicalcium and tricalcium phosphate of animal origin used in the production of the complete feed must contain less than 10 % total phosphorus;

(f) any compound feed containing blood products derived from non- ruminants used in the production of the complete feed must contain less than 50 % total protein.

SECTION C

Import of feed materials and compound feed intended to be used for feeding non-ruminant farmed animals other than fur animals

Before release for free circulation in the Union, importers shall ensure that each of the consignment of the following feed materials and compound feed, which are intended to be used for the feeding of non-ruminant farmed animals, other than fur animals, in accordance with Chapter II of this Annex, is analysed in accordance with the methods of analysis for the determination of constituents of animal origin for the control of feed set out Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of unauthorised constituents of animal origin:

(a) processed animal protein, including fishmeal, derived from non-ruminants;

(b) blood products derived from non-ruminants;

(c) compound feed containing the feed materials listed in (a) and (b).

SECTION D

Use and storage on farms of feed intended to be used for feeding non-ruminant farmed animals

1. The use and storage of the following feed shall be prohibited on farms keeping farmed animal species for which such feed is not intended:

(a) processed animal protein, including fishmeal, derived from non-ruminants;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) blood products derived from non-ruminants;

(d) compound feed containing the feed materials listed in (a) to (c).

2. By way of derogation from point 1, the competent authority may authorise the use and storage of compound feed referred to in point 1(d) in farms keeping farmed animal species for which the compound feed is not intended provided that on-farm measures are implemented to prevent such compound feed being fed to an animal species for which it is not intended.

CHAPTER IV

Specific conditions for the application of derogations provided for in Chapter II

SECTION A

Specific conditions applicable to the production and the use of fishmeal and compound feed containing fishmeal intended to be used for feeding non-ruminant farmed animals other than fur animals

The following specific conditions shall apply to the production and use of fishmeal and compound feed containing fishmeal intended to be used for the feeding of non-ruminant farmed animals other than fur animals:

(a) the fishmeal must be produced in processing plants dedicated exclusively to the production of products derived from aquatic animals, except sea mammals;

(b) the accompanying commercial document or health certificate, as appropriate, of fishmeal and compound feed containing fishmeal and any packaging containing such products must be clearly marked with the words ‘contains fishmeal — shall not be fed to ruminants’.

SECTION B

Specific conditions applicable to the use of dicalcium phosphate and tricalcium phosphate of animal origin and compound feed containing such phosphates intended to be used for feeding non-ruminant farmed animals other than fur animals

The accompanying commercial document or health certificate, as appropriate, of dicalcium phosphate or tricalcium phosphate of animal origin, compound feed containing such phosphates and any packaging of such products shall be clearly marked with the words ‘contains dicalcium/tricalcium phosphate of animal origin — shall not be fed to ruminants’.

SECTION C

Specific conditions applicable to the production and use of blood products derived from non-ruminants and compound feed containing those products intended to be used for feeding non-ruminant farmed animals other than fur animals

The following specific conditions shall apply to the production and use of blood products derived from non-ruminants and to compound feed containing such blood products, intended to be used for the feeding of non-ruminant farmed animals other than fur animals:

(a) The blood intended to be used for the production of blood products shall be derived from slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants.

By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing non-ruminant blood intended for the production of blood products for use in feed for non-ruminant farmed animals.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination between ruminant and non-ruminant blood.

Those measures shall include the following minimum requirements:

(i) the slaughtering of non-ruminants must be carried out in lines that are physically separate from lines used for the slaughtering of ruminants;

(ii) the collection, storage, transport and packaging facilities for blood of non-ruminant origin must be kept separate from those used for blood of ruminant origin;

(iii) a regular sampling and analysis of blood of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis must be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.

(b) The blood intended to be used for the production of blood products for non-ruminants shall be transported to a processing plant in vehicles and containers dedicated exclusively for the transport of non-ruminant blood.

By way of derogation from that specific condition, vehicles and containers which have been previously used for the transport of blood derived from ruminants may be used for the transport of non-ruminant blood provided that they have been thoroughly cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

(c) The blood products shall be produced in processing plants exclusively processing non-ruminant blood.

By way of derogation from that specific condition, the competent authority may authorise the production of blood products for use in feed for non-ruminant farmed animals in processing plants processing ruminant blood.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination.

Those measures shall include the following minimum requirements:

(i) the production of non-ruminant blood products must be carried out in a closed system that is kept physically separated from that used for the production of ruminant blood products;

(ii) the collection, storage, transport and packaging facilities for bulk raw material and bulk finished products of non-ruminant origin must be kept separate from those for bulk raw material and bulk finished of ruminant origin;

(iii) an ongoing reconciliation process between the incoming blood respectively derived from ruminants and non-ruminants and the corresponding blood products must be applied;

(iv) a regular sampling and analysis of blood products of non ruminant origin must be carried out to verify the absence of cross-contamination with blood products of ruminant origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

(d) The accompanying commercial document or health certificate, as appropriate, of the blood products, compound feed containing blood products and any packaging of these products must be clearly marked with the words ‘contains blood products — shall not be fed to ruminants’.

SECTION D

Specific conditions applicable to the production and use of processed animal protein, other than fishmeal, derived from non-ruminants and compound feed containing such processed animal protein intended to be used for feeding aquaculture animals

The following specific conditions shall apply to the production and use of processed animal protein, other than fishmeal, derived from non-ruminants and compound feed containing such protein intended to be used for feeding aquaculture animals:

(a) The animal by-products intended to be used for the production of processed animal protein referred to in this Section shall be derived either from slaughterhouses which do not slaughter ruminants and which are registered by the competent authority as not slaughtering ruminants or from cutting plants which do not bone or cut up ruminant meat.

By way of derogation from that specific condition, the competent authority may authorise the slaughter of ruminants in a slaughterhouse producing non-ruminant animal by-products intended for the production of processed animal protein referred to in this Section.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of measures aimed to prevent cross-contamination between ruminant and non-ruminant by-products.

Those measures shall include the following minimum requirements:

(i) the slaughtering of non-ruminants must be carried out in lines that are physically separate from those used for the slaughtering of ruminants;

(ii) the collection, storage, transport and packaging facilities for animal by-products of non-ruminant origin must be kept separate from those for animal by-products of ruminant origin;

(iii) a regular sampling and analysis of animal by-products of non-ruminant origin must be carried out to detect the presence of ruminant proteins. The method of analysis used must be scientifically validated for that purpose. The frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles.

(b) The animal by-products of non-ruminant origin intended to be used for the production of processed animal protein referred to in this Section shall be transported to a processing plant in vehicles and containers which are not used for the transport of animal by-products of ruminant origin.

By way of derogation from that specific condition, they may be transported in vehicles and containers which have been previously used for the transport of animal by-products derived from ruminants, provided that those vehicles and containers have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

(c) The processed animal protein referred to in this Section shall be produced in processing plants that are dedicated exclusively to processing non-ruminant animal by-products sourced from slaughterhouses and cutting plants referred to in point (a).

By way of derogation from that specific condition, the competent authority may authorise the production of processed animal protein referred to in this Section in processing plants processing ruminant animal by-products.

That authorisation may be granted only where the competent authority is satisfied, following an inspection, concerning the effectiveness of the measures aimed to prevent cross-contamination between processed animal protein of ruminant origin and processed animal protein of non-ruminant origin.

Those preventive measures shall include the following minimum requirements:

(i) the production of processed animal protein derived from ruminants must be carried out in a closed system that is physically separated from that used for the production of the processed animal protein referred to in this Section;

(ii) the keeping of animal by-products derived from ruminants during storage and transport in facilities that are physically separated from those for animal by-products derived from non-ruminants;

(iii) the keeping of processed animal protein derived from ruminants during storage and packaging in facilities that are physically separated from those used for finished products derived from non-ruminants;

(iv) regular sampling and analysis of the processed animal protein referred to in this Section must be carried out to verify the absence of cross-contamination with ruminant processed animal protein using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on hazard analysis and

critical control points (HACCP) principles; the results of such sampling and analysis shall be kept available to the competent authority for a period of at least five years.

(d) Compound feed containing processed animal protein referred to in this Section shall be produced in establishments authorised for that purpose by the competent authority and which are dedicated exclusively to the production of feed for aquaculture animals.

By way of derogation from that specific condition:

(i) the production of compound feed for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, except fur animals, may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:

— compound feed destined for ruminants must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for non-ruminant animals are manufactured and kept;

— compound feed destined for aquaculture animals must be manufactured and kept, during storage, transport and packaging, in facilities that are physically separate from those facilities where compound feed for other non-ruminant animals are manufactured and kept;

— records detailing the purchases and uses of processed animal protein referred to in this Section and the sales of compound feed containing such protein must be kept available to the competent authority for a period of at least five years;

— regular sampling and analysis of the compound feed destined for farmed animals other than aquaculture animals in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years;

(ii) a specific authorisation for the production of complete feed from compound feed containing processed animal protein referred to in this Section shall not be required for home compounders that comply with the following conditions:

— they are registered by the competent authority,

— they keep only aquaculture animals,

— they produce complete feed for aquaculture animals for use only in the same holding, and

— the compound feed containing processed animal protein referred to in this Section used in their production contains less than 50 % total protein.

(e) The accompanying commercial document or health certificate, as appropriate, of processed animal protein referred to in this Section and any packaging shall be clearly marked with the following words: ‘processed animal protein derived from non

ruminants — shall not be used for the production of feed for farmed animals except aquaculture animals and fur animals'.

The accompanying commercial document or health certificate, as appropriate, of the compound feed for aquaculture animals containing processed animal protein referred to in this Section and any packaging shall be clearly marked the following words: 'contains processed animal protein derived from non ruminants — shall not be fed to farmed animals except aquaculture animals and fur animals'.

