CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions and safe commodities

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.
For the purpose of official BSE risk status recognition, BSE excludes 'atypical BSE' as a condition beleived to occur spontaneously in all cattle populations at a very low rate.

1) When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:
   a) *milk* and *milk products*;
   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
   c) hides and skins;
   d) gelatine and collagen prepared exclusively from hides and skins;
   e) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;
   f) dicalcium phosphate (with no trace of protein or fat);
   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14.;
   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*.
3) When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 11.4.2.

The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1) the outcome of a *risk assessment*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

   a) Entry assessment

   Entry assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

      i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;
      ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
      iii) imported *meat-and-bone meal* or *greaves*;
      iv) imported cattle, sheep and goats;

v) imported animal feed and feed ingredients;

vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;

vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the entry assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

ii) 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;

iii) 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;

iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;

2) ongoing awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.4.20. to 11.4.22.;

3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member Country should conduct Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member Country should conduct Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22.

Article 11.4.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

1) a *risk assessment*, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

2) the Member Country has demonstrated that Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22. is in place and the relevant points target, in accordance with Table 1, has been met;

3) EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and

i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; and

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

OR

b) if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; and

i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; and

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

iii) all BSE *cases*, as well as:

– all cattle 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 are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The Member Country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.4.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

1) a *risk assessment*, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;

2) the Member Country has demonstrated that Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;

3) EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2 to 4 of Article 11.4.2. have not been complied with for seven years;

ii) 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;

OR

b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

and all BSE *cases*, as well as:

– all cattle 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 are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The Member Country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.4.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 11.4.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

For all commodities from cattle not listed in point 1 of Article 11.4.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.4.3.

Article 11.4.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case

For cattle selected for export

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)iii) of Article 11.4.3.;
2) 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.

Article 11.4.8.

Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.4.4.;
2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.4.4.;
3) cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.4.9.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
2) all BSE *cases*, as well as:
    a) all cattle 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

b) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

3) cattle selected for export:

a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;

b) 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 was effectively enforced.

Article 11.4.10.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions in Article 11.4.3.;

2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;

3) in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived 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.

Article 11.4.11.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.4.4.;

2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;

3) cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the tissues listed in points 1 and 2 of Article 11.4.14.,

b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 11.4.12.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the cattle from which the *fresh meat* and *meat products* originate:

a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

b) passed ante- and post-mortem inspections;

c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
   a) the tissues listed in points 1 and 3 of Article 11.4.14.,
   b) nervous and lymphatic tissues exposed during the deboning process,
   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.4.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves

1) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.4.3., but where there has been an indigenous *case* of BSE, should not be traded if such products were derived from cattle born before 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.
2) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 11.4.4. and 11.4.5. should not be traded between countries.

Article 11.4.14.

Recommendations on commodities that should not be traded

1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.4.4. and 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
2) From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 11.4.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
3) From cattle that were at the time of *slaughter* over 12 months of age originating from a country, *zone* or *compartment* defined in Article 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

Article 11.4.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2) they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that
   a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;
   b) the bones have been subjected to a process which includes all of the following steps:
      i) degreasing,
      ii) acid demineralisation,

iii) acid or alkaline treatment,

iv) filtration,

v) sterilisation at ≥138°C for a minimum of 4 seconds,

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.4.16.

Recommendations for the importation of tallow (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante- and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.4.14.

Article 11.4.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.4.15.

Article 11.4.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the tallow derivatives originate from a country, zone or *compartment* posing a negligible BSE risk; or

2) they are derived from tallow meeting the conditions referred to in Article 11.4.16.; or

3) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 11.4.19.

Procedures for the reduction of BSE infectivity in meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

1) The raw material should be reduced to a maximum particle size of 50 mm before heating.

2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.20.

Surveillance: introduction

1) Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), *surveillance* for BSE may have one or more goals:
   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;
   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;
   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
   d) supporting a claimed BSE status;
   e) gaining or regaining a higher BSE status.
2) When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:
   a) cattle not exposed to the infective agent;
   b) cattle exposed but not infected;
   c) infected cattle, which may lie within one of three stages in the progress of BSE:
      i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;
      iii) the smallest number will show clinical signs.
3) The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a *surveillance* programme but should be determined in accordance with all the factors listed in Article 11.4.2. The *surveillance* programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.
4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for *surveillance* purposes:
   a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
   b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);
   c) cattle over 30 months of age which are found dead or killed on farm, during transport or at an *abattoir* (fallen stock);
   d) cattle over 36 months of age at routine *slaughter*.
5) A gradient is used to describe the relative value of *surveillance* applied to each subpopulation. *Surveillance* should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Articles 11.4.20. to 11.4.22.
6) When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 11.4.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

   Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle *animals* on a daily basis. Since BSE causes no pathognomonic clinical signs, all Member Countries with cattle populations will observe individual *animals* displaying clinical signs consistent with BSE. It should be recognised that *cases* may display only some of these signs, which may also vary in severity, and such *animals* should still be investigated as potential BSE affected *animals*. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

   This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such *animals* will depend on the ongoing owner/veterinarian awareness programme. This and the

quality of the investigation and *laboratory* examination systems (Article 11.4.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

   These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

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

   These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

   Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 11.4.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member Country should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

The approach assigns ‘point values’ to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A *surveillance* strategy should be designed to ensure that samples are representative of the *herd* of the country, *zone* or *compartment*, 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 should be fully documented, and the documentation retained for seven years.

The points targets and *surveillance* point values in this chapter were obtained by applying the following factors to a statistical model:

1) the design prevalence for Type A or Type B *surveillance*;

2) a confidence level of 95%;
3) the pathogenesis, and pathological and clinical expression of BSE:
   a) sensitivity of diagnostic methods used;
   b) relative frequency of expression by age;
   c) relative frequency of expression within each subpopulation;
   d) interval between pathological change and clinical expression;
4) demographics of the cattle population, including age distribution and population size;
5) influence of BSE on culling or attrition of *animals* from the cattle population via the four subpopulations;
6) percentage of infected *animals* in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect *animals* provide many times more information than samples from healthy or dead-of-unknown-cause *animals*, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

7) cattle population numbers stratified by age;

8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter utilises Tables 1 and 2 to determine a desired *surveillance* points target and the point values of *surveillance* samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a Member Country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, *animals* from the other subpopulations should be tested.

1. Type A surveillance

The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. Type B surveillance

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

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.4.3.) to confirm the conclusions of the *risk assessment*, 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, *zones* or *compartments* of controlled BSE risk status (Article 11.4.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3. Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be

estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500
90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,300	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the *animals* that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range

comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Member Countries should sample at least three of the four subpopulations.

Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.

Surveillance subpopulation			
Routine slaughter[1]	**Fallen stock[2]**	**Casualty slaughter[3]**	**Clinical suspect[4]**
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			
0.0	0.1	0.2	45

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.4.23.

BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

1. Entry assessment

Entry assessment consists of assessing the likelihood that a BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with a BSE agent:

a) *meat-and-bone meal* or *greaves*;

b) live *animals*;

c) animal feed and feed ingredients;

d) products of animal origin for human consumption.

2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

a) epidemiological situation concerning BSE agents in the country or *zone*;

b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

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

d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous *case* born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.4.24.

The potential for the entry of the BSE agent through the importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 11.4.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the likelihood of entry of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

Evidence required:

– Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
– Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
– Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past eight years.
– Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
– Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
– Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 11.4.25.

The potential for the entry of the BSE agent through the importation of live animals potentially infected with BSE

Assumptions:

– Countries which have imported ruminants from countries infected with BSEs are more likely to experience BSE.
– Cattle pose the only known risk although other species are under study.

– *Animals* imported for breeding may pose a greater risk than *animals* imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than *animals* imported for *slaughter*.
– Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
– Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: Have live *animals* been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:
– country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
– feeding and management of the *animals* in the country of origin;
– use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
– species;
– dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
– age at *slaughter*.

Evidence required:
– Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
– Documentation describing origins, species and volume of imports.
– Documentation describing the fate of imported *animals*, including their age at *slaughter*.
– Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.26.

The potential for the entry of the BSE agent through the importation of products of animal origin potentially infected with BSE

Assumptions:
– Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
– Countries which have imported products of animal origin from countries with BSEs are more likely to experience BSE.
– Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
– Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: What products of animal origin have been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:
– the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.4.14.);
– country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
– feeding and management of the *animals* in the country of origin;
– use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
– species;
– dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
– age at *slaughter*.

Evidence required:

– Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
– Documentation describing origins, species and volume of imports.
– Documentation describing the end use of imported animal products, and the disposal of waste.
– Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.27.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin

Assumptions:

– That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
– That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
– Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.4.3. and 11.4.4.)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.4.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

– BSE has a long *incubation period* and insidious onset of signs, so *cases* may escape detection.

– Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.

– Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.

– BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
– BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.4.19.
– BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called ‘Specified Risk Materials’, or SRM).

Question to be answered: How has animal waste been processed over the past eight years?

Rationale: If potentially infected *animals* or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilised in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

– Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

– Documentation describing the definition and disposal of specified risk material, if any.

– Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

– Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

– Documentation describing monitoring and enforcement of the above.

Article 11.4.29.

Conclusions of the risk assessment

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.

