

## [<sup>F1</sup>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 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<sup>(1)</sup> 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);

**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, Division CHAPTER D. (See end of Document for details)

(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

<b>Surveillance sub-population</b>			
<b>Routine slaughter<sup>a</sup></b>	<b>Fallen stock<sup>b</sup></b>	<b>Casualty slaughter<sup>c</sup></b>	<b>Clinical suspect<sup>d</sup></b>
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
<b>a</b> Bovine animals over 36 months of age at routine slaughter.			
<b>b</b> Bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock).			
<b>c</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).			
<b>d</b> Bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects).			

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*TABLE 2*

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

<b>Points targets for country or region</b>		
<b>Adult bovine animals population size(24 months and older)</b>	<b>Type A surveillance</b>	<b>Type B surveillance</b>
> 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]

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#### Textual Amendments

- F2** 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 \(Text with EEA relevance\).](#)

#### 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 surveillance target.]

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- (1) [<sup>F1</sup>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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- 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).

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