SECTION E

Specific conditions applicable to the production, placing on the market and use of milk replacers containing fishmeal for the feeding of unweaned ruminants

The following specific conditions shall apply to the production, placing on the market and use of milk replacers containing fishmeal in the feeding of unweaned farmed animals of the ruminant species:

(a) The fishmeal used in milk replacers shall be produced in processing plants dedicated exclusively to the production of products derived from aquatic animals, except sea mammals, and shall comply with general conditions laid set out in Chapter III.

(b) The use of fishmeal for unweaned farmed animals of the ruminant species shall only be authorised for the production of milk replacers, distributed in dry form and administered after dilution in a given quantity of liquid, intended for the feeding of unweaned ruminants as a supplement to, or substitute for, post-colostral milk before weaning is complete.

(c) Milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be produced in establishments which do not produce other compound feed for ruminants and which are authorised for this purpose by the competent authority.

By way of derogation from that special condition, the production of other compound feed for ruminants in establishments which also produce milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species may be authorised by the competent authority, following an on-site inspection, subject to compliance with the following conditions:

(i) other compound feed destined for ruminants must be kept in facilities that are physically separate from those used for bulk fishmeal and bulk milk replacers containing fishmeal during storage, transport and packaging;

(ii) other compound feed destined for ruminants must be manufactured in facilities that are physically separate from facilities where milk replacers containing fishmeal are manufactured;

(iii) records detailing the purchases and uses of fishmeal and the sales of milk replacers containing fishmeal must be kept available to the competent authority for a period of at least five years;

(iv) regular sampling and analysis of the other compound feed destined for ruminants must be carried out in order to verify the absence of unauthorised constituents of animal origin using the methods of analysis for the determination of constituents of animal origin for the control of feed set

out in Annex VI to Regulation (EC) No 152/2009; the frequency of such sampling and analysis shall be determined on the basis of a risk assessment carried out by the operator as part of its procedures based on the HACCP principles; the results must be kept available to the competent authority for a period of at least five years.

(d) Before release for free circulation in the Union, importers shall ensure that each consignment of imported milk replacers containing fishmeal is analysed in accordance with methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009 in order to verify the absence of unauthorised constituents of animal origin.

(e) The accompanying commercial document or health certificate, as appropriate, of milk replacers containing fishmeal, intended for unweaned farmed animals of the ruminant species, and any packaging containing such milk replacers, must be clearly marked with the words '*contains fishmeal — shall not be fed to ruminants except unweaned ruminants*'.

(f) Bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species shall be transported by means of vehicles and containers which are not used for the transport of other feed intended for ruminants.

By way of derogation from that special condition, vehicles and containers which will be subsequently used for the transport of other bulk feed intended for ruminants may be used for the transport of bulk milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species provided that such vehicles and containers have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority. Whenever such a procedure is used, a documented trace of such use shall be kept available to the competent authority for a period of at least two years.

(g) On farms where ruminants are kept, on-farm measures shall be in place to prevent milk replacers containing fishmeal being fed to other ruminants than unweaned ruminants. The competent authority shall establish a list of farms where milk replacers containing fishmeal are used through a system of prior notification by the farm or another system thereby ensuring compliance with this specific condition.

CHAPTER V

General requirements

SECTION A

Listing

Member States shall keep up-to-date and make publicly available lists of:

(a) slaughterhouses from which blood produced in accordance with point (a) of Section C of Chapter IV can be sourced;

(b) authorised processing plants producing blood products in accordance with point (c) of Section C of Chapter IV;

(c) slaughterhouses and cutting plants from which animal by-products intended to be used for the production of processed animal protein in accordance with point (a) of Section D of Chapter IV can be sourced;

(d) authorised processing plants producing processed animal protein derived from non-ruminants which operate in accordance with point (c) of Section D of Chapter IV;

(e) authorised establishments referred to in Section B of Chapter III, in point (d) of Section D of Chapter IV and in point (c) of Section E of Chapter IV;

(f) home compounders which have been registered and operate in accordance with the conditions laid down in Section B of Chapter III and point (d) of Section D of Chapter IV.

SECTION B

Transport of feed materials and compound feed containing products derived from ruminants

1. Bulk feed materials and bulk compound feed containing products derived from ruminants other than those listed in the following points (a), (b) and (c) shall be transported in vehicles and containers which are not used for the transport of feed intended for farmed animals other than fur animals:

(a) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) hydrolysed proteins derived from ruminant hides and skins.

2. By way of derogation from point 1, vehicles and containers which have been previously used for the transport of bulk feed materials and bulk compound feed listed in that point, may be used for the transport of feedingstuffs intended for farmed animals other than fur animals provided that they have been cleaned beforehand in order to avoid cross-contamination in accordance with a documented procedure which has been given prior authorisation by the competent authority.

Whenever such a procedure is used, a documented trace of this use shall be kept available to the competent authority for a period of at least two years.

SECTION C

Production of compound feed containing products derived from ruminants

Compound feed which contains products derived from ruminants other than those listed in points (a), (b) and (c) shall not be produced in establishments which produce feed for farmed animals other than fur animals:

(a) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) hydrolysed proteins derived from ruminant hides and skins.

SECTION D

Use and storage on farms of feed materials and compound feed for farmed animals containing products derived from ruminants

The use and storage of feed materials and compound feed for farmed animals containing products derived from ruminants other than those listed in points (a), (b) and (c) shall be prohibited in farms keeping farmed animals other than fur animals:

(a) milk, milk-based products, milk-derived products, colostrum and colostrum products;

(b) dicalcium and tricalcium phosphate of animal origin;

(c) hydrolysed proteins derived from ruminant hides and skins.

SECTION E

Export of processed animal protein and products containing such protein

1. The export of processed animal protein derived from ruminants, and of products containing such protein shall be prohibited.

By way of derogation, that prohibition shall not apply to processed petfood including canned petfood which contains processed animal protein derived from ruminants and which has undergone treatment and which is labelled in accordance with Union legislation.

2. The export of processed animal protein derived from non-ruminants, and of products containing such protein, shall only be authorised subject to compliance with the following conditions:

(a) they are destined for uses not prohibited by Article 7 and this Annex;

(b) a written agreement is concluded prior the exportation between the competent authority of the exporting Member State, or the Commission, and the competent authority of the importing third country which includes an undertaking from the importing third country to respect the intended use and not to re-export the processed animal protein or the products containing such protein for uses prohibited by Article 7 and this Annex.

3. Written agreements concluded in accordance with point 2(b) above shall be presented in the framework of the Standing Committee on the Food Chain and Animal Health.

4. Points 2 and 3 shall not apply to the export of the following:

(a) fishmeal and compound feed containing fishmeal;

(b) compound feed intended for aquaculture animals;

(c) petfood.

SECTION F

Official controls

1. Official controls carried out by the competent authority in order to verify compliance with the rules laid down set out in this Annex shall include inspections and sampling

for analysis on processed animal protein and feed in compliance with the methods of analysis for the determination of constituents of animal origin for the control of feed set out in Annex VI to Regulation (EC) No 152/2009.

2. The competent authority shall verify on a regular basis the competence of laboratories carrying out analyses for such official controls, in particular by evaluating the results of inter-proficiency tests.

If the competence is considered unsatisfactory, a retraining of the laboratory staff shall be undertaken by the laboratory as the minimal corrective measure, prior to carrying out further analyses.**]**

[F4ANNEX V

SPECIFIED RISK MATERIAL

1. Definition of specified risk material

The following tissues shall be designated as specified risk material if they come from animals whose origin is in a Member State or third country or of one of their region with a controlled or undetermined BSE risk:

(a) as regards bovine animals:

(i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;

(ii) **[**F12the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and**]**

(iii) **[**F13the tonsils, the last four meters of the small intestine, the caecum and the mesentery of animals of all ages.**]**

(b) as regards ovine and caprine animals

(i) the skull including the brain and eyes, the tonsils and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum, and

(ii) the spleen and ileum of animals of all ages.

Textual Amendments

F12 Substituted by Commission Regulation (EC) No 357/2008 of 22 April 2008 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F13 Substituted by Commission Regulation (EU) 2015/728 of 6 May 2015 amending the definition of specified risk material set out in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F14 2. Specific requirements for Member States with negligible BSE risk status

Tissues listed in point 1.(a)(i) and 1.(b), which are derived from animals whose origin is in Member States with a negligible BSE risk, shall be considered as specified risk material.]

Textual Amendments

F14 Substituted by Commission Regulation (EU) 2015/1162 of 15 July 2015 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

3. Marking and disposal

Specified risk material shall be stained with a dye or, as appropriate, otherwise marked, immediately on removal, and disposed of in accordance with the provisions laid down in Regulation (EC) No 1774/2002, and in particular in Article 4(2) thereof.

4. Removal of specified risk material

4.1. Specified risk material shall be removed at:

(a) slaughterhouses, or, as appropriate, other places of slaughter;

(b) cutting plants, in the case of vertebral column of bovine animals;

(c) where appropriate, in intermediate plants referred to in Article 10 of Regulation (EC) No 1774/2002 or users and collection centres authorised and registered pursuant to Article 23(2)(c)(iv), (vi) and (vii) of Regulation (EC) No 1774/2002.

4.2. By way of derogation from point 4.1, the use of an alternative test to the removal of specified risk material may be authorised under the following conditions:

(a) tests must be carried out in slaughterhouses on all animals eligible for the removal of specified risk material;

(b) no bovine, ovine or caprine product intended for human food or animal feed may leave the slaughterhouse before the competent authority has received and accepted the results of the tests on all slaughtered animals potentially contaminated if BSE has been confirmed in one of them;

(c) when an alternative test gives a positive result, all bovine, ovine and caprine material which has been potentially contaminated in the slaughterhouse is destroyed in accordance with point 3, unless all parts of the body including the hide of the affected animal can be identified and kept separate.