1 See point 4) of Article 11.4.21.

2 See point 3) of Article 11.4.21.

3 See point 2) of Article 11.4.21.

4 See point 1) of Article 11.4.21.

第 11.4 章

牛海綿状脳症

第 11.4.1 条

一般規定及び安全物品

本章の勧告は、牛（*Bos taurus* 及び *B. indicus*）において牛海綿状脳症（BSE）の病原因子が存在していることに関連する人及び動物の衛生リスクの管理のみを意図するものである。BSE リスクステータスの認定に当たっては、全ての牛群で低い確率で自然発生すると考えられている「非定型 BSE」を除外する。

1) 次に掲げる物品及びこれらの物品から生産された製品であって牛の他の組織を含まないものの輸入又は経由の承認に際して、獣医当局は、輸出国、地域又はコンパートメントの牛群の BSE リスクステータスにかかわらず、BSE に関連するいかなる条件も要求しないものとする。

   a) 乳及び乳製品

   b) 精液並びに国際受精卵移植協会の勧告に従い採取及び処理された体内採取牛受精卵

   c) 獣皮及び原皮

   d) 獣皮及び原皮のみで製造されたゼラチン及びコラーゲン

   e) 不溶性不純物が最大でも重量の 0.15％の獣脂及びこの獣脂から作られる派生物

   f) 第 2 リン酸カルシウム（たん白質又は脂を含まないもの）

   g) 骨を含まない骨格筋（機械的除去肉を除く。）であって、と畜前に圧縮空気又はガスを頭蓋腔に注入する装置を用いたスタンニング、又はピッシングを受けていない牛から生産され、と畜前後の検査に合格し、第 11.4.14 条に掲げる組織による汚染を避ける製造されたもの

   h) 血液及び血液副産物であって、と畜前に圧縮空気又はガスを頭蓋腔に注入する装置を用いたスタンニング、又はピッシングを受けていない牛由来のもの

2) 本章に掲げる以外の物品の輸入又は経由を承認する場合には、獣医当局は、輸出国、地域又はコンパートメントの牛群の BSE リスクステータスに応じた BSE に関連する本章に規定される条件を要求するものとする。

3) 本章に規定される条件に従って物品の輸入を承認する場合には、輸入国のリスクステータスは、輸出国、地域又はコンパートメントの BSE リスクステータスによる影響を受けない。

診断法の基準は、陸生マニュアルに規定される。

第 11.4.2 条

国、地域又はコンパートメントの牛群の BSE リスクステータス

国、地域又はコンパートメントの牛群の BSE リスクステータスは、次に掲げる基準に基づき決定されるものとする。

1) 陸生規約の規定に基づく、BSE の発生に関係する可能性のあるすべての要素及びそれらの歴史的展望を同定するリスク評価の結果。加盟国は、状況が変化しているかどうかを決定するため当該リスク評価を毎年見直すものとする。

a) 侵入評価

侵入評価は、次に掲げる事項を考慮して、BSE の病原因子が、当該国、地域もしくはコンパートメントにそれに汚染したおそれのある物品を通じて導入される又は当該国、地域もしくはコンパートメントにすでに存在している可能性の評価からなる。

i) 当該国、地域又はコンパートメントの土着の反すう動物群における BSE 病原因子の有無。存在する場合には、その存在に関する検証結果

ii) 土着の反すう動物群からの肉骨粉又は獣脂かすの生産

iii) 輸入された肉骨粉又は獣脂かす

iv) 輸入された牛、めん羊及び山羊

v) 輸入された動物飼料及び飼料添加物

vi) 人の消費のために輸入された反すう動物由来の生産物であって、第 11.4.14 条に掲げる組織が含まれ、牛に給餌されたおそれがあるもの

vii) 牛に投与されることを目的として輸入された反すう動物由来の生産物

当該評価を実施する場合には、上に規定される物品の廃棄に関するサーベイランスその他の疫学的調査結果が考慮されるものとする。

b) 暴露評価

侵入評価がリスク要因を同定した場合には、牛が BSE の病原因子へ暴露している可能性に関する評価を含む暴露評価が、次に掲げる事項を考慮して実施されるものとする。

i) 反すう動物由来の肉骨粉もしくは獣脂かす又はこれらに汚染された飼料もしくは飼料添加物の牛の摂取による BSE の病原因子の循環及び増幅

ii) 反すう動物のと体（死亡家畜を含む。）、副産物及びと畜場廃棄物の利用、化製処理のパラメータ並びに飼料製造の方法

iii) 反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌の有無。これ

には飼料の交差汚染を防止する措置も含まれる。

iv) 牛群に対して実施されたこれまでの BSE サーベイランスの水準及び当該サーベイランスの結果

2) 獣医師、農家並びに牛の輸送、販売及びと畜に従事する者を対象とする認知プログラムが実施中であり、同プログラムにおいて、第 11.4.20 条から第 11.4.22 条までに規定される標的亜群において、BSE に該当する臨床所見を示すすべての症例を報告するよう奨励していること

3) BSE に該当する臨床所見を示すすべての牛の義務的な通報及び検査

4) 陸生マニュアルに基づいて検査所で実施される、前述のサーベイランス及びモニタリングシステムの枠組で収集された脳その他の組織の検査

リスク評価によってリスクが無視できることが示される場合には、当該加盟国は、第 11.4.20 条から第 11.4.22 条までの規定に従い、タイプ B のサーベイランスを実施するものとする。

リスク評価によってリスクが無視できることが示されない場合には、当該加盟国は、第 11.4.20 条から第 11.4.22 条までの規定に従い、タイプ A のサーベイランスを実施するものとする。

第 11.4.3 条

無視できる BSE のリスク

国、地域又はコンパートメントの牛群に由来する物品は、以下の条件を満たす場合には、BSE の病原因子を伝播する無視できるリスクをもたらす。

1) これまでの及び現存のリスク要因を同定するために、第 11.4.2 条第 1 号に規定されるリスク評価が実施されており、当該加盟国が、以下に規定される定められた期間、同定されたそれぞれのリスクを管理するため、適切な特定措置がとられていることを証明していること。

2) 当該加盟国が、第 11.4.20 条から第 11.4.22 条に従いタイプ B のサーベイランスが実施され、表 1 において該当する目標ポイントが満たされていることを証明していること。

3) かつ

a) BSE の症例がないこと、又は発生がある場合には、すべての BSE 症例が輸入されたものであり、完全に処分されていることが証明されており、次に掲げる要件を満たしていること。

i) 少なくとも 7 年間、第 11.4.2 条第 2 号から第 4 号までの基準が満たされていること。

ii) 少なくとも 8 年間、反すう動物由来の肉骨粉又は獣脂かすが反すう動物に給餌されていないことを、交差汚染に対するそれを含めた適切な水準の管理及び検査を通じて証明されていること。

又は、

b) 土着の症例がある場合には、すべての土着の症例が 11 年よりも前に出生しており、及び、

i) 少なくとも 7 年間、第 11.4.2 条第 2 号から第 4 号までの基準が満たされていること。

ii) 少なくとも 8 年間、反すう動物由来の肉骨粉又は獣脂かすが反すう動物に給餌されていないことを、交差汚染に対するそれを含めた適切な水準の管理及び検査を通じて証明されていること。

iii) すべての BSE 症例、及び、

- 出生後最初の 1 年間に、1 歳に至るまでの BSE 症例と同居したことがあり、その間、汚染していた可能性のある同一飼料を給餌されていたことが調査で示されているすべての牛、又は

- 調査の結果が確定していない場合には、BSE 症例と同一群で、当該症例の出生の前後 12 か月以内に生まれたすべての牛

上記の牛が、当該国、地域又はコンパートメントで生きている場合には永続的に同定され、その移動が管理され、と畜された又は死亡した場合には、完全に処分されていること。

当該加盟国又は地域は、提出された証拠が OIE に受理されてはじめて無視できるリスクのリストに含まれることになる。当該リストの維持には、前 12 ヶ月のサーベイランスの結果及び飼料管理に関する情報が毎年再提出されることを必要とし、疫学的状況その他有意な事象の変化は第 1.1 条の要件に従い OIE に報告しなければならない。

第 11.4.4 条

管理された BSE のリスク

国、地域又はコンパートメントの牛群に由来する物品は、以下の条件を満たす場合には、BSE の病原因子を伝搬する管理されたリスクをもたらす。

1) これまでの及び現存のリスク要因を同定するために、第 11.4.2 条第 1 号に規定されるリスク評価が実施されており、当該加盟国が、すべての同定されたリスクを管理するため、適切な措置がとられていることを証明しているが、これらの措置が定められている期間実施されていないこと。

2) 当該加盟国が、第 11.4.20 条から第 11.4.22 条までに従いタイプ A のサーベイランスを実施しており、表 1 において該当する目標ポイントが満たされていること。目標ポイントが満たされている場合には、タイプ A のサーベイランスに代えてタイプ B のサーベイランスを行うことができる。

3) かつ

a) BSE の症例がないこと、又は発生がある場合には、すべての BSE 症例が輸入されたものであり、完全に処分されていることが証明されており、第 11.4.2 条第

2 号から第 4 号までの基準が満たされており、並びに反すう動物由来の肉骨粉又は獣脂かすが反すう動物に給餌されていないことが、交差汚染に対するそれを含めた適切な水準の管理及び検査を通じて証明されているが、次の 2 つの条件のうち一つでも該当していること。

i) 第 11.4.2 条第 2 号から第 4 号までの基準を満たす期間が 7 年間に達していない。

ii) 反すう動物由来の肉骨粉又は獣脂かすの反すう動物への給餌に対する管理が 8 年間実施されていることを証明することができない。

又は

b) 土着の BSE の症例があり、第 11.4.2 条の第 2 号から第 4 号までの基準が満たされており、反すう動物由来の肉骨粉又は獣脂かすが反すう動物に給餌されていないことを、交差汚染に対するそれを含めた適切な水準の管理及び検査を通じて証明されていること。

