[F1 ANNEX II

DETERMINATION OF BSE STATUS

Textual Amendments

F1 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

1. Structure of the risk analysis

The risk analyses shall comprise a release assessment and an exposure assessment.

2. Release assessment (external challenge)

2.1. The release 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 account in carrying out the release 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[1] 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).

TABLE 2

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

Points targets for countries or regions		
Adult bovine animals population size(24 months and older)	**Type A surveillance**	**Type B surveillance**
≥ 1 000 000	300 000	150 000
800 0001 000 000	240 000	120 000

600 000800 000	180 000	90 000
400 000600 000	120 000	60 000
200 000400 000	60 000	30 000
100 000200 000	30 000	15 000
50 000100 000	15 000	7 500
25 00050 000	7 500	3 750

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.**]**

(1) **[**[F1]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.**]**

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Status:
Point in time view as at 02/11/2007.

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, ANNEX II.