4.3. By way of derogation from point 4.1, Member States may decide to allow:

(a) the removal of spinal cord of ovine and caprine animals in cutting plants specifically authorised for this purpose;

(b) the removal of bovine vertebral column from carcasses or parts of carcasses in butcher shops specifically authorised, monitored and registered for this purpose;

(c) the harvesting of head meat from bovine animals in cutting plants specifically authorised for this purpose in accordance with the provisions laid down in point 9.

4.4. The rules on removal of specified risk material laid down in this Chapter shall not apply to Category 1 material as defined in Regulation (EC) No 1774/2002 used under the supervision of competent authorities for feeding of endangered and protected species of necrophagous birds.

5. Measures concerning mechanically separated meat

Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 9(3), it shall be prohibited in all Member States to use bones or bone-in cuts of bovine, ovine and caprine animals for the production of mechanically separated meat.

6. Measures concerning laceration of tissues

Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 8(3), in all Member States, until all Member States are classified as countries with negligible BSE risk, laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity after stunning shall be prohibited in bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

7. Harvesting of tongues from bovine animals

Tongues of bovine animals of all ages intended for human or animal consumption shall be harvested at the slaughterhouse by a transverse cut rostral to the lingual process of the basihyoid bone.

8. Harvesting of bovine head meat

8.1. Head meat of bovine animals above 12 months of age shall be harvested at slaughterhouses, in accordance with a control system, recognised by the competent authority, to ensure the prevention of possible contamination of head meat with central nervous system tissue. The system shall include at least the following provisions:

(a) harvesting shall take place in a dedicated area, physically separated from the other parts of the slaughterline;

(b) where the heads are removed from the conveyor or hooks before harvesting the head meat, the frontal shot hole and foramen magnum shall be sealed with an impermeable and durable stopper. Where the brainstem is sampled for laboratory testing for BSE, the foramen magnum shall be sealed immediately after that sampling;

(c) head meat shall not be harvested from heads where the eyes are damaged or lost immediately prior to, or after slaughter, or which are otherwise damaged in a way which might result in contamination of the head with central nervous tissue;

(d) head meat shall not be harvested from heads which have not been properly sealed in accordance with the second indent;

(e) without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during the harvesting, in particular in the case when the seal referred to in the second indent is lost or the eyes damaged during the activity:

(f) a sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

8.2. By way of derogation from the requirements of point 8.1, Member States may decide to apply at the slaughterhouse an alternative control system for the harvesting of bovine head meat, leading to an equivalent reduction in the level of contamination of head meat with central nervous system tissue. A sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented. Member States using this derogation shall inform the Commission and the other Member States in the framework of the Standing Committee of the Food Chain and Animal Health of their control system and the results of the sampling.

8.3. If the harvesting is performed without removing the bovine head from the conveyor or hooks, points 8.1 and 8.2 shall not apply.

9. Harvesting of bovine head meat in authorised cutting plants

By way of derogation from point 8, Member States may decide to allow the harvesting of head meat from bovine in cutting plants specifically authorised for this purpose and provided that the following conditions are complied with:

(a) the heads intended for transport to the cutting plant shall be suspended on a rack during the storing period and the transport from the slaughterhouse to the cutting plant;

(b) the frontal shot hole and the foramen magnum shall be properly sealed with an impermeable and durable stopper before being moved from the conveyor or hooks to the racks. Where the brainstem is sampled for laboratory testing for BSE, the foramen magnum shall be sealed immediately after that sampling;

(c) the heads which have not been properly sealed in accordance with point (b), where the eyes are damaged or lost immediately prior to or after slaughter or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue shall be excluded from transport to the specifically authorised cutting plants;

(d) a sampling plan for the slaughterhouse using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify the proper implementation of the measures to reduce contamination;

(e) the harvesting of head meat shall be carried out in accordance with a control system, recognized by the competent authority, to ensure the prevention of possible contamination of head meat. The system shall include at least:

  (i) all heads shall be visually checked for signs of contamination or damage and proper sealing before the harvesting of the head meat begins;

  (ii) head meat shall not be harvested from heads which have not been properly sealed, where the eyes are damaged or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue. Head meat shall also not be harvested from any head where contamination from such heads is suspected;

  (iii) without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during transport and harvesting, in particular where the seal is lost or the eyes damaged during the activity;

(f) a sampling plan for the cutting plant using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

10. Rules on trade and export

10.1. Member States may allow dispatch of heads or of un-split carcasses containing specified risk material to another Member State only after that Member State has agreed to receive the material and has approved the conditions of dispatch and transport.

10.2. By way of derogation from point 10.1, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be dispatched from one Member State to another without the latter's prior agreement.

10.3. Exports outside the Community of heads and of fresh meat of bovine, ovine or caprine animals containing specified risk materials shall be prohibited.

11. Controls

11.1. Member States shall carry out frequent official controls to verify the correct application of this Annex and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants or other places where specified risk material is removed, such as butcher shops or establishments referred in point 4.1 (c).

11.2. Member States shall in particular set up a system to ensure and check that specified risk material is handled and disposed of in accordance with Regulation (EC) No 999/2001 and Regulation (EC) No 1774/2002.

11.3. A control system shall be put in place for the removal of the vertebral column as specified in point 1(a). The system shall include at least the following measures:

(a) when removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000;

(b) specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required, shall be added on the commercial document relating to consignments of meat. When applicable, the specific information shall be added to the document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004[(16)] in the case of imports;

(c) butcher shops shall keep, for at least one year, the commercial documents referred to in (b).**]**

ANNEX VI

PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING RUMINANT MATERIAL, AS REFERRED TO IN ARTICLE 9(1)

[F3ANNEX VII

CONTROL AND ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

CHAPTER A

Measures following the suspicion of the presence of a TSE in ovine and caprine animals

If a TSE is suspected in an ovine or caprine animal on a holding in a Member State and until the results of the confirmatory examinations are available, all other ovine and caprine animals on that holding shall be placed under an official movement restriction.

If there is evidence that the holding where the animal was present when the TSE was suspected is unlikely to be the holding where the animal could have been exposed to the TSE, the Member State may decide that other holdings or only the holding of exposure shall be placed under official control, depending on the epidemiological information available.

The milk and the milk products derived from the ovine and caprine animals of a holding placed under official control, which are present on that holding from the date when the presence of the TSE is suspected until the results of the confirmatory examinations are available, shall only be used within that holding.

CHAPTER B

Measures following confirmation of the presence of a TSE in bovine, ovine and caprine animals

1. The inquiry referred to in Article 13(1)(b) must identify:

(a) in the case of bovine animals:
- — all other ruminants on the holding of the animal in which the disease was confirmed,
- — where the disease was confirmed in a female animal, its progeny born within a period of two years prior to, or after, the clinical onset of the disease,
- — all animals of the cohort of the animal in which the disease was confirmed,
- — the possible origin of the disease,
- — other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- — the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

(b) in the case of ovine and caprine animals:

— all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,

— insofar as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,

— all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,

— the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,

— the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least the following:

2.1. In the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:

— not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,

— to defer the killing and destruction of animals of the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.

2.2. In the case of confirmation of TSE in an ovine or caprine animal:

2.2.1. In cases where BSE cannot be excluded

[[F5]If BSE cannot be excluded after the results of the secondary molecular testing carried out in accordance with the methods and protocols set out in Annex X, Chapter C, point 3.2(c) (ii), the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b).**]**

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

The milk and the milk products derived from the animals to be destroyed, which were present on the holding between the date of confirmation that BSE cannot be excluded and the date of complete destruction of the animals, shall be disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council[(17)].

Following the killing and complete destruction of all animals, the conditions set out in point 3 shall apply to the holding.

2.2.2. In cases where BSE and atypical scrapie can be excluded

If BSE and atypical scrapie are excluded in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2(c), the holding shall be subject to the conditions set out in point (a) and, pursuant to the decision of the Member State responsible for the holding, to the conditions of either option 1 set out at point (b), or option 2 set out at point (c), or option 3 set out at point (d):

(a) The milk and milk products derived from the animals to be destroyed or slaughtered and which were present on the holding between the date of confirmation of the case of TSE and the date of the completion of the measures to be applied in the holding as laid down in point (b) and (c), or derived from the infected flock/herd until all the restrictions laid down in point (d) and point 4 are lifted, shall not be used for the feeding of ruminants, except for the feeding of ruminants within that holding.

The placing on the market of such milk and milk products as feed for non-ruminants shall be limited to the territory of the Member State responsible for the holding.

The commercial document accompanying consignments of such milk and milk products and any packaging containing such consignments shall be clearly marked with the words: ‘shall not be fed to ruminants’.

The use and the storage of feedingstuffs containing such milk and milk products shall be prohibited on holdings where ruminants are kept.

Bulk feedingstuffs containing such milk and milk products shall be transported by means of vehicles which do not transport feedingstuffs for ruminants at the same time.

If those vehicles are subsequently used for the transport of feedingstuffs intended for ruminants, they shall be thoroughly cleaned in order to avoid cross- contamination, in accordance with a procedure approved by the Member State responsible for the holding.

(b) Option 1 — killing and complete destruction of all animals

The killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b).

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

By way of derogation from the conditions set out in the first paragraph of option 1, Member States may decide instead to carry out the measures listed in (i) or (ii):

(i) to replace the killing and complete destruction of all animals, without delay, by their slaughtering for human consumption, without delay, provided that:

— the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;

— all animals which are over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

(ii) to exempt the lambs and kids less than three months old from killing and complete destruction without delay, provided that they are slaughtered for human consumption not later than when they are three months of age.