さらに、すべての BSE 症例、及び、

- 出生後最初の 1 年間に、1 歳に至るまでの BSE 症例と同居したことがあり、その間、汚染していた可能性のある同一飼料を給餌されていたことが調査で示されているすべての牛、又は

- 調査の結果が確定していない場合には、BSE 症例と同一群で、出生の前後 12 か月以内に生まれたすべての牛

上記の牛が、当該国、地域又はコンパートメントで生きている場合には、永続的に同定され、その移動が管理され、と畜された又は死亡した場合には、完全に処分されていること。

当該加盟国又は地域は、提出された証拠が OIE に受理されてはじめて管理されたリスクのリストに含まれることになる。当該リストの維持には、前 12 か月間のサーベイランスの結果及び飼料管理に関する情報が毎年再提出されることを必要とし、疫学的状況その他有意な事象の変化は第 1.1 章の要件に従い OIE に報告しなければならない。

第 11.4.5 条

不明の BSE リスク

国、地域又はコンパートメントの牛群は、他の分類の要件を満たしていることを証明できない場合には、不明の BSE リスクをもたらす。

第 11.4.6 条

無視できる BSE リスクをもたらす国、地域又はコンパートメントからの牛由来物品の輸入に関する勧告

<u>第 11.4.1 条第 1 号に含まれない牛由来のすべての物品について</u>

獣医当局は、当該国、地域又はコンパートメントが第 11.4.3 条の要件を満たしている

ことを証明する国際獣医証明書の提示を要求するものとする。

第 11.4.7 条

無視できる BSE リスクをもたらす土着の症例がある国、地域又はコンパートメントからの牛の輸入に関する勧告

輸出用に選定された牛について

獣医当局は、当該動物が次に掲げる要件を満たしていることを証明する国際獣医証明書の提示を求めるものとする。

1) それが第 11.4.3 条第 3 号 b の iii に規定されるような暴露牛でないことを証明し得る恒常的な個体識別システムにより同定されていること。

2) 反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌禁止が効果的に施行された日より後に生まれたこと。

第 11.4.8 条

管理された BSE リスクをもたらす国、地域又はコンパートメントからの牛の輸入に関する勧告

牛について

獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該国、地域又はコンパートメントが第 11.4.4 条に掲げる条件を満たしていること。

2) 輸出のために選定された牛が、第 11.4.4 条の第 3 号 b に規定されるような暴露牛でないことを証明し得る恒常的な個体識別システムにより同定されていること。

3) 輸出のために選定された牛が、反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌禁止が効果的に施行された日付より後に生まれたこと。

第 11.4.9 条

不明の BSE リスクをもたらす国、地域又はコンパートメントからの牛の輸入に関する勧告

牛について

獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌が禁止されており、当該禁止が効果的に施行されていること。

2) すべての BSE 症例、及び、

   a) 出生後最初の 1 年間に、1 歳に至るまでの BSE 症例と同居したことがあり、その間、汚染していた可能性のある同一飼料を給餌されていたことが調査で示さ

れているすべての牛、又は

b) 調査の結果が確定していない場合には、BSE 症例と同一群で、当該症例の出生の前後 12 か月以内に生まれたすべての牛

上記の牛が、当該国、地域又はコンパートメントで生きている場合には、永続的に同定され、その移動が管理され、と畜された又は死亡した場合には、完全に処分されていること。

3) 輸出のために選定された牛は、

a) 上記第 2 号に規定されるような暴露牛でないことを証明し得る恒常的な個体同定システムにより同定されていること。

b) 反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌禁止が効果的に施行された日の少なくとも 2 年後に生まれていること。

第 11.4.10 条

無視できる BSE リスクをもたらす国、地域又はコンパートメントからの肉及び肉製品の輸入に関する勧告

牛の生鮮肉及び肉製品（第 11.4.1 条第 1 号に掲げるものを除く。）について

獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該国、地域又はコンパートメントが第 11.4.3 条の条件を満たしていること。

2) 当該生鮮肉及び肉製品の由来する牛が、と畜前後の検査に合格していること。

3) 土着の発生があった無視できるリスクの国にあっては、当該生鮮肉及び肉製品の生産のために供された牛が、反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌禁止が効果的に施行された日より後に生まれたこと。

第 11.4.11 条

管理された BSE リスクをもたらす国、地域又はコンパートメントからの肉及び肉製品の輸入に関する勧告

牛の生鮮肉及び肉製品（第 11.4.1 条第 1 号に掲げるものを除く。）について

獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該国、地域又はコンパートメントが第 11.4.4 条の条件を満たしていること。

2) 当該生鮮肉及び肉製品の由来する牛が、と畜前後の検査に合格していること。

3) 輸出が予定されている生鮮肉及び肉製品の生産に供される牛は、と畜前に圧縮空気又はガスを頭蓋腔に注入する装置を用いたスタンニング、又はピッシングを受けていないこと。

4) 当該生鮮肉及び肉製品が、次に掲げる物を含まない又はそれに汚染されないことを

保証される方法により、生産され、取り扱われていること。

a) 第 11.4.14 条第 1 号及び第 2 号に掲げる組織

b) 30 か月齢を超える牛の頭蓋及びせき柱から機械的に除去された肉

第 11.4.12 条

不明のリスクをもたらす国、地域又はコンパートメントからの肉及び肉製品の輸入に関する勧告

牛の生鮮肉及び肉製品（第 11.4.1 条第 1 号に掲げるものを除く。）について

獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該生鮮肉及び肉製品の由来する牛が次の要件を満たしていること。

a) 反すう動物に由来する肉骨粉又は獣脂かすが給餌されていないこと。

b) と畜前後の検査に合格していること。

c) と殺前に圧縮空気又はガスを頭蓋腔に注入する装置を用いたスタンニング、又はピッシングを受けていないこと。

2) 当該生鮮肉及び肉製品が、次に掲げる物を含まない又はそれに汚染されないことを保証される方法により、生産され、取り扱われていること。

a) 第 11.4.14 条第 1 号及び第 2 号に掲げる組織

b) 脱骨過程でさらされた神経及びリンパ組織

c) 12 か月齢を超える牛の頭蓋及びせき柱から機械的に除去された肉

第 11.4.13 条

反すう動物由来の肉骨粉又は獣脂かすに関する勧告

1) 反すう動物由来の肉骨粉もしくは獣脂かす又はそれらの生産物を含む物品であって、第 11.4.3 条に規定される国、地域又はコンパートメントで、BSE の土着の症例があった場所を原産とするものは、当該生産物が、反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給餌禁止が効果的に施行された日より前に生まれた牛に由来する場合には、貿易しないものとする。

2) 反すう動物由来の肉骨粉もしくは獣脂かす又はそれらの生産物を含む物品であって、第 11.4.4 条及び第 11.4.5 条に規定される国、地域又はコンパートメントを原産とするものは、国間の貿易をしないものとする。

第 11.4.14 条

非貿易物品に関する勧告

1) 第 11.4.4 条及び第 11.4.5 条に規定される国、地域又はコンパートメントを原産と

し、あらゆる月齢の牛に由来する次に掲げる物品及びそれらに汚染されたいかなる物品も、食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品及び医用機器の製造に供する目的で貿易しないものとする：扁桃及び回腸遠位部。また、これらの物品を用いて製造されたたん白質製品、食品、飼料、肥料、化粧品、医薬品又は医用機器（本章の他の条に含まれるものを除く。）についても貿易しないものとする。

2) 第 11.4.4 条に規定される国、地域又はコンパートメントを原産とし、と畜時に 30 か月齢を超える牛に由来する次に掲げる物品及びそれらに汚染されたいかなる物品も、食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品及び医用機器の製造に供する目的で貿易しないものとする：脳、眼、せき髄、及び頭蓋及びせき柱。また、これらの物品を用いて製造されたたん白質製品、食品、飼料、肥料、化粧品、医薬品又は医用機器（本章の他の条に含まれるものを除く。）についても貿易しないものとする。

3) 第 11.4.5 条に規定される国、地域又はコンパートメントを原産とし、と畜時に 12 か月齢を超える牛に由来する次に掲げる物品及びそれらに汚染されたいかなる物品も、食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品及び医用機器の製造に供する目的で貿易しないものとする：脳、眼、せき髄、及び頭蓋及びせき柱。また、これらの物品を用いて製造されたたん白質製品、食品、飼料、肥料、化粧品、医薬品又は医用機器（本章の他の条に含まれるものを除く。）もまた貿易しないものとする。

第 11.4.15 条

骨から製造され、食品もしくは飼料、化粧品、生物学的製剤を含む医薬品又は医用機器に供することを目的とするゼラチン及びコラーゲンの輸入に関する勧告

輸入国の獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該物品は、無視できる BSE リスク国、地域又はコンパートメントに由来すること。

