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ANNEX II

DETERMINATION OF BSE STATUS

CHAPTER A

The BSE status of a Member State or a third country or of one of their regions, hereinafter referred to as 'country or region', shall be determined on the basis of the following criteria:

- (a) the outcome of a risk analysis identifying all the potential factors for the appearance of BSE referred to in Chapter B and their development over time;
- (b) an education programme for veterinarians, breeders and those who transport, trade in and slaughter bovine animals, which seeks to encourage them to report all cases of neurological manifestations in adult bovine animals;
- (c) the compulsory reporting and examination of all bovine animals showing clinical signs of BSE;
- (d) a system of continuous surveillance and monitoring of BSE with particular reference to the risks described in Chapter B, taking account of the guidelines in the table of Chapter A of Annex III or in accordance with the appropriate international standards; reports on the number of examinations carried out and the results thereof must be kept for at least seven years;
- (e) the examination in an approved laboratory of samples of encephala or other tissues collected under the surveillance system mentioned in point (d).

CHAPTER B

The risk analysis referred to in Chapter A(a) shall be based on the following factors:

- the consumption by bovine animals of meat and bone meal or greaves derived from ruminants;
- the importation of meat and bone meal or greaves potentially contaminated by a TSE or animal feed containing meat and bone meal or greaves;
- the importation of animals or ova/embryos potentially infected by a TSE;
- the epidemiological status of the country or region in regard to animal TSEs;
- the extent of knowledge about the structure of the bovine, ovine and caprine population in the country or region;
- the source of animal waste, the parameters of the processes for treating such waste and the methods of producing animal feed.

CHAPTER C

Definition of categories

The BSE status of Member States or third countries or one of the regions thereof shall be determined by classification into the following categories:

A. CATEGORY 1 : Country or region free of BSE

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A country or region where a risk analysis based on the information laid down in Chapter B has been conducted which demonstrated that appropriate measures have been taken for the relevant period of time, to manage any risk identified and

1. EITHER no BSE case has been recorded and:
 - (i) the criteria in Chapter A(b) to (e) have been complied with for at least seven years, or
 - (ii) the criteria in Chapter A(c) have been complied with for at least seven years and it has been demonstrated that for at least eight years no meat and bone meal or greaves derived from ruminants or mammals has been fed to ruminants;
2. OR where all cases of BSE have been clearly demonstrated to originate directly from the importation of live bovine animals or bovine embryos/ova, and all the affected bovine animals as well as, if these are females, their last progeny born within two years prior to, or after, the first clinical signs of onset of the disease, if alive in the country or region, have been killed and completely destroyed and, either
 - (i) the criteria in Chapter A(b) to (e) have been complied with for at least seven years, or
 - (ii) the criteria in Chapter A(c) have been complied with for at least seven years and it has been demonstrated that for at least eight years no meat and bone meal or greaves have been fed to ruminants;
3. OR where the last indigenous case of BSE was reported more than seven years ago, the criteria in Chapter A(b) to (e) have been complied with for at least seven years and the feeding of ruminants with meat and bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced for at least eight years.

B. CATEGORY 2 : BSE provisionally free country or region where no indigenous case has been reported

Country or region where a risk analysis as described in Chapter B has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified, and

1. EITHER where there has been no case of BSE and:
 - (i) the criteria in Chapter A(b) to (e) are complied with, but have not been complied with for seven years, or
 - (ii) it has been demonstrated that for at least eight years no meat and bone meal or greaves has been fed to ruminants, but the criteria in Chapter A(c) have not been complied with for seven years;

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2. OR where all cases of BSE have been clearly demonstrated to originate directly from the importation of live bovine animals or bovine embryos/ova, and all the affected bovine animals as well as, if these are females, their last progeny born within two years prior to, or after, the first clinical signs of onset of the disease, if alive in the country or region, have been killed and completely destroyed, and either:
 - (i) the criteria in Chapter A(b) to (e) are complied with, but have not been complied with for seven years, or
 - (ii) it has been demonstrated that for at least eight years no meat and bone meal or greaves has been fed to ruminants, but the criteria in Chapter A(c) have not been complied with for seven years.

C. CATEGORY 3 : BSE provisionally free country or region where at least one indigenous case has been reported

Any country or region where a risk analysis based on the information referred to in Chapter B has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified and:

1. EITHER the last indigenous case of BSE was reported more than seven years ago, the criteria in Chapter A(b) to (e) are complied with and the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants is effectively enforced, but:
 - (i) the criteria in Chapter A(b) to (e) have not been complied with for seven years, or
 - (ii) the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants has not been effectively enforced for eight years;
2. OR where the last indigenous case has been reported less than seven years ago, the BSE incidence rate, calculated on the basis of indigenous cases, has been less than one case per million during each of the last four consecutive twelve-month periods within the bovine animal population over 24 months of age in the country or region or — when in a country or a region the bovine animal population over 24 months of age is less than 1 million animals — one case per real number of this population (calculated on the basis of Eurostat statistics), and where:
 - (i) the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants has been effectively enforced for at least eight years;
 - (ii) the criteria in Chapter A(b) to (e) have been complied with for at least seven years;
 - (iii) the affected bovine animals as well as:

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- if these are females, their last progeny born within two years prior to, or after, clinical onset of the disease;
- all bovine animals from the cohort,

are killed and completely destroyed if they are still alive in the country or region concerned.

For this classification account may be taken, by way of derogation from point (iii), of the existence of other measures offering an equivalent level of protection in relation to the killing of animals at risk.

D. CATEGORY 4 : Country or region with low incidence of BSE

Any country or region where:

1. the criteria listed in Chapter A are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than or equal to one indigenous case per million and less than or equal to one hundred cases per million within the bovine animal population over 24 months of age in the country or region; or
2. the criteria listed in Chapter A are complied with and the BSE incidence rate, calculated as specified in point 1 has been less than one indigenous case per million for less than four consecutive 12 month periods and the affected cattle as well as:
 - if these are females, their last progeny born within two years prior to, or after the first clinical signs of onset of the disease,
 - all bovine animals from the cohort,

if alive in the country or region, are killed and completely destroyed.

For this classification account may be taken, by way of derogation from this point, of the existence of other measures offering an equivalent level of protection in relation to the killing of animals at risk.

Countries or regions where the BSE incidence rate, calculated over the past 12 months, has been less than one indigenous case per million within the cattle population over 24 months of age in the country or region, but where a risk analysis as described in Chapter A has been conducted which demonstrates that at least one of the criteria enabling the country or region to be classified in category 2 or 3 is not complied with, must be regarded as countries or regions belonging to category 4.

E. CATEGORY 5 : Country or region with high incidence of BSE

Any country or region where:

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1. the criteria listed in Chapter A are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than one hundred cases per million within the bovine animal population over 24 months of age in the country or region; or
2. the BSE incidence rate, calculated over the past 12 months, has been greater than or equal to one case per million and less than or equal to one hundred cases per million within the bovine animal population over 24 months of age in the country or region, and at least one of the criteria listed in Chapter A is not complied with.

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