Pending the killing and complete destruction or slaughtering for human consumption of all animals, the measures set out in point 2.2.2.(a) and point 3.4.(b) third and fourth indents shall apply on the holding where it has been decided to apply option 1.

Following the killing and complete destruction or slaughtering for human consumption of all animals the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 1.

(c) Option 2 — killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine animals present on the holding followed by the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

— breeding rams of the ARR/ARR genotype,

— breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,

— ovine animals carrying at least one ARR allele which are intended solely for slaughter for human consumption,

— if the Member State responsible for the holding so decides, lambs and kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age. These lambs and kids shall be exempted from the genotyping.

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory

methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

By way of derogation from the conditions set out in the first paragraph of option 2, Member States may decide instead to carry out the measures listed in (i), (ii) and (iii):

(i) to replace the killing and complete destruction of the animals referred to in the first paragraph of option 2 by their slaughtering for human consumption, provided that:

— the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;

— all animals which are over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

(ii) to delay the genotyping and subsequent killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a period not exceeding three months in situations where the index case is confirmed close to the commencement of the lambing season, provided that the ewes, goats and their new-born are kept isolated from ovine and caprine animals of other holdings during the whole period;

(iii) to delay the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine flocks and holdings where ovine and caprine animals are kept together. The application of the derogation set out in the present paragraph shall be limited to cases where the Member State responsible for the holding considers that the epidemiological situation cannot be handled without killing the relevant animals, but that this cannot be carried out immediately due to the low level of resistance in the ovine population of the holding coupled with other considerations, including economic factors. Breeding rams other than those of the ARR/ARR genotype shall be killed or castrated without delay and all possible measures to quickly build up genetic resistance in the ovine population of the holding, including by reasoned breeding and culling of ewes to increase the frequency of the ARR allele and eliminate the VRQ allele, shall be implemented. The Member State responsible for the holding shall ensure that the number of animals to be killed at the end of the period of delay is not greater than immediately after the index case was confirmed.

Pending the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2, the following measures shall apply on the holding where it has been decided to apply option 2: point 2.2.2.(a), point 3.1., point 3.2.(a) and (b), point 3.3. and point 3.4.(a) first and second indents, (b) first, third and fourth indents, and (c). However, where the Member State responsible for the holding decides to delay the killing and complete destruction or slaughtering for human consumption of the animals in accordance with point (iii), the following measures shall instead apply on the holding: point 2.2.2.(a) and points 4.1. to 4.6.

Following the killing and complete destruction, or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 2.

(d) Option 3 — no mandatory killing and complete destruction of animals

A Member State may decide not to kill and completely destroy the animals identified by the inquiry referred to in the second and third indents of point 1(b) where the criteria laid down in at least one of the following four indents are met:

— it is difficult to obtain replacement ovine animals of genotypes allowed under point 3.2.(a) and (b),

— the frequency of the ARR allele within the breed or holding is low,

— it is deemed necessary in order to avoid inbreeding,

— it is deemed necessary by the Member State based on a reasoned consideration of all the epidemiological factors.

The Member States allowing recourse to option 3 in the management of classical scrapie outbreaks shall keep records of the reasons and criteria founding each individual application decision.

When additional classical scrapie cases are detected in a holding where option 3 is being applied, the relevance of the reasons and criteria founding the decision to apply option 3 to this holding shall be reassessed by the Member State. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the Member State shall switch the management of this holding from option 3 to either option 1 or option 2, as laid down in points (b) and (c).

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined within a period of three months from the date of confirmation of the index case of classical scrapie.

The conditions set out in point 2.2.2.(a) and point 4 shall immediately apply to a holding where it has been decided to apply option 3.

2.2.3. In cases where atypical scrapie is confirmed

Where the TSE case confirmed on a holding is an atypical scrapie case, the holding shall be subject to the following intensified TSE monitoring protocol for a period of two years from the date of the detection of the last atypical scrapie case: all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 months which have died or been killed on the holding shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

If a case of TSE other than atypical scrapie is confirmed during the intensified TSE monitoring period of two years referred to in the first paragraph, the holding shall be subject to the measures referred to in point 2.2.1 or point 2.2.2.

2.3. If an animal infected with TSE has been introduced from another holding:

(a) a Member State may decide, based on the history of the infected animal, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed;

(b) in the case of land used for common grazing by more than one flock or herd, Member States may decide to limit the application of eradication measures to a single flock or herd, based on a reasoned consideration of all the epidemiological factors;

(c) where more than one flock or herd is kept on a single holding, Member States may decide to limit the application of the eradication measures to the flock or herd in which the TSE has been confirmed, provided it has been verified that the flocks or herds have been kept isolated from each other and that the spread of infection between the flocks or herds through either direct or indirect contact is unlikely.

3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified on a holding, in accordance with point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c):

3.1. The holding shall be subjected to an intensified TSE monitoring protocol including the testing for the presence of TSE, in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

(a) animals which were kept in the holding at the time when the TSE case was confirmed, in accordance with point 2.2.2.(c), and which have been slaughtered for human consumption;

(b) animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

3.2. Only the following animals may be introduced to the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) female ovine animals carrying at least one ARR allele and no VRQ allele;

(c) caprine animals, provided that a cleaning and disinfection of all animal housing on the premises has been carried out following destocking.

3.3. Only the following breeding rams and ovine germinal products may be used in the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) semen from rams of the ARR/ARR genotype;

(c) embryos carrying at least one ARR allele and no VRQ allele.

3.4. Movement of animals from the holding shall either be allowed for the purposes of destruction, or shall be subject to the following conditions:

(a) the following animals may be moved from the holding for all purposes, including breeding:
- ARR/ARR ovine animals;
- ewes carrying one ARR allele and no VRQ allele, provided that they are moved to other holdings which are restricted following the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);
- caprine animals, provided that they are moved to other holdings which are restricted following the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

(b) the following animals may be moved from the holding to go directly for slaughter for human consumption:
- ovine animals carrying at least one ARR allele;
- caprine animals;
- if the Member State so decides, lambs and kids less than three months old on the date of slaughter;
- all animals when the Member State has decided to apply the derogations laid down in point 2.2.2.(b)(i) and point 2.2.2.(c)(i);

(c) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:
- the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter;
- at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

3.5. The restrictions set out in points 3.1 to 3.4 shall continue to apply to the holding:

(a) until the date of attainment of ARR/ARR status by all ovine animals on the holding, provided that no caprine animals are kept on the holding; or

(b) for a period of two years from the date when all the measures referred to in point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c) have been completed, provided that no TSE case other than atypical scrapie is detected during this two-year

period. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.

4. Following the decision to implement option 3 laid down in point 2.2.2.(d) or the derogation provided for in point 2.2.2.(c)(iii), the following measures shall immediately apply to the holding:

4.1. The holding shall be subjected to an intensified TSE monitoring protocol including the testing for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

(a) animals which have been slaughtered for human consumption;

(b) animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

4.2. Only the following ovine animals may be introduced to the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) female ovine animals carrying at least one ARR allele and no VRQ allele.

However, by way of derogation from points (a) and (b), a Member State may allow the animals referred to in points (c) and (d) to be introduced to the holding where the breed reared in the holding is listed by the Member State as a local breed in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006[(18)], and where the frequency of the ARR allele within the breed is low:

(c) male ovine animals carrying at least one ARR allele and no VRQ allele;

(d) female ovine animals carrying no VRQ allele.

4.3. Only the following breeding rams and ovine germinal products may be used in the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) semen from rams of the ARR/ARR genotype;

(c) embryos carrying at least one ARR allele and no VRQ allele.

However, by way of derogation from points (a), (b) and (c), a Member State may allow the breeding rams and ovine germinal products referred to in points (d), (e) and (f) to be used in the holding where the breed reared in the holding is listed by the Member State as a local breed in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006, and where the frequency of the ARR allele within the breed is low:

(d) male ovine animals carrying at least one ARR allele and no VRQ allele;

(e) semen from male ovine animals carrying at least one ARR allele and no VRQ allele;

(f) embryos carrying no VRQ allele.

4.4. Movement of animals from the holding shall be allowed for the purposes of destruction, or shall be subject to the following conditions:

(a) rams and ewes of the ARR/ARR genotype may be moved from the holding for all purposes, including breeding, provided that they are moved to other holdings which are subject to the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

(b) the following animals may be moved from the holding to go directly for slaughter for human consumption:

— either ovine animals carrying at least one ARR allele and, if the Member State so decides, lambs and kids less than three months old on the date of slaughter;

— or all animals when the Member State has decided to apply the derogation from option 2 laid down in point 2.2.2.(c)(iii) or option 3 laid down in point 2.2.2.(d).

(c) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:

— the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter;

— at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

4.5. Movement of germinal products from the holding shall be subject to the following conditions: the Member State shall ensure that no semen, embryo and ova are dispatched from the holding.

4.6. Common grazing of all ovine and caprine animals in the holding with ovine and caprine animals of other holdings shall be prohibited during the lambing and kidding period.

Outside of the lambing and kidding period, common grazing shall be subject to restrictions to be determined by the Member State, based on a reasoned consideration of all the epidemiological factors.

4.7. The restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall continue to apply for a period of two years following the detection of the last TSE case, other than atypical scrapie, on the holdings where option 3 laid down in point 2.2.2.(d) has been implemented. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.

In holdings where the derogation from option 2 provided for in point 2.2.2.(c)(iii) has been implemented, the restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall apply until the complete destruction or slaughtering for human consumption of the animals identified for killing in accordance with point 2.2.2.(c), after which the restrictions laid out in point 3 shall be applicable.

CHAPTER C

Minimum requirements for a breeding programme for resistance to TSEs in ovine animals in accordance with article 6A

PART 1

General requirements

1. The breeding programme shall concentrate on flocks of high genetic merit, as defined in point 3 of Annex I of Commission Decision 2002/1003/EC.