又は

2) 当該物品は、管理された又は不明の BSE リスク国、地域もしくはコンパートメント原産であること、と畜前後の検査に合格した牛に由来すること、並びに次に掲げる要件を満たしていること。

a) 頭蓋及びと畜時に 30 か月齢を超えている牛のせき柱が除かれていること。

b) 当該骨が、次に掲げる処置をすべて含む処理を受けていること。

i) 脱脂

ii) 酸による脱灰

iii) 酸又はアルカリ処理

iv) 濾過

v) 138℃を超える温度で 4 秒以上の消毒

又は、（高圧熱処理などの）感染性の低減に関して同等以上の処理

第 11.4.16 条

食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医用機器に供することを目的とする獣脂（第 11.4.1 条に規定されるものを除く。）の輸入に関する勧告

輸入国の獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該獣脂は、無視できる BSE リスク国、地域又はコンパートメントに由来すること。又は、

2) 当該獣脂は、管理された BSE リスク国、地域又はコンパートメント原産であること、と畜前後の検査に合格した牛に由来すること、並びに第 11.4.14 条の第 1 号及び第 2 号に掲げる組織を用いて製造されていないこと。

第 11.4.17 条

食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医用機器に供することを目的とする第 2 リン酸カルシウム（第 11.4.1 条に規定されるものを除く。）の輸入に関する勧告

輸入国の獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該第 2 リン酸カルシウムは、無視できる BSE リスクを持つ国、地域又はコンパートメントに由来すること。又は

2) 当該第 2 リン酸カルシウムは、管理された又は不明の BSE リスクを持つ国、地域又はコンパートメント原産であり、第 11.4.15 条に従い生産された骨ゼラチンの副産物であること。

第 11.4.18 条

食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医用機器に供することを目的とする獣脂派生品（第 11.4.1 条に規定される獣脂の派生品を除く。）の輸入に関する勧告

輸入国の獣医当局は、次に掲げる事項を証明している国際獣医証明書の提示を求めるものとする。

1) 当該獣脂派生品は、無視できる BSE リスク国、地域又はコンパートメントに由来すること、又は

2) 当該獣脂派生品は、第 11.4.16 条に掲げる条件を満たしている獣脂に由来していること、又は

3) 当該獣脂派生品は、高温高圧を利用した加水分解、鹸化又はエステル交換によって生産されていること。

第 11.4.19 条

肉骨粉中の BSE 感染性の低減方法

次に掲げる方法が、反すう動物のたん白質を含む肉骨粉の製造過程において、存在する可能性がある伝達性海綿状脳症病原因子の感染性を低減するために使用されるものとする。

1) 加熱前に、当該原料は、最大粒子サイズが 50㎜ になるまで粉砕されていること。

2) 当該原料が、133℃を下回らない温度で最低 20 分間、絶対気圧 3 気圧の湿熱条件下で加熱されていること。

第 11.4.20 条

サーベイランス：序論

1) 国、地域又はコンパートメントの牛海綿状脳症（BSE）に関連するリスク分類に応じて、BSE のサーベイランスは、次に掲げるひとつ以上の目的を有する。

   a) 国、地域又はコンパートメントにおける事前に決定された有病率での BSE の検出

   b) 国、地域又はコンパートメントにおける BSE の状況変化のモニタリング

   c) 監査と併せて、給餌禁止その他のリスク低減措置の有効性のモニタリング

   d) 申請のあった BSE ステータスの裏付け

   e) より高い BSE ステータスの取得又は再取得

2) 国又は地域に BSE の病原因子が存在している場合には、牛群は、多い順に次に掲げる区分から構成されることになる。

   a) 感染性病原因子に暴露されていない牛

   b) 暴露されたが感染していない牛

   c) 感染牛、BSE の進行度合いに関する次の 3 段階のいずれかの状態にある

      i) ほとんどは最新の方法によって BSE が検知できる段階に達する前に、死亡又は殺されている。

      ii) 検査によって臨床症状を呈する前に BSE が検知可能な段階にまで進行している個体がいる。

      iii) 少数が臨床所見を呈している。

3) 国、地域又はコンパートメントの BSE ステータスは、サーベイランスプログラムを踏まえただけでは決定できないものであり、第 11.4.2 条に掲げる要素のすべてに

従って決定されるべきものである。サーベイランスプログラムは、前号の区分及びその中の感染牛の相対的分布に関連する診断の限界を考慮すること。

4) 前述に規定される区分内の BSE 病原因子の分布及び発現に照らして、次の４つの牛亜群がサーベイランス目的のため同定されている。

a) BSE に該当する行動又は臨床所見を呈している 30 か月齢を超える牛（臨床的疑い例）

b) 歩行困難、横臥、援助なしの起立及び歩行不可能な 30 か月齢を超える牛、並びに緊急と殺に送られた又はと畜前の検査で処分すべきとされた 30 か月齢を超える牛（偶発的もしくは緊急と殺牛又はダウナー牛）

c) 農場、輸送中又はと畜場で死亡又は殺されたことが認められた 30 か月齢を超える牛（死亡畜）

d) 36 ヶ月齢を超える健康と畜牛

5) それぞれの亜群に適用されるサーベイランスの相対的価値を示すために傾斜配分が使用されている。サーベイランスは、1 つ目の亜群に焦点を当てるものであるが、その他の亜群に対する検査は、当該国、地域又はコンパートメントの BSE の状況の正確な評価に有用である。このアプローチは、第 11.4.20 条から第 11.4.22 条までと矛盾するものではない。

6) サーベイランス戦略を定める場合には、当局は、農場のサンプルを得ることに本質的な困難があることを考慮し、それを克服する必要がある。これらの困難には、高額な費用、所有者を教育及び動機づける必要性、潜在的に消極的な社会経済的な意見への対応が含まれる。

第 11.4.21 条

サーベイランス：牛亜群の説明

1. <u>BSE に該当する行動又は臨床所見を呈している 30 か月齢を超える牛（臨床的疑い例）</u>

難治性の疾病にかかり、興奮しやすい、採乳時の持続的な蹴り、群内序列の変化、ドア、門又は柵でのためらいなどの進行性の行動の変化を呈する牛並びに感染症の症状なく進行性の神経症状を呈している牛は、検査の候補である。これらの行動の変化は、非常に捉えにくいものであるため、日常動物を扱う者によって確認されるのが最もよい。BSE は特徴的な臨床所見を引き起こさないので、牛群を持つすべての加盟国は、BSE に該当する臨床症状を呈する個別の動物を観察することになる。症例が、これらの症状のいくつかのみを呈する場合があり、その現れ方も多様であることを認識すべきであり、そのような動物は、潜在的な BSE に感染牛として調査されるものである。そのような疑わしい症例が発生する割合は、疫学的状況によってさまざまであり、したがって、確実に予想することはできない。

この亜集団は最も高い罹患率を示す。当該動物の正確な認識、報告及び分類は現在実施中の所有者/獣医師を対象とする認知プログラムに依存する。獣医当局によって実施される、この認知プログラムの実施並びに調査及び検査室内検査のシステム（第 11.4.2 条）の品質は、サーベイサランスシステムの信頼性のためには非常に

重要である。

2. 歩行困難、横臥、援助なしの起立及び歩行不可能な 30 か月齢を超える牛、並びに緊急と殺された又はと畜前の検査で処分すべきとされた 30 か月齢を超える牛（偶発的もしくは緊急と殺牛又はダウナー牛）

これらの牛は、BSE に該当するとは認識されない第 1 号に掲げる臨床所見のいくつかを示していたかもしれない。BSE が確認されている加盟国の経験は、この亜群が、2 番目に高い有病率を示すことを示している。この理由のため、本亜群は、BSE を検出するための対象として 2 番目に適切な群である。

3. 農場、輸送中又はと畜場で死亡又は殺されたことが認められた 30 か月齢を超える牛（死亡畜）

これらの牛は、死亡前に先に示した臨床所見のいくつかを示していたかもしれないが、BSE に該当するとは認識されていなかった。BSE が確認されている加盟国での経験は、この亜群が、3 番目に高い有病率を示すことを示している。

4. 36 か月齢を超える健康と畜牛

BSE が確認されている加盟国の経験は、この亜群が、最も低い有病率を示すことを示している。この理由のため、この亜群は、BSE を検出するための対象として適切性が最も低い。しかしながら、この亜群からの採材は、既知の種類、月齢構造及び地理的起源の牛群への継続的なアクセスを提供することから、動物間の流行の進展及び適用された管理措置の有効性のモニタリングの補助になるかもしれない。36 か月齢以下の健康と畜牛の検査は、相対的には非常に小さな値しか持たない（表２）。

第 11.4.22 条

サーベイランス活動

BSE に対するサーベイランス戦略を効率的に実施するため、加盟国は、成牛群の年齢分布及び当該国、地域又はコンパートメント内の年齢及び亜群により分類された BSE 試験牛の数についての文書記録又は信頼できる推計を利用することする。

当該手法は、サンプルが採取された亜群及びその亜群の感染牛を発見する可能性に基づいて、「評価点」をそれぞれのサンプルに割り当てるものである。サンプルに割り当てられる点数は、当該サンプルが採取される亜群及び採取された動物の年齢によって決定される。その後、当該合計点の累計は、国、地域又はコンパートメントの目標ポイントと定期的に比較される。

サーベイランス戦略は、サンプルが、国、地域又はコンパートメントの群を代表していることを保証され、生産のタイプ及び地理的位置といった牛群統計上の要因及び文化的固有の農業手法の潜在的な影響などの考慮が含まれるように設計されること。用いられた手法及び作成された前提条件は、十分に文書化され、当該文書は 7 年間保管されること。