However, Member States where a breeding programme is in place may decide to allow sampling and genotyping of breeding rams only, in flocks not participating in the breeding programme.

2. A database shall be established containing at least the following information:

(a) the identity, breed and number of animals in all flocks participating in the breeding programme;

(b) the identification of the individual animals sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme;

(c) the results of any genotyping tests.

3. A system of uniform certification shall be established in which the genotype of each animal sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme, is certified by reference to its individual identification number.

4. A system for the identification of animals and samples, the processing of samples and the delivery of results shall be established which minimises the possibility of human error. The effectiveness of that system shall be subject to regular random checking.

5. Genotyping of blood or other tissues collected for the purposes of the breeding programme, including from breeding rams sampled in flocks not participating in the breeding programme, shall be carried out in laboratories that have been approved under the breeding programme.

6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.

7. Breeding programmes shall be drawn up for each breed, taking account of:

(a) frequencies of the different alleles within the breed;

(b) rarity of the breed;

(c) avoidance of inbreeding or genetic drift.

PART 2

Specific rules for participating flocks

1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the flock, while reducing the prevalence of those alleles which have been shown to contribute to susceptibility to TSEs.

2. The minimum requirements for participating flocks shall be the following:

(a) all animals in the flock that are to be genotyped shall be individually identified using secure means;

(b) all rams intended for breeding within the flock shall be genotyped before being used for breeding;

(c) any male animal carrying the VRQ allele shall be slaughtered or castrated, within six months following the determination of its genotype; any such animal shall not leave the holding except for slaughter;

(d) female animals that are known to carry the VRQ allele shall not leave the holding except for slaughter;

(e) male animals, including semen donors used for artificial insemination, other than those certified under the breeding programme, shall not be used for breeding within the flock.

3. Member States may decide to grant derogations from the requirements set out in point 2(c) and (d) for the purposes of the protection of breeds and production traits.

4. Member States shall inform the Commission of any derogation granted under point 3 and of the criteria used.

PART 3

Specific rules for breeding rams sampled in flocks not participating in the breeding programme

1. Rams to be sampled shall be individually identified using secure means.

2. Any ram found to carry the VRQ allele shall not leave the holding except for slaughter.

PART 4

The framework for the recognition of the TSE-resistant status of flocks of ovine animals

1. The framework for the recognition of the TSE-resistant status of flocks of ovine animals shall recognise the TSE-resistant status of flocks of ovine animals that as a result of participation in the breeding programme as provided for in Article 6a, satisfy the criteria required in that programme.

That recognition shall be granted on at least the following two levels:

(a) level I flocks shall be flocks composed entirely of ovine animals of the ARR/ARR genotype;

(b) level II flocks shall be flocks whose progeny have been sired exclusively by rams of the ARR/ARR genotype.

Member States may decide to grant recognition on further levels to suit national requirements.

2. Regular random sampling of ovine animals from TSE-resistant flocks shall be carried out:

(a) on the holding or at the slaughterhouse to verify their genotype;

(b) in the case of level I flocks, in animals over 18 months of age at the slaughterhouse, for TSE testing in accordance with Annex III.

PART 5

Reports to be provided to the Commission by the Member States

Member States introducing national breeding programmes to select for resistance to TSE in their ovine populations shall:

1. notify to the Commission the requirements for such programmes;

2. submit to the Commission an annual report on their progress.

The report for each calendar year shall be submitted at the latest by 31 March of the following year.**]**

ANNEX VIII

PLACING ON THE MARKET AND EXPORT

[[F3]CHAPTER A

Conditions for intra-Union trade in live animals, semen and embryos

SECTION A

Conditions which apply to ovine and caprine animals and semen and embryos thereof

1. Holdings with a negligible risk of classical scrapie and a controlled risk of classical scrapie:

1.1. Member States may establish or supervise an official scheme for the recognition of holdings with a negligible risk of classical scrapie and holdings with a controlled risk of classical scrapie.

When they do so, they shall maintain a list of holdings of ovine and caprine animals with a negligible risk and holdings with a controlled risk of classical scrapie.

1.2. A holding of ovine animals having the TSE-resistance level I status, as laid down in Annex VII, Chapter C, Part 4, point 1.(a), and where no case of classical scrapie has

been confirmed for at least seven years may be recognised as having a negligible risk of classical scrapie.

A holding of ovine animals, caprine animals, or ovine and caprine animals may also be recognised as having a negligible risk of classical scrapie provided that it has complied with the following conditions for at least seven years:

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals may be introduced:

  (i) ovine and caprine animals from holdings with a negligible risk of classical scrapie;

  (ii) ovine and caprine animals from holdings which have met the conditions laid down in points (a) to (i) for a minimum of seven years or for at least the same period of time as the holding where they are to be introduced;

  (iii) ovine animals of the ARR/ARR prion protein genotype.

(d) the holding is subject to regular checks to verify compliance with the provisions set out in point (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;

(e) no case of classical scrapie has been confirmed;

(f) all ovine and caprine animals over 18 months of age slaughtered for human consumption are inspected by an official veterinarian, and all those exhibiting wasting signs, neurological signs or sent for emergency slaughter are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

  Until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3 over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

  From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption shall be tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

  By way of derogation from the conditions set out in the second and third paragraphs of point (f), Member States may decide to apply the provisions of the first paragraph of point (f) to the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with from 1 January 2014:

(g) **[**[F5]only the following ovine and caprine embryos/ova may be introduced:

(i) embryos/ova from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency

— they showed no clinical sign of classical scrapie at the time of embryo/ova collection;

(ii) ovine embryos/ova carrying at least one ARR allele.**]**

(h) only the following ovine and caprine semen may be introduced:

(i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) ovine semen from a ram of the ARR/ARR prion protein genotype;

(i) ovine and caprine animals on the holding have no direct or indirect contact, including sharing grazing, with ovine and caprine animals from holdings of a lower status.

1.3. A holding of ovine and/or caprine animals may be recognised as having a controlled risk of classical scrapie provided that it has complied with the following conditions for a period of at least three years:

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals may be introduced:

(i) ovine and caprine animals from holdings with a negligible or a controlled risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions laid down in points (a) to (i) for a minimum of three years or for at least the same period of time as the holding where they are to be introduced;

(iii) ovine animals of the ARR/ARR prion protein genotype.

(d) the holding is subject to regular checks to verify compliance with the provisions set out in point (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;

(e) no case of classical scrapie has been confirmed;

(f) all ovine and caprine animals over 18 months of age slaughtered for human consumption are inspected by an official veterinarian, and all those exhibiting wasting signs, neurological signs or sent for emergency slaughter are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

Until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3 over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption shall be tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

By way of derogation from the conditions set out in the second and third paragraphs of point (f), Member States may decide to apply the provisions of the first paragraph of point (f) to the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with from 1 January 2014:

(g) **[**[F5]only the following ovine and caprine embryos/ova may be introduced:

(i) embryos/ova from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency

— they showed no clinical sign of classical scrapie at the time of embryo/ova collection;

(ii) ovine embryos/ova carrying at least one ARR allele.**]**

(h) only the following ovine and caprine semen may be introduced:

(i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or with a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) ovine semen from a ram of the ARR/ARR prion protein genotype;

(i) ovine and caprine animals of the holding have no direct or indirect contact, including sharing grazing, with ovine and caprine animals from holdings of lower status.

1.4. If a case of classical scrapie is confirmed in a holding with a negligible risk or a controlled risk of classical scrapie, or in a holding found to have an epidemiological link to a holding with a negligible risk or a controlled risk of classical scrapie as a result of an inquiry referred to in Part 1 of Chapter B of Annex VII, the holding with a negligible risk or a controlled risk of classical scrapie shall be immediately deleted from the list referred to in point 1.1.

The Member State shall immediately inform the other Member States which have imported ovine and caprine animals originating from, or semen or embryos collected from ovine and caprine animals kept in that holding during the last seven years in the case of a holding with a negligible risk or during the last three years in the case of a holding with a controlled risk.

2. Member States or zones of a Member State with a negligible risk of classical scrapie

2.1. Where a Member State considers that its territory or part of its territory poses a negligible risk of classical scrapie, it shall submit to the Commission appropriate supporting documentation, setting out in particular that:

(a) a risk assessment has been conducted, and it has demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any risk identified. This risk assessment shall identify all potential factors for classical scrapie occurrence and their historic perspective, in particular the:

  (i) importation or introduction of ovine and caprine animals or their semen and embryos potentially infected with classical scrapie;

  (ii) extent of knowledge of the population structure and husbandry practices of ovine and caprine animals;

  (iii) feeding practices, including consumption of meat-and-bone meal or greaves derived from ruminants;

  (iv) importation of milk and milk products of ovine and caprine animals origin intended for use in feeding of ovine and caprine animals;

(b) for a period of at least seven years, ovine and caprine animals displaying clinical signs compatible with classical scrapie have been tested;

(c) for a period of at least seven years, a sufficient number of ovine and caprine animals over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95 percent level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1 percent and no case of classical scrapie has been reported during that period;

(d) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole Member State for a period of at least seven years;

(e) introductions from other Member States of ovine and caprine animals and semen and embryos thereof are carried out in accordance with point 4.1.(b) or point 4.2.;

(f) introductions from third countries of ovine and caprine animals and semen and embryos thereof are carried out in accordance with Chapter E or Chapter H of Annex IX.

2.2. The negligible risk status for classical scrapie of the Member State or of the zone of the Member State may be approved in accordance with the procedure referred to in Article 24(2).

The Member State is to notify the Commission of any change in the information submitted according to point 2.1. relating to the disease.

The negligible risk status approved in accordance with point 2.2. may, in the light of such notification, be withdrawn in accordance with the procedure referred to in Article 24(2).

[F15 2.3. The Member States or zone of the Member State with a negligible risk for classical scrapie are the following:

— Austria.]

Textual Amendments

F15 Inserted by Commission Regulation (EU) No 1148/2014 of 28 October 2014 amending Annexes II, VII, VIII, IX and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

3. National control programme for classical scrapie:

3.1. a Member State which has a national control programme for classical scrapie covering all of its territory:

(a) may submit its national control programme to the Commission, outlining in particular:

— the distribution of classical scrapie in the Member State,

— the reasons for national control programme, taking into consideration the importance of the disease and the cost/benefit ratio,

— the status categories defined for holdings and the standards which must be attained in each such category,

— the test procedures to be used,

— the national control programme monitoring procedures,

— the action to be taken if, for any reason, a holding loses its status,

— the measures to be taken if the results of checks carried out in accordance with the national control programme programme are positive,

(b) the programme referred to in point (a) may be approved if it complies with the criteria laid down in that point, in accordance with the procedure referred to in Article 24(2); amendments or additions to the programmes submitted by Member States may be approved in accordance with the procedure referred to in Article 24(2).

[F5 3.2. The national scrapie control programmes of the following Member States are hereby approved:

— Denmark

— Finland

— Sweden.]

4. Intra-Union trade in ovine and caprine animals and semen and embryos thereof

The following conditions shall apply:

4.1. ovine and caprine animals:

(a) ovine and caprine animals for breeding intended for Member States other than those with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:

(i) come from a holding or holdings with a negligible risk or a controlled risk of classical scrapie; however ovine and caprine animals for breeding coming from a holding or holdings which have complied with all the requirements laid down in point 1.3. (a) to (f), for a period of at least three years may be subject to intra-Union trade until 31 December 2014; or

(ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie; or

(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype, provided they do not come from a holding subject to the restrictions laid down in Annex VII, Chapter B, points 3 and 4.

(b) ovine and caprine animals for all intended use except immediate slaughter intended for the Member States with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:

(i) come from a holding or holdings with a negligible risk of classical scrapie; however ovine and caprine animals coming from a holding or holdings which have complied with all the requirements laid down in point 1.2. (a) to (i), for a period of at least seven years may be subject to intra-Union trade until 31 December 2014; or

(ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie; or

(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype, provided they do not come from a holding subject to the restrictions laid down in Annex VII, Chapter B, points 3 and 4.

4.2. semen and embryos of ovine and caprine animals shall:

(a) be collected from animals which have been kept continuously since birth on a holding or holdings with a negligible risk or a controlled risk of classical scrapie; or

(b) be collected from animals which have been kept continuously for the last three years before the collection on a holding or holdings which have complied with all the requirements laid down in Part 1, point 1.3. (a) to (f) for three years; or

(c) be collected from animals which have been kept continuously since birth in a country or zone with a negligible risk of classical scrapie; or

(d) in the case of ovine semen, be collected from male animals of the ARR/ARR prion protein genotype; or

(e) **[**[F5]in the case of ovine embryos, be carrying at least one ARR allele.**]**

SECTION B

Conditions which apply to bovine animals

The United Kingdom shall ensure that bovine animals born or reared on its territory before 1 August 1996 are not dispatched from its territory to other Member States or third countries.**]**

CHAPTER B

Conditions relating to progeny of TSE suspect or confirmed animals referred to in Article 15(2)

. . . . . .

It shall be prohibited to place on the market the last-born progeny to which female bovine animals infected with a TSE or BSE-confirmed ovine or caprine animals gave birth during the preceding two-year period or during the period that followed the appearance of the first clinical signs of the onset of the disease.

[[F4]CHAPTER C

Conditions for intra-Community trade in certain products of animal origin

SECTION A

Products

The following products of animal origin are exempt from the prohibition referred to in Article 16(3), provided that they are derived from bovine, ovine and caprine animals that satisfy the requirements of Section B:

— fresh meat,
— minced meat,
— meat preparations,
— meat products.

SECTION B

Requirements

The products referred to in Section A must satisfy the following requirements:

(a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

(c) the products of bovine, ovine and caprine animal origin are not derived from:

(i) specified risk material as defined in Annex V;

(ii) nervous and lymphatic tissues exposed during the deboning process; and

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.**]**

CHAPTER D

Conditions applicable to exports

Live bovine animals and products of animal origin derived therefrom are to be subject — as regards exports to third countries — to the rules laid down in this Regulation for intra-Community trade.

ANNEX IX

IMPORTATION INTO THE COMMUNITY OF LIVE ANIMALS, EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN

F16CHAPTER A

[F16. . . . . .**]**

Textual Amendments

F16 Deleted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F4CHAPTER B

Imports of bovine animals

SECTION A

Imports from a country or a region with a negligible BSE risk

Imports of bovine animals from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the animals were born and continuously reared in a country or region classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;

(b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, part I, point (4) (b) (iv) of Annex II; and

(c) if there have been BSE indigenous cases in the country concerned, the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

SECTION B

Imports from a country or a region with a controlled BSE risk

Imports of bovine animals from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, Part II, point (4)(b)(iv) of Annex II;

(c) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

SECTION C

Imports from a country or a region with undetermined BSE risk

Imports of bovine animals from a country or a region with an undetermined BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region has not been categorized in accordance with Article 5(2) of Regulation (EC) No 999/2001 or has been categorized as a country or region with undetermined BSE risk;

(b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, Part II, point (4)(b)(iv) of Annex II;

(c) the animals were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

CHAPTER C

Imports of products of animal origin from bovine, ovine or caprine animals

[F3 SECTION A

Products

The following products of bovine, ovine and caprine origin, as defined by points 1.10, 1.13, 1.15, 7.1, 7.5, 7.6, 7.7, 7.8 and 7.9 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council, shall be subject to the conditions laid down in Sections B, C or D of this Chapter depending on the BSE risk category of the country of origin:

— fresh meat,
— minced meat,
— meat preparations,
— meat products,
— rendered animal fat,
— greaves,
— gelatine and collagen other than derived from hides and skins,
— treated intestines.**]**

SECTION B

Imports from a country or a region with a negligible BSE risk

Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country with negligible BSE risk and passed ante-mortem and post-mortem inspections;

(c) if in the country or region there have been BSE indigenous cases:

  (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

  (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

SECTION C

Imports from a country or a region with a controlled BSE risk

1. Imports of products of bovine, ovine and caprine animal origin referred to in section A from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived passed ante-mortem and post-mortem inspections;

(c) animals from which the products of bovine, ovine and caprine animal origin destined for export were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

(d) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

2. By way of derogation from point 1(d) carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

3. When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000.

4. The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as he number where removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

[F17 5. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Article 5(2) as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed *ante-mortem* and *post-mortem* inspections;

(c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V.**]**

Textual Amendments

F17 Inserted by Commission Regulation (EC) No 1275/2007 of 29 October 2007 amending Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

SECTION D

Imports from a country or a region with an undetermined BSE risk

1. Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with an undetermined BSE risk, shall be subject to the presentation of an animal health certificate attesting that:

(a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

(c) the products of bovine, ovine and caprine animal origin are not derived from:

(i) specified risk material as defined in Annex V;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

2. By way of derogation from point 1(c), carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

3. When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000.

4. Specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required and from which removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

[F17 5. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the presentation of an animal health certificate attesting that:

(a) the country or region is classified in accordance with Article 5(2) as a country or region posing an undetermined BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed *ante-mortem* and *post-mortem* inspections;

(c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V.**]**

[[F3]CHAPTER D

Imports of animal by-products and derived products from bovine, ovine and caprine origin

SECTION A

Animal by-products

This Chapter shall apply to the following animal by-products and derived products, as defined in points (1) and (2) of Article 3 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council, provided that those products are of bovine, ovine and caprine animal origin:

(a) Rendered fats derived from Category 2 material, which are intended to be used as organic fertilisers or soil improvers, as defined in point 22 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;

(b) Bones and bone products derived from Category 2 material;

(c) Rendered fats derived from Category 3 material which are intended to be used as organic fertilisers or soil improvers or as feed, as defined in points 22 and 25 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;

(d) Pet food including dog chews;

(e) Blood products;

(f) Processed animal protein;

(g) Bones and bone products derived from Category 3 material;

(h) Gelatine and collagen derived from materials other than hides and skins;

(i) Category 3 material and derived products other than those referred to in points (c) to (h) excluding:

(i) fresh hides and skins, treated hides and skins;

(ii) gelatine and collagen derived from hides and skins;

(iii) fat derivatives.

SECTION B

Health certificate requirements

Imports of the animal by-products and derived products of bovine, ovine and caprine origin referred to in Section A shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(a) the animal by-product or derived product does not contain and is not derived from specified risk material or mechanically separated meat obtained from bones of bovine, ovine or caprine animals and, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2), the animals from which this animal by-product or derived product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity; or

(b) the animal by-product or derived product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2).