本条の目標ポイント及びサーベイランスポイント数は、次に掲げる要因を統計モデルに適用することによって得られている。

1) タイプ A 及びタイプ B サーベイランスの有病率の決定

2) 95％の信頼性

3) BSE の病原論並びに病理学的及び臨床的発現

   a) 使用された診断方法の感度

   b) 年齢による発現の相対頻度

   c) それぞれの亜群の中の発現の相対頻度

   d) 病理学的変化と臨床的変化との差

4) 年齢分布及び牛の飼養規模を含む牛群統計

5) 4 つの亜群を通じた牛群からの動物の選抜除去又は自然減への BSE の影響

6) 牛群中の検出されていない感染牛の割合

当該方法は、牛群に関する非常に基礎的な情報を受け入れ、推定及び正確性の劣るデータとともに利用できるが、慎重な収集とデータの文書化によって、その価値は有意に高められる。臨床的に疑われる動物からのサンプルは、健康動物又は原因不明で死亡した動物からのサンプルの何倍もの情報を提供することから、入力データに注意を払うことによって、処理費用及び必要なサンプル数を大幅に減少させることができる。不可欠な入力データは次に掲げるものである。

7) 年齢別に区分された牛群数

8) 年齢及び亜群別に区分された BSE の検査を受けた牛の数

本条は、必要となるサーベイランス目標ポイント及び収集されたサーベイランスサンプルのポイント数を決定するため、表 1 及び表 2 を利用する。

国、地域又はコンパートメントの上記のそれぞれの亜群の中で、加盟国は、BSE 発生国又は地域から輸入されたことが確認可能な牛及び BSE 発生国又は地域に由来する潜在的汚染飼料を給餌された牛を対象に含むことができる。

すべての臨床的疑い例は、累計ポイントにかかわらず調査されるものである。加えて、他の亜群からの動物も検査されること。

1. <u>タイプ A サーベイランス</u>

   タイプ A サーベイランスの適用は、信頼率 95％で、設計有病率が、対象の国、地域又はコンパートメントの成牛群の少なくとも 10 万頭当たり 1 頭の BSE の検出を可能にする。

2. <u>タイプ B サーベイランス</u>

   タイプ B サーベイランスの適用は、信頼率 95％で、設計有病率が、対象の国、地域又はコンパートメントの成牛群の少なくとも 5 万頭当たり 1 頭の BSE の検出を可能にする。

タイプ B サーベイランスは、無視できる BSE リスクステータスの国、地域又はコンパートメント（第 11.4.3 条）が、例えば、措置の失敗を確認する可能性を最大化することを目標とするサーベイランスを通じて、同定されたリスク要因を軽減する措置の効率性を立証することによって、リスク評価の結果を確認するために実施することができる。

また、タイプ B サーベイランスは、管理された BSE リスクステータスの国、地域又はコンパートメント（第 11.4.4 条）が、タイプ A サーベイランスを使用した相当目標ポイントを達成した後で、タイプ A サーベイランスを通じて得た情報の信頼性を維持するために実施することができる。

3. 目標ポイントの選択

サーベイランスの目標ポイントは、表 1 から選択されるものである。表 1 には、さまざまな規模の成牛群に対する目標ポイントが示されている。国、地域又はコンパートメントの成牛群の大きさは、推計で出すか又は百万頭と設定することができる。統計学的理由から、百万は、母集団が大きくなってもサンプル数がそれ以上増加しない最小数である。

表 1　国、地域又はコンパートメントにおける成牛個体数別目標ポイント

国、ゾーン、コンパートメントの目標ポイント		
成牛の頭数 24 ヶ月齢超	タイプ A サーベイランス	タイプ B サーベイランス
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500
90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,300	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600

5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

4. 収集されたサンプルのポイント数の決定

収集されたサーベイランスサンプルのポイント数を決定するため表 2 を利用することができる。当該手法は、サンプルが収集された亜群及び採材された動物の年齢に基づく感染検出の可能性によって、それぞれのサンプルのポイント数を割り当てている。本手法は、第 1.4 章に規定されるサーベイランスの一般原則及び BSE の疫学を考慮している。

採材される動物の正確な年齢確認ができない場合もあることから、表 2 は、評価点を 5 つの年齢分類と組み合わせている。それぞれの分類のポイント数は、当該グループを構成する年齢範囲における平均として決定されている。当該年齢グループは、当該疾病の潜伏期に関する科学的知見及び世界の BSE の経験に従い、BSE を発現する相対的な可能性を基に選択されている。サンプルは、亜群及び年齢の組み合わせの中から収集することができるが、当該国、地域又はコンパートメントの牛群の動勢を反映しているべきである。また、加盟国は、4 つの亜群のうち少なくとも 3 群から採材するものとする。

表 2　所与の亜群及び年齢分類の動物から収集されたサンプルのサーベイランスポイント数

サーベイランス牛群			
通常と殺[1]	死亡牛[2]	事故死牛[3]	臨床的に疑わしい例[4]
1 歳以上 2 歳未満			
0.01	0.2	0.4	N/A
2 歳以上 4 歳未満（若齢成牛）			
0.1	0.2	0.4	260
4 歳以上 7 歳未満（中年成牛）			
0.2	0.9	1.6	750
7 歳以上 9 歳未満（高齢成牛）			
0.1	0.4	0.7	220
9 歳以上			
0.0	0.1	0.2	45

国、地域又はコンパートメントが、その牛群の動勢及び疫学的特性に基づいて、「偶発的もしくは緊急と殺牛又はダウナー牛」及び「死亡牛」の亜群の正確な区分けができないと判断した場合には、これらの亜群をひとつにすることもできる。その場合には、当該混合亜群のサーベイランスポイント数は、「死亡牛」のそれとなる。

収集されたサンプルの総数は、表 1 で決められた目標ポイントを達成するため、最長 7 年間の累計とすることができる。

サーベイランスポイントは、7 年間有効である（潜伏期間の 95 パーセンタイル）。

第 11.4.23 条

BSE リスク評価：序論

国又は地域の牛群の BSE リスクステータスを決定する第一段階は、BSE の発生に関係する可能性のあるすべての要素及びそれらに関する現在に至るまでの過去の経緯・状況を同定する陸生コード第 2 部に基づくリスク評価の実施（毎年見直す）である。

1. 侵入評価

   侵入評価は、BSE の病原因子が、それに汚染している可能性のある次に掲げる物品の輸入により、当該国、地域もしくはコンパートメントに導入される可能性の評価からなる。

   a) 肉骨粉及び獣脂かす

   b) 生きている動物

   c) 飼料及び飼料添加物

   d) 人の消費用の動物由来製品

2. 暴露評価

   暴露評価は、次に掲げる事項の考慮を通じた BSE の病原因子の牛に暴露する可能性の評価からなる。

   a) 当該国又は地域の BSE 病原因子に関する疫学的状況

   b) 反すう動物由来肉骨粉もしくは獣脂かす又はこれらに汚染された飼料もしくは飼料添加物の牛による摂取を通じた BSE の病原因子の循環及び増幅

   c) 反すう動物のと体（死亡畜を含む。）、副産物及びと畜場廃棄物の原産地及び利用、化製処理のパラメータ並びに飼料製造の方法

   d) 牛飼料の交差汚染を防止する措置を含む飼料規制の実施及び施行、飼料規制の施行日より後に生まれた土着の症例の徹底的な疫学的調査。

次に掲げる勧告は、獣医サービス部局によるリスク評価の実施を支援することを意図する。これらは、国単位での BSE リスク評価を実施する場合に、取り組む必要がある課題に関する指針を提供する。これらは、国の分類のための申請書を準備する場合の自己評価にも同じく適用される。これらの勧告は、国の評価のためのデータの提出のために使用される質問票でのより詳細な記述によって補完される。

第 11.4.24 条

肉骨粉又は獣脂かすの輸入を通じて BSE の病原因子が侵入する可能性

第 11.4.27 条に概説される暴露評価が、過去 8 年間、肉骨粉又は獣脂かすが意図的又は偶然に給餌されていないことを示している場合には、本条は該当しない。ただし、肉骨

粉又は獣脂かすが反すう動物に給餌されていないことを保証するため、現行の管理制度（関連法令を含む。）に関する文書が示されなければならない。

仮定：反すう動物由来の肉骨粉又は獣脂かすは、BSE の伝播における唯一重要な役割を担っている。

回答すべき質問：肉骨粉、獣脂かす又はいずれかを含む飼料が過去 8 年間輸入されていたのか。されていた場合、どこから、どれくらいの量か。

理論的解釈：肉骨粉、獣脂かす又は肉骨粉もしくは獣脂かすのいずれかを含む飼料の原産地に関する情報は、BSE 病原因子の侵入の可能性を評価するために必要である。高い BSE リスクの国を原産とする肉骨粉及び獣脂かすは、低いリスクの国のそれよりも高い拡散リスクを持つ。未知の BSE リスクの国を原産とする肉骨粉及び獣脂かすは、未知の侵入の可能性を持つ。

必要な証拠：

- 肉骨粉、獣脂かす又は肉骨粉もしくはそれらを含む飼料が輸入されていないとの主張を裏付ける文書、又は

- 肉骨粉、獣脂かす又はそれらを含む飼料が輸入されている場合には、原産国及びもし輸出国と異なる場合はそれに関する文書

- 過去 8 年間に輸入された肉骨粉、獣脂かす又はそれらを含む飼料の原産国別年間輸入量に関する文書

- 肉骨粉、獣脂かす又はそれらを含む飼料の（家畜の品種及び種類の根拠に関する）組成を記載した文書

- 肉骨粉、獣脂かす又はそれらを含む飼料の生産に使用された化製処理法が、BSE の病原因子が存在する場合に、それを不活化する又はその濃度を有意に減少させるとする理由の根拠となる生産国からの文書