In addition to points (a) and (b), imports of the animal by-products and derived products referred to in Section A, containing milk or milk products of ovine or caprine animal origin and intended for feed, shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(c) the ovine and caprine animals from which those products are derived have been kept continuously since birth in a country where the following conditions are fulfilled:

(i) classical scrapie is compulsorily notifiable;

(ii) an awareness, surveillance and monitoring system is in place;

(iii) official restrictions apply to holdings of ovine or caprine animals in case of a suspicion of TSE or a confirmation of classical scrapie;

(iv) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(v) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period at least seven years;

(d) the milk and milk products of ovine or caprine animals derive from holdings where no official restriction is imposed due to a suspicion of TSE;

(e) the milk and milk products of ovine or caprine animals derive from holdings where no case of classical scrapie has been diagnosed for the last seven years or, following the confirmation of a case of classical scrapie:

(i) all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele; or

(ii) all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for two years at least since the confirmation of the last classical scrapie case to intensified TSE monitoring, including testing with negative results for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

— animals which have been slaughtered for human consumption; and

— animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into the Union are to be subject to the presentation of an animal health certificate attesting that they have been kept continuously since birth in a country where the following conditions are fulfilled:

1. classical scrapie is compulsorily notifiable;

2. an awareness, surveillance and monitoring system is in place;

3. ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

4. the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least seven years;

In addition to the conditions set out in points 1 to 4, the animal health certificate shall attest that:

5. For ovine and caprine animals for breeding imported into the Union and intended for Member States other than those with a negligible risk of classical scrapie or those with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions shall be complied with:

— the imported ovine and caprine animals come from a holding or holdings that have complied with the conditions of point 1.3 of Section A of Chapter A of Annex VIII; or

— they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.

6. For ovine and caprine animals for all uses except immediate slaughter imported into the Union and intended for a Member State with a negligible risk of classical scrapie or with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions shall be complied with:

— they come from a holding or holdings that have complied with the conditions of point 1.2 of Section A of Chapter A of Annex VIII; or

— they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.**]]**

[F4CHAPTER F

Imports of products of animal origin from farmed and wild cervid animals

1. When fresh meat, minced meat, meat preparations and meat products as defined by Regulation (EC) No 853/2004, derived from farmed cervid animals, are imported into the Community from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

This product contains or is derived exclusively from meat, excluding offal and spinal cord, of farmed cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognized by the competent authority with negative results and is not derived from animals coming from a herd where chronic wasting disease has been confirmed or is officially suspected.

2. When fresh meat, minced meat, meat preparations and meat products as defined by Regulation (EC) No 853/2004, derived from wild cervid animals, are imported into the Community from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

This product contains or is derived exclusively from meat, excluding offal and spinal cord, of wild cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognized by the competent authority with negative results and is not derived from animals coming from a region where chronic wasting disease has been confirmed in the last three years or is officially suspected.**]**

F16CHAPTER G

[F16. . . . . .

F16. . . . . .**]**

[F3CHAPTER H

Import of ovine and caprine semen and embryos

Ovine and caprine semen and embryos imported into the Union are to be subject to the presentation of an animal health certificate attesting that the donor animals:

1. have been kept continuously since birth in a country where the following conditions are fulfilled:

(i) classical scrapie is compulsorily notifiable;

(ii) an awareness, surveillance and monitoring system is in place;

(iii) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(iv) the feeding to ovine and caprine animals of meat-and-bone meal, or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least seven years;

2. have been kept continuously for the last three years before the collection of the exported semen or embryos in a holding or holdings which have been satisfying for the last three years at least all the requirements laid down in point 1.3. (a) to (f) of Section A of Chapter A of Annex VIII, or:

(i) in the case of ovine semen, the semen has been collected from male animals of the ARR/ARR prion protein genotype.

(ii) **[**[F5]in the case of ovine embryos, the embryos carry at least one ARR allele.**]]**

[[F5]ANNEX X

REFERENCE LABORATORIES, SAMPLING AND LABORATORY ANALYSIS METHODS

CHAPTER A

National reference laboratories

1. The designated national reference laboratory is to:

(a) have at its disposal facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type and strain of the agent of TSE, and to confirm results obtained by official diagnostic laboratories. Where it is not capable of identifying the strain-type of the agent, it shall set up a procedure to ensure that the identification of the strain is referred to the EU reference laboratory;

(b) verify diagnostic methods used in official diagnostic laboratories;

(c) be responsible for coordination of diagnostic standards and methods within the Member State. To this end, it:

— may provide diagnostic reagents to official diagnostic laboratories;

— is to control the quality of all diagnostic reagents used in the Member State

— is to periodically arrange comparative tests

— is to hold isolates of the agents of the disease in question, or corresponding tissues containing such agents, coming from cases confirmed in the Member State

— is to ensure confirmation of results obtained in diagnostic laboratories;

(d) is to cooperate with the EU reference laboratory, which includes the participation in the periodic comparative tests organised by the EU reference laboratory. Should a national reference laboratory fail in a comparative test organised by the EU reference laboratory, it shall take immediately all the corrective actions to remedy the situation and successfully pass the repeat comparative test or the next comparative test organised by the EU reference laboratory.

2. However, by way of derogation from point 1, Member States which do not have a national reference laboratory shall use the services of the EU reference laboratory or of national reference laboratories located in other Member States or European Free Trade Association (EFTA) Members.

3. The national reference laboratories are:

Austria:	Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES) Institut für veterinärmedizinische Untersuchungen Robert Koch Gasse 17 A-2340 Mödling
Belgium:	CERVA-CODA-VAR Centre d'Étude et de Recherches Vétérinaires et Agrochimiques, Centrum voor Onderzoek in Diergeneeskunde en Agrochemie, Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
Bulgaria:	Национален диагностичен научноизследователски ветеринарномедицински институт ‘Проф. Д-р Георги Павлов’ Национална референтна лаборатория ‘Трансмисивни спонгиформни енцефалопатии’ бул. ‘Пенчо Славейков’ 15 София 1606 (National Diagnostic Veterinary Research Institute ‘Prof. Dr Georgi Pavlov’, National Reference Laboratory for Transmissible Spongiform Encephalopathies, 15 Pencho Slaveykov Blvd., 1606 Sofia)
Croatia:	Hrvatski veterinarski institut, Savska Cesta 143 10000 Zagreb
Cyprus:	State Veterinary Laboratories Veterinary Services CY-1417 Athalassa

	Nicosia
Czech Republic:	Státní veterinární ústav Jihlava (State Veterinary Institute Jihlava) National Reference Laboratory for BSE and Animal TSEs Rantířovská 93 586 05 Jihlava
Denmark:	Veterinærinstituttet Danmarks Tekniske Universitet Bülowsvej 27 DK-1870 Frederiksberg C (National Veterinary Institute, Technical University of Denmark, 27, Bülowsvej, DK — 1870 Frederiksberg C)
Estonia:	Veterinaar- ja Toidulaboratoorium (Estonian Veterinary and Food Laboratory) Kreutzwaldi 30 Tartu 51006
Finland:	Finnish Food Safety Authority Evira Research and Laboratory Department Veterinary Virology Research Unit-TSEs Mustialankatu 3 FI-00790 Helsinki
France:	ANSES-Lyon, Unité MND 31, avenue Tony Garnier 69 364 LYON Cedex 07
Germany:	Friedrich-Loeffler-Institut Institute for Novel and Emerging Infectious Diseases at the Friederich-Loeffler-Institut Federal Research Institute for Animal Health Suedufer 10 D-17493 Greifswald Insel Riems
Greece:	Ministry of Agriculture — Veterinary Laboratory of Larissa 6th km of Larissa — Trikala Highway GR-41110 Larissa
Hungary:	Veterinary Diagnostic Directorate, National Food Chain Safety Office (VDD NFCSO) Tábornok u. 2 1143 Budapest
Ireland:	Central Veterinary Research Laboratory Department of Agriculture, Food and the Marine

	Backweston Campus Celbridge Co. Kildare
Italy:	Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta — CEA Via Bologna, 148 I-10154 Torino
Latvia:	Institute of Food Safety, Animal Health and Environment (BIOR) Lejupes Str. 3 Riga LV 1076
Lithuania:	National Food and Veterinary Risk Assessment Institute J. Kairiūkščio str. 10 LT-08409 Vilnius
Luxembourg:	CERVA-CODA-VAR Centre d'Étude et de Recherches Vétérinaires et Agrochimiques, Centrum voor Onderzoek in Diergeneeskunde en Agrochemie, Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
Malta:	Veterinary Diagnostic Laboratory Department of Food Health and Diagnostics Veterinary Affairs and Fisheries Division Ministry for Rural Affairs and the Environment Albert Town Marsa
Netherlands:	Central Veterinary Instutute of Wageningen UR Edelhertweg 15 8219 PH Lelystad P.O. Box 2004 NL-8203 AA Lelystad
Poland:	Państwowy Instytut Weterynaryjny (PIWet) 24-100 Puławy al. Partyzantów 57
Portugal:	Setor diagnóstico EET Laboratório de Patologia Unidade Estratégica de Investigação e Serviços de Produção e Saúde Animal

	Instituto Nacional de Investigação Agrária e Veterinária Rua General Morais Sarmento 1500-311 Lisboa
Romania:	Institutul de Diagnostic și Sănătate Animală (Institute for Diagnosis and Animal Health) Department of Morphology Strada Dr Staicovici nr. 63, 5 București 050557
Slovakia:	State Veterinary Institute Zvolen Pod dráhami 918 SK-960 86, Zvolen
Slovenia:	University of Ljubljana, Veterinary faculty National Veterinary Institute Gerbičeva 60 SI-1000 Ljubljana
Spain:	Laboratorio Central de Veterinaria (Algete) Ctra. M-106 pk 1,4 28110 Algete (Madrid)
Sweden:	National Veterinary Institute S-751 89 Uppsala
United Kingdom:	Animal Health and Veterinary Laboratories Agency Woodham Lane New Haw, Addlestone, Surrey KT15 3NB

CHAPTER B

EU reference laboratory

1. The EU reference laboratory for TSEs is:

   The Animal Health and Veterinary Laboratories Agency

   Woodham Lane

   New Haw

   Addlestone

   Surrey KT15 3NB

   United Kingdom

2. The functions and duties of the EU reference laboratory are:

(a) to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing TSEs and the determination of the prion protein genotype in ovine animals, specifically by:

— storing and supplying corresponding tissues containing the TSE agents, for the development or production of the relevant diagnostic tests or for typing strains of the TSE agents

— supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States

— building up and retaining a collection of corresponding tissues containing the agents and strains of TSEs

— organising periodic comparative tests for the procedures for the diagnosis of TSEs and for the determination of the prion protein genotype in ovine animals at EU level

— collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the EU

— characterising isolates of the TSE agent by the most up-to-date methods to allow greater understanding of the epidemiology of the disease

— keeping abreast of trends in surveillance, epidemiology and prevention of TSEs throughout the world

— maintaining expertise on prion diseases to enable rapid differential diagnosis

— acquiring a thorough knowledge of the preparation and use of diagnostic methods used to control and eradicate TSEs;

(b) to assist actively in the diagnosis of outbreaks of TSEs in Member States by studying samples from TSE-infected animals sent for confirmatory diagnosis, characterisation and epidemiological studies;

(c) to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the EU.