- 輸入された肉骨粉及び獣脂かすの最終結末を記載した文書

第 11.4.25 条

BSE に感染している可能性を有している動物の輸入を通じた BSE の病原因子が侵入する可能性

仮定：

- BSE 汚染国から反すう動物を輸入している国は、比較的 BSE が発生しやすい。

- 他の種については検討中であるものの、牛は、唯一の既知のリスクである。

- 繁殖用に輸入された動物は、母子伝搬の仮定上のリスクがあること及びと畜のために輸入された動物よりも長い期間飼養されることから、と畜用に輸入された動物よりも大きなリスクをもたらす可能性がある。

- リスクは、原産国の BSE ステータスとの関連から、輸入の年月日の影響を受ける。

－　リスクは、輸入量に比例する（第 2.1.3 条）。

答えるべき質問：過去 7 年以内に動物が輸入されていたのか。

理論的解釈：侵入の可能性は次の項目に基づく。

－　原産国、より多くのデータが利用可能になることで変わる BSE ステータス。臨床症状の発見、後述するアクティブサーベイランス、地理的 BSE リスク評価によって変わりうる。

－　原産国における飼料給餌及び動物の飼養管理

－　臨床症状をもたらすリスクとならないような、輸入動物由来の物の使用。輸入動物のと畜、化製処理及び肉骨品への再利用は、たとえ肉骨粉及び獣脂かす又はそれらを含む飼料が輸入されていなかったとしても、土着の家畜の潜在的な暴露経路となり得る。

－　動物種

－　給餌方法によって一方のカテゴリーの暴露をより大きくしたことで、原産国における暴露の違いが生まれた場合、乳牛と肉牛の割合。

－　と畜時の月齢

必要な証拠：

－　輸入の原産国に関する文書。飼育された国、その国での飼育期間、生存中に飼育されたその他の国についても明確にされていること。

－　原産地、動物種及び輸入量を記載した文書

－　と畜時の月齢を含む輸入動物の最終結果を記載した文書

－　原産国の BSE ステータスに関する知見を積み重ねる観点から、リスクが定期的に見直されていることを証明する文書

第 11.4.26 条

BSE に感染している可能性のある動物由来製品の輸入を通じた、BSE の病原因子が侵入する可能性

仮定：

－　精液、受精卵、獣皮及び皮膚又は乳は、BSE 伝搬の重要な役割を担っているとは見なされない。

－　BSE 発生国から動物由来製品を輸入している国は、BSE が比較的発生しやすい。

－　リスクは、原産国の BSE ステータスとの関連から、輸入の年月日の影響を受ける。

－　リスクは輸入量に比例する（第 2.1.3 条）。

回答すべき質問：過去 7 年以内にどのような動物由来製品が輸入されていたのか。

理論的解釈：侵入の可能性は次の項目に基づく。

－ 動物由来製品の原料となった動物種、製品には BSE 感染性を含むことが知られている組織が含まれていたのか（第 11.4.14 条）。

－ 原産国、より多くのデータが利用可能になることで変わる BSE ステータス。臨床症状の発見、後述するアクティブサーベイランス、地理的 BSE リスク評価によって変わりうる。

－ 原産国における飼料給餌及び動物の飼養管理

－ 臨床症状をもたらすリスクとならないような、輸入製品由来の物の使用。輸入動物のと畜、化製処理及び肉骨品への再利用は、たとえ肉骨粉及び獣脂かす又はそれらを含む飼料が輸入されていなかったとしても、土着の家畜の潜在的な暴露経路となり得る。

－ 動物種

－ 給餌方法によって一方のカテゴリーの暴露をより大きくしたことで、原産国における暴露の違いが生まれた場合、乳牛と肉牛の割合。

－ と畜時の月齢

必要な証拠：

－ 輸入の原産国に関する文書。飼育された国、その国での飼育期間、生存中に飼育されたその他の国についても明確にされていること。

－ 原産地、動物種及び輸入量を記載した文書

－ と畜時の月齢を含む輸入動物の最終結果を記載した文書

－ 原産国の BSE ステータスに関する知見を積み重ねる観点から、リスクが定期的に見直されていることを証明する文書

第 11.4.27 条

反すう動物由来の肉骨粉又は獣脂かすの消費を通じた、牛が BSE の病原因子に暴露する可能性

仮定：

－ 反すう動物由来の肉骨粉又は獣脂かすの牛による消費が、BSE 伝播の唯一重要な役割を担っている。

－ 飼料に使用されている商業的に入手可能な動物由来製品が、反すう動物由来の肉骨粉又は獣脂かすを含んでいる可能性がある。

－ 乳及び血液は、BSE の伝搬の役割を担っているとは見なされない。

回答すべき質問：過去 8 年以内に反すう動物由来の肉骨粉又は獣脂かすが牛に給餌されていたのか。（第 11.4.3 条及び第 11.4.4 条参照）

理論的解釈：牛が、過去 8 年以内に、反すう動物由来の肉骨粉又は獣脂かすを含んでいる可能性のある動物由来製品（乳及び血液を除く。）を給餌されていない場合には、肉骨粉及び獣脂かすは、リスクとして見なされない。

第 11.4.28 条

動物廃棄物の由来、化製処理過程のパラメータ及び飼料の製造方法

仮定：

- BSE は長期の潜伏期間を持ち、症状の開始が潜行性である。このため症例が発見されない場合がある。

- 病状発現前の BSE の感染性は、いかなる方法によっても確実に検出することが不可能であり、とりわけ特定危険部位が除去されない場合には、それが化製処理に入り込む場合がある。

- 高力価の BSE 感染性を含有するおそれが最も高い組織（脳、脊髄、眼）は、人の消費用として摘出されることはないが、化製される場合はある。

- BSE が、突然死、慢性病又は横臥姿勢として表出し、死亡牛又は、人の食用には不適切であるとして廃棄処分が言い渡された原料として現れる場合がある。

- BSE の病原因子の化製処理における生残は、処理方法に影響を受ける。適切な化製処理過程は、第 11.4.19 条に記載されている。

- BSE の病原因子は、中枢神経系及び細網内皮組織（いわゆる「特定危険部位」又は SRM）の中に非常に高濃度で存在する。

回答すべき質問：過去 8 年間、動物廃棄物はどのように処理されていたのか。

理論的解釈：感染した可能性のある動物又は汚染した可能性のある物質が化製処理された場合には、肉骨粉が BSE 感染性を有しているリスクがある。

肉骨粉が飼料生産に利用されている場合には、交差汚染のリスクが存在する。

必要な証拠：

- 死亡牛及び人の消費に適さないとされた物質の回集及び廃棄を記載した文書

- もしあれば、特定危険部位の定義及び廃棄を記載した文書

- 化製処理過程並びに肉骨粉及び獣脂かすの生産に使用されたパラメータを記載した文書

- 使用される添加物の詳細を含む飼料生産の方法、あらゆる家畜用飼料における肉骨粉の使用の程度及び単胃動物用飼料に使用される添加物への牛飼料の交差汚染を防止する措置を記載した文書

－　上記事項のモニタリング及びその執行を記載した文書

第 11.4.29 条

リスク評価の結論

国又は地域の牛群における BSE の総合的なリスクは、BSE の感染性に対する、既知又は潜在的な暴露の水準及び動物への給餌法を通じた当該感染性の循環及び増幅される可能性と比例する。国又は地域の牛群に BSE リスクがないと結論付けるためのリスク評価のため、同定されたあらゆるリスクを管理するための適切な措置がとられていることを証明していること。

---

[1] 第 11.4.21 条第 4 項参照
[2] 第 11.4.21 条第 3 項参照
[3] 第 11.4.21 条第 2 項参照
[4] 第 11.4.21 条第 1 項参照

（仮抄訳）

加盟国の牛海綿状脳症リスクステータス評価に係る

OIE アドホックグループ報告書（抜粋）

パリ、2014 年 11 月 25-27 日

４．非定型 BSE を考慮した、BSE に係る陸生動物衛生規約第 11.4 章の見直し

グループは、BSE の陸生コード第 11.4 章において非定型 BSE を考慮すべきかどうか、どのように考慮すべきかを検討するため、いくつかの根本的問題に関する最新の科学的知見をまとめた。グループは、本件は２年前にも議論しており、2012 年 11 月の会議録で確認できることを言及した。また、内容を思案するため、科学委員会及び加盟国を招待した。

議論の結果、グループは、BSE リスクステータスの認定、維持及びサーベイランスへの影響を含め、BSE に係る陸生コード第 11.4 章において、非定型 BSE と従来の BSE を区別すべきとの意見で一致した。

第 11.4.25 条について、グループは、牛以外の反すう動物の輸入はリスクとされないことで意見が一致したので、反すう動物-反すう動物給餌禁止の記載を除き、本章全体において、反すう動物を cattle 又は bovine に入れ替えるよう提案する。繰り返すが、この変更は、本章の視点が反すう動物から牛に変わったことと一致している。

本章は次のとおり修正される。

<u>第 11.4.1 条：総則及び安全物品</u>

グループは、本章の勧告が非定型 BSE 及び従来の BSE 両方をカバーすることを明確にする。

<u>第 11.4.2 条：国、地域又はコンパートメントの牛群の BSE リスクステータス</u>

グループは、非定型 BSE がいかなる牛群においても同じ低い有病率で発生すると考えるべきとの意見で一致した。このため、グループは、リスク評価が従来の BSE 発生に係る潜在要因を考慮すべきことを明確にする。

侵入評価：従来の BSE の因子の有無を注意深く考慮すべきである。このため、グループは 1) a) i) をわずかに変えることを提案する。

暴露評価：全ての土着の牛群における非定型 BSE の低い有病率を考慮して、グループは、侵入評価に関わらず、全ての場合において暴露評価を実施するよう強調する。

サーベイランス：従来の BSE 発生が減少していることの今後のサーベイランスへの影響及び非定型 BSE の相対的重要性が増していることを考慮して、グループは、成牛群の規模毎のサーベイランス目標を再び設定することを含め、サーベイランスシステムを徹底

的に見直すべきであることを確認した。

グループは、非定型 BSE と従来の BSE を区別するための適当な試験について、現行の陸生マニュアルが情報を提供していないことを確認した。グループは、加盟国が BSE の OIE レファレンスラボラトリーの支援を受けて知見を立証するよう提言する。

このため、グループは、非定型 BSE と従来の BSE を区別することが可能な試験を考慮するため、陸生マニュアルの BSE 章を改正する必要があるかどうか、Biological Standard Commission と議論するよう、科学委員会に提案する。

<u>第 11.4.3 条：無視できる BSE のリスク</u>

グループは、第 11.4.2 条の要件が満たされ、適切な程度の規制が、反すう動物-反すう動物の給餌禁止が直近８年間有効であったことを保証する場合に限り、非定型 BSE の発生は（年齢、出生年に関わらず）公的リスクステータスに影響すべきでないとの意見で一致した。グループは、非定型 BSE が飼料給餌と関連しないので、BSE 症例のコホートの追跡は非定型 BSE 症例には適用されないことを明確にする。

<u>第 11.4.4 条：管理された BSE のリスク</u>

グループは、第 11.4.3 条と同じ変更を提案する。

<u>第 11.4.7 条：無視できる BSE リスクをもたらす土着の症例がある国、地域又はコンパートメントからの牛の輸入に関する勧告</u>

グループは、上記の変更に沿って、本勧告は、従来の BSE の土着の症例がある無視できる BSE リスクの国、地域又はコンパートメントに有効となることを明確にする。

<u>第 11.4.9 条：不明の BSE リスクをもたらす国、地域又はコンパートメントからの牛の輸入に関する勧告</u>

グループは、第 11.4.3 条に沿った変更を提案する。

<u>第 11.4.10 条：無視できる BSE リスクをもたらす国、地域又はコンパートメントからの肉及び肉製品の輸入に関する勧告</u>

グループは、従来の BSE の土着の症例が１件以上ある無視できる BSE リスクの国、地域又はコンパートメントに 3)の要件が適用されることを明確にする。

さらにグループは、非定型 BSE がもたらすリスクを考慮し、物品が、新たに用意する第 11.4.14 条の 4)に掲げる組織（96 か月超の牛の脳、眼、せき髄及び頭蓋）に汚染されていないことを保証する提言を提案する。

<u>第 11.4.13 条：反すう動物由来の肉骨粉又は獣脂かすに関する勧告</u>

グループは、全ての土着の牛群において非定型 BSE が存在しうることを確認し、反すう動物肉骨粉の貿易のリスクを議論した。グループは、給餌禁止が循環を防ぐ上で最も重要な低減措置であることを考慮しつつ、無視できる BSE リスクとして認められた国で、発生報告の有無に関わらず、反すう動物-反すう動物の給餌禁止が効果的に施行された後に生まれた牛由来であっても、反すう動物由来肉骨粉の貿易を制限することを提案する。

第 11.4.14 条：非貿易物品に関する勧告

グループは、どの牛群においても非定型 BSE が存在しうること、非定型 BSE 症例の年齢分布を考慮して、無視できる BSE リスク国の 96 か月齢（８歳）超の牛の脳、眼、せき髄及び頭蓋を貿易しないよう提言する。

第 11.4.16 条：食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医用機器に供することを目的とする獣脂（第 11.4.1 条に規定されるものを除く。）の輸入に関する勧告　及び　第 11.4.18 条：食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医用機器に供することを目的とする獣脂派生品（第 11.4.1 条に規定される獣脂の派生品を除く。）の輸入に関する勧告

第 11.4.14 条の変更を反映した、これら２条項の変更を提案する。

第 11.4.20 条：サーベイランス：序論

グループは、本条が非定型 BSE 及び従来の BSE 両方に有効となることを考慮した。

第 11.4.21 条：サーベイランス：牛亜群の説明

グループは、従来の BSE と非定型 BSE の違いが牛亜群の定義において記載されるだろうと見積もった。

1. BSE に該当する行動又は臨床所見を呈している 30 か月齢を越える牛(臨床的疑い例)

グループは、非定型は従来の BSE の臨床症状を示さないため、これを従来の BSE に限定すべきとの意見で一致した。

第 11.4.22 条：サーベイランス活動

グループは、従来の BSE の疫学の進展及び非定型サーベイランスの特異性を考慮して、統計モデルを徹底的に見直すべきであるとの意見で一致した。

グループは、BSE 統計モデルの見直しにあたって、以下の事項を考慮することを強調した。

-年齢及び規模による BSE 陽性の相対的リスクの再計算

-現行の対象規模は維持

-現行の目標有病率及びサーベイランスの利点の適正化

-95％の信頼性は維持

-少なくとも成牛群の 10 万頭当たり 1 頭の有病率の設定（現行のタイプ A サーベイランス）

-高齢牛のための重み付けの見直し

-若齢牛のサンプル収集は維持

-陽性数及びその年齢を含めた､全ての検査済み動物の欧州委員会データベース及び OIE

データベース

グループは、この会議から数週間後に BSE サーベイランスモデルを見直すことで意見が一致し、BSE 発生の推計に基づく新しいモデルを提案した。提案モデルの BSE サーベイランスポイント数は、すでに BSE リスクステータスを有する OIE 加盟国には適用されない。

グループは、サーベイランスの７年とは従来の BSE の潜伏期間の 95％パーセンタイルであることを確認した。しかしグループは、サーベイランスの継続の必要性に関して、その後もポイントを積み上げる可能性があることで意見が一致した。従来の BSE に関連して、７年という案は維持する。しかしグループは、非定型 BSE の潜伏期間が判明すれば、これを見直す必要が生じることで意見が一致した。

第 11.4.23 条：BSE リスク評価：序論

第 11.4.2 条の変更を反映し、用語を明確にするための変更を提案する。

第 11.4.24 条：肉骨粉又は獣脂かすの輸入を通じて BSE の病原因子が侵入する可能性

グループは、前の条項の変更提案に沿ってテキストを調節した。

第 11.4.25 条：BSE に感染している可能性を有している動物の輸入を通じた BSE の病原因子が侵入する可能性

グループは、本条において、牛以外の反すう動物の輸入はリスクとされないこと、従来の BSE 発生がある国からの輸入の場合、牛の輸入は従来の BSE の侵入リスクを有しうることを明確した。

グループは、疫学的な重要性は無視できるものされているため、仮定上の母子伝搬に関する記載は削除した。

第 11.4.26 条：BSE に感染している可能性のある動物由来製品の輸入を通じた、BSE の病原因子が侵入する可能性

グループは、前の条項と同じ変更に加えて、給餌禁止が行われていることから、乳牛の給餌方法に関する記載を削除することを提案する。

さらにグループは、本条が動物でなく動物由来製品の輸入に関するものであることから、飼育期間に関する記載を削除する。ただし、グループは、製品に BSE 感染性を有すると知られている組織を含むべきでないことも明確にする。

第 11.4.27 条：反すう動物由来の肉骨粉又は獣脂かすの消費を通じた、牛が BSE の病原因子に暴露する可能性

グループは、安全物品が第 11.4.1 条に明記されていることから、本条で乳及び血液だけを記載し続けるのは適当でないと考える。

第 11.4.28 条：動物廃棄物の由来、化製処理過程のパラメータ及び飼料の製造方法

グループは、最初から４つ目までは本条の目的とは関連のないことから削除することで意見が一致した。

グループは、中枢神経系のみを特定危険部位（SRM）とみなすため、細網内皮組織を BSE の病原因子が高濃度で存在する組織に含めることはできないと考え、これを除外する。

第 11.4.29 条：リスク評価の結論

グループは、従来の BSE に関するリスクと非定型 BSE に関するリスクを明確にする。

Annex XXI

NOTE:
The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- November 2014 report of the *ad hoc* Group on the Evaluation of Bovine Spongiform Encephalopathy Risk Status of Member Countries attached to the February 2015 report of the Scientific Commission

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions and safe commodities

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only. BSE includes 'classical' BSE and 'atypical' BSE, a condition believed to occur spontaneously in all cattle population at a similar low rate.

1) When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins;

   d) gelatine and collagen prepared exclusively from hides and skins;

   e) tallow with maximum level of insoluble impurities of 0.15 percent in weight and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat);

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14.;

   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*.

3) When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 11.4.2.