CHAPTER C

Sampling and laboratory testing

1. Sampling

Any samples intended to be examined for the presence of a TSE shall be collected using the methods and protocols laid down in the latest edition of the Manual for diagnostic tests and vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) (the Manual). In addition to, or in the absence of, OIE methods and protocols, and to ensure that sufficient material is available, the competent authority shall ensure the use of sampling methods and protocols in accordance with guidelines issued by the EU reference laboratory.

In particular the competent authority shall collect the appropriate tissues, according to the available scientific advice and the guidelines of the EU reference laboratory, in order to ensure the detection of all known strains of TSE in small ruminants and shall keep at least half of the collected tissues fresh but not frozen until the result of the rapid test is negative. Where the result is positive or inconclusive the residual tissues must be subject to confirmatory testing,

and be processed subsequently in accordance with the EU reference laboratory guidelines on discriminatory testing and classification — 'TSE strain characterisation in small ruminants: A technical handbook for National Reference Laboratories in the EU'.

The samples shall be correctly marked as to the identity of the sampled animal.

2. **Laboratories**

Any laboratory examination for TSE shall be carried out in official diagnostic laboratories designated for that purpose by the competent authority.

3. **Methods and protocols**

3.1. *Laboratory testing for the presence of BSE in bovine animals*

(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) Western blot;

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

(iv) histopathological examination;

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

If 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 EU reference laboratory —'OIE rules for the official confirmation of BSE in bovines (based on an initial reactive result in an approved rapid test) by using a second rapid test', 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 the blot image 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; where 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 animal shall be regarded as a positive BSE case.

(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) Western blot;

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

(iv) histopathological examination;

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

Where 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 EU reference laboratory — 'OIE rules for the official confirmation of BSE in bovines (based on an initial reactive result in an approved rapid test) by using a second rapid test, 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 the blot image 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; where 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 second subparagraph is positive.

(c) *Further examination of positive BSE cases*

Samples from all positive BSE cases shall be forwarded to a laboratory, appointed by the competent authority, which has participated successfully in the latest proficiency testing organised by the EU reference laboratory for discriminatory testing of confirmed BSE cases, where they shall be further tested in accordance with the methods and protocols laid down in the EU reference laboratory's method for the classification of bovine TSE isolates (a two-blot method for the provisional classification of bovine TSE isolates).

3.2. *Laboratory testing for the presence of TSE in ovine and caprine animals*

(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) Western blot;

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

(iv) 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. Where 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 points (i) to (iv) of the first subparagraph is positive, the animal shall be regarded as a positive TSE case and further examination as referred to in point (c) shall be performed.

(b) *TSE monitoring*

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part II (Monitoring in ovine and caprine animals) shall be examined by a rapid test, in order to ensure the detection of all known strains of TSE.

When the result of the rapid test is inconclusive or positive, the sampled tissues shall immediately be sent to an official laboratory for confirmatory examinations by histopathology, immunohistochemistry, Western blotting or demonstration of characteristic fibrils by electron microscopy, as referred to in point (a). If the result of the confirmatory examination is negative or inconclusive, the tissues shall be submitted to a further examination by immunohistochemistry or Western blotting.

If the result of one of the confirmatory examinations is positive, the animal shall be regarded as a positive TSE case and further examination as referred to in point (c) shall be performed.

(c) *Further examination of positive TSE cases*

(i) Primary molecular testing with a discriminatory Western blotting method

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 examined using a discriminatory Western blotting method listed in the guidelines of the

EU reference laboratory by an official diagnostic laboratory designated by the competent authority, which has participated successfully in the latest proficiency testing organised by the EU reference laboratory for the use of such a method.

(ii) Secondary molecular testing with additional molecular testing methods

TSE cases in which the presence of BSE cannot be excluded according to the guidelines issued by the EU reference laboratory by the primary molecular testing referred to in point (i), shall be referred immediately to the EU reference laboratory, with all the relevant information available. The samples shall be submitted to further investigation and confirmation by at least one alternative method, differing immunochemically from the original primary molecular method, depending on the volume and nature of the referred material, as described in the guidelines of the EU reference laboratory. These additional tests will be carried out in the following laboratories approved for the relevant method:

Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail

31, avenue Tony Garnier

BP 7033

F-69342 Lyon Cedex

Commissariat à l'Energie Atomique

18, route du Panorama

BP 6

F-92265 Fontenay-aux-Roses Cedex

Animal Health and Veterinary Laboratories Agency

Woodham Lane

New Haw

Addlestone

Surrey KT15 3NB

United Kingdom

The results shall be interpreted by the EU reference laboratory assisted by a panel of experts referred to as the Strain Typing Expert Group (STEG), including a representative of the relevant national reference laboratory. The Commission shall be informed immediately about the outcome of that interpretation.

(iii) Mouse bioassay

Samples indicative of BSE or inconclusive for BSE, following secondary molecular testing, shall be further analysed by mouse bioassay for final confirmation. The nature or quantity of available material may influence the bioassay design, which will be approved by the EU reference laboratory assisted by the STEG on a case by case basis. Bioassays will be performed by the EU reference laboratory, or by laboratories designated by the EU reference laboratory.

The results shall be interpreted by the EU reference laboratory assisted by the STEG. The Commission shall be informed immediately about the outcome of that interpretation.

3.3. *Laboratory testing for the presence of TSEs in species other than those referred to in points 3.1 and 3.2*

Where methods and protocols are established for tests carried out to confirm the suspected presence of a TSE in a species other than bovine, ovine and caprine, they shall include at least a histopathological examination of brain tissue. The competent authority may also require laboratory tests such as immunohistochemistry, Western blotting, demonstration of characteristic fibrils by electron microscopy or other methods designed to detect the disease associated form of the prion protein. In any case at least one other laboratory examination shall be carried out if the initial histopathological examination is negative or inconclusive. At least three different examinations with positive results shall be carried out in the event of the first appearance of the disease.

In particular, where BSE is suspected in a species other than bovine animals, the cases shall be referred to the EU reference laboratory assisted by the STEG for further characterisation.

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

— the sandwich immunoassay for PrPRes 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 PrPRes with monoclonal antibodies (Prionics-Check LIA test),

— the immunoassay using a chemical polymer for selective PrPSc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA & HerdChek BSE-Scrapie Antigen (IDEXX Laboratories)),

— 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 PrPSc (Roboscreen Beta Prion BSE EIA Test Kit).

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 PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP 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 immunoassay using a chemical polymer for selective PrPSc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (HerdChek BSE-Scrapie Antigen (IDEXX Laboratories)),

— the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (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 EU reference laboratory and ensures that the test performance does not change. Producers must provide the EU reference laboratory with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the EU reference laboratory and provided that the EU 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.

5. **Alternative tests**

(To be defined)**]**

[F16]ANNEX XI

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Textual Amendments

F18 Substituted by Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

(1) **[**F1**[**F2**OJ L 300, 14.11.2009, p. 1.]]**

(2) **[**F1**[**F2**OJ L 54, 26.2.2011, p. 1.]]**

(3) **[**F1**[**F2**OJ L 31, 1.2.2002, p. 1.]]**

(4) **[**F1**[**F2**OJ L 229, 1.9.2009, p. 1.]]**

(5) **[**F1**[**F2**OJ L 328, 24.11.2006, p. 14.]]**

(6) **[**F1**[**F3**http://vla.defra.gov.uk/science/docs/sci_tse_rl_handbookv4jan10.pdf]]**

(7) **[**F1**[**F3**OJ L 349, 24.12.2002, p. 105.]]**

(8) **[**F1**[**F3**http://vla.defra.gov.uk/science/docs/sci_tse_rl_2blot.pdf]]**

(9) **[**F1**[**F3**OJ L 5, 9.1.2004, p. 8.]]**

(10) **[**F4**Design prevalence is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.]**

(11) **[**F6**[**F3**OJ L 139, 30.4.2004, p. 55.]]**

(12) **[**F6**[**F3**OJ L 139, 30.4.2004, p. 206.]]**

(13) **[**F6**OJ L 99, 20.4.1996, p. 14.]**

(14) **[**F6**[**F10**OJ L 204, 11.8.2000, p. 1.]]**

(15) **[**F2**OJ L 54, 26.2.2009, p. 1.]**

(16) **[**F4**OJ L 21, 28.1.2004, p. 11.]**

(17) **[**F3**OJ L 300, 14.11.2009, p. 1.]**

(18) **[**F3**OJ L 368, 23.12.2006, p. 15.]**

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

F2 Substituted by Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F3 Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F4 Substituted by Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F6 Substituted by Commission Regulation (EC) No 2245/2003 of 19 December 2003 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals.

F10 Inserted by Commission Regulation (EC) No 571/2008 of 19 June 2008 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the criteria for revision of the annual monitoring programmes concerning BSE (Text with EEA relevance).

Status:
Point in time view as at 05/08/2015.

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.