The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

Annex XXI (contd)

1) the outcome of a *risk assessment*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for 'classical' BSE occurrence and their historic perspective. Members should review the *risk assessment* annually to determine whether the situation has changed.

   a) Entry assessment

      Entry assessment consists of assessing, through consideration of the following, the likelihood that the 'classical' BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

      i) the presence or absence of the 'classical' BSE agent in the indigenous ~~ruminant~~ cattle population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

      ii) production of *meat-and-bone meal* or *greaves* from the indigenous ~~ruminant~~ cattle population;

      iii) imported *meat-and-bone meal* or *greaves*;

      iv) imported cattle~~, sheep and goats~~;

      v) imported animal feed and feed ingredients;

      vi) imported products of ~~ruminant~~ bovine origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;

      vii) imported products of ~~ruminant~~ bovine origin intended for *in vivo* use in cattle.

      The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

   b) Exposure assessment

      ~~If the entry assessment identifies a *risk* factor, a~~An exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

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

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

      iii) 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;

      iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.4.20. to 11.4.22.;

3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member should conduct Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22.

Article 11.4.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

1) a *risk assessment*, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

2) the Member has demonstrated that Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22. is in place and the relevant points target, in accordance with Table 1, has been met;

3) EITHER:

   a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as 'atypical' BSE and has been completely destroyed; and

      i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; ~~and~~

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

   OR

   b) if there has been an indigenous *case* of 'classical' BSE, every indigenous *case* was born more than 11 years ago; and

      i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; ~~and~~

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

      iii) all BSE *cases*~~,~~ have been completely destroyed;

      iv) for 'classical' BSE *cases* only ~~as well as~~:

         – all cattle 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 are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

      if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Annex XXI (contd)

The Member or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.4.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

1) a *risk assessment*, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;

2) the Member has demonstrated that Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;

3) EITHER:

   a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as 'atypical' BSE and has been completely destroyed, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

      i) the criteria in points 2 to 4 of Article 11.4.2. have not been complied with for seven years;

      ii) 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;

   OR

   b) there has been an indigenous *case* of 'classical' BSE, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and

      i) all BSE *cases*, have been completely destroyed;

      ii) for 'classical' BSE *cases* only ~~as well as~~:

         ~~i)~~ all cattle 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

         ~~ii)~~ if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

      if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The Member or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Annex XXI (contd)

Article 11.4.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 11.4.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

For all commodities from cattle not listed in point 1 of Article 11.4.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.4.3.

Article 11.4.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case of 'classical' BSE

For cattle selected for export

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~*animals*~~ cattle:

1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)~~iii)~~iv) of Article 11.4.3.;

2) 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.

Article 11.4.8.

Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.4.4.;

2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.4.4.;

3) cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Annex XXI (contd)

Article 11.4.9.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2) all BSE *cases*~~,~~ have been completely destroyed;

3) for 'classical' BSE *cases* only ~~as well as~~:

   a) all cattle 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

   b) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

4~~3~~) cattle selected for export:

   a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;

   b) 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 was effectively enforced.

Article 11.4.10.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions in Article 11.4.3.;

2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;

3) in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived 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.

Article 11.4.11.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.4.4.;

2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;

3) cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 2 of Article 11.4.14.,

   b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 11.4.12.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the cattle from which the *fresh meat* and *meat products* originate:

   a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

   b) passed ante- and post-mortem inspections;

   c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 3 of Article 11.4.14.,

   b) nervous and lymphatic tissues exposed during the deboning process,

   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.4.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves

1) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.4.3., but where there has been an indigenous *case* of BSE, should not be traded if such products were derived from cattle born before 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.

Annex XXI (contd)

2) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 11.4.4. and 11.4.5. should not be traded between countries.

Article 11.4.14.

Recommendations on commodities that should not be traded

1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.4.4. and 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

2) From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 11.4.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

3) From cattle that were at the time of *slaughter* over 12 months of age originating from a country, *zone* or *compartment* defined in Article 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

Article 11.4.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2) they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that

   a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;

   b) the bones have been subjected to a process which includes all of the following steps:

      i) degreasing,

      ii) acid demineralisation,

      iii) acid or alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.4.16.

Recommendations for the importation of tallow (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante- and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.4.14.

Article 11.4.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.4.15.

Article 11.4.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the tallow derivatives originate from a country, zone or *compartment* posing a negligible BSE risk; or

2) they are derived from tallow meeting the conditions referred to in Article 11.4.16.; or

3) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 11.4.19.

Procedures for the reduction of BSE infectivity in meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

1) The raw material should be reduced to a maximum particle size of 50 mm before heating.

2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Annex XXI (contd)

Article 11.4.20.

Surveillance: introduction

1) Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), *surveillance* for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;

   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

2) When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

   c) infected cattle, which may lie within one of three stages in the progress of BSE:

      i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

      iii) the smallest number will show clinical signs.

3) The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a *surveillance* programme but should be determined in accordance with all the factors listed in Article 11.4.2. The *surveillance* programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for *surveillance* purposes:

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

   b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);

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

   d) cattle over 36 months of age at routine *slaughter*.

5) A gradient is used to describe the relative value of *surveillance* applied to each subpopulation. *Surveillance* should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Articles 11.4.20. to 11.4.22.

6) When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 11.4.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

   Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all Members with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that *cases* may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious *cases* are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

   This subpopulation is the one exhibiting the highest prevalence of 'classical' BSE. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and *laboratory* examination systems (Article 11.4.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

   These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

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

   These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

   Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 11.4.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

Annex XXI (contd)

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A *surveillance* strategy should be designed to ensure that samples are representative of the *herd* of the country, *zone* or *compartment*, 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 should be fully documented, and the documentation retained for seven years.

The points targets and *surveillance* point values in this chapter were obtained by applying the following factors to a statistical model:

1) the design prevalence for Type A or Type B *surveillance*;

2) a confidence level of 95 percent;

3) the pathogenesis, and pathological and clinical expression of BSE:

   a) sensitivity of diagnostic methods used;

   b) relative frequency of expression by age;

   c) relative frequency of expression within each subpopulation;

   d) interval between pathological change and clinical expression;

4) demographics of the cattle population, including age distribution and population size;

5) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

6) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

7) cattle population numbers stratified by age;

8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter utilises Tables 1 and 2 to determine a desired *surveillance* points target and the point values of *surveillance* samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a Member may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

   The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95 %.

2. Type B surveillance

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

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.4.3.) to confirm the conclusions of the *risk assessment*, 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, *zones* or *compartments* of controlled BSE risk status (Article 11.4.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3. Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500
90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,000	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

Annex XXI (contd)

4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Members should sample at least three of the four subpopulations.

Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.

Surveillance subpopulation			
Routine slaughter[1]	**Fallen stock**[2]	**Casualty slaughter**[3]	**Clinical suspect**[4]
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			
0.0	0.1	0.2	45

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations ‘casualty or emergency slaughter, or downer cattle’ and ‘fallen stock’ is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of ‘fallen stock’.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.4.23.

BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

Annex XXI (contd)

1. Entry assessment

Entry assessment consists of assessing the likelihood that a 'classical' BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with it ~~a BSE agent~~:

a) *meat-and-bone meal* or *greaves*;

b) live animals;

c) animal feed and feed ingredients;

d) products of animal origin for human consumption.

2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of cattle to the agent of 'classical' or 'atypical' ~~the~~ BSE ~~agent to cattle~~, through a consideration of the following:

a) epidemiological situation concerning BSE agents in the country or *zone*;

b) recycling and amplification of the BSE agents through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

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

d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous *case* born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.4.24.

The potential for the entry of the BSE agent through the importation of meat-and-bone meal or greaves

~~This point is irrelevant if the exposure assessment outlined below in Article 11.4.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight years.~~ ~~Nevertheless, d~~Documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants in the past eight years.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the likelihood of entry of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

Evidence required:

– Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR

Annex XXI (contd)

– Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.

– Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past eight years.

– Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.

– Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.

– Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 11.4.25.

The potential for the entry of the BSE agent through the importation of live ~~animals~~ cattle potentially infected with BSE

Assumptions:

– Countries which have imported ~~ruminants~~ cattle from countries ~~infected~~ with 'classical' BSE~~s~~ are more likely to experience 'classical' BSE.

~~– Cattle pose the only known risk although other species are under study.~~

– ~~*Animals*~~ Cattle imported for breeding may pose a greater risk than ~~*animals*~~ cattle imported for *slaughter* ~~because of the hypothetical risk of maternal transmission and~~ because they are kept to a greater age than ~~*animals*~~ cattle imported for *slaughter*.

– Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

– Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: Have live ~~*animals*~~ cattle been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

– country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of ~~geographical~~ the BSE risk;

– feeding and management of the ~~*animals*~~ cattle in the country of origin;

– use ~~to which~~ of the *commodity*~~.~~ ~~has been put as apart from representing risk of developing clinical *disease*,~~ tThe *slaughter*, rendering and recycling ~~in~~ as *meat-and-bone meal* of imported ~~*animals*~~ cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;

~~– species;~~

– dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

– age at *slaughter*.

Evidence required:

– Documentation on the country of origin of imports. This should identify the country of breeding of ~~*animals*~~ cattle, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

– Documentation describing origins~~, species~~ and volume of imports.

– Documentation describing the fate of imported ~~*animals*~~ cattle, including their age at *slaughter*.

– Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.26.

The potential for the entry of the BSE agent through the importation of products of ~~animal~~ bovine origin potentially infected with BSE

Assumptions:

– ~~Semen, embryos, hides and skins or milk~~ Safe commodities as listed in Article 11.4.1. are not considered to play a role in the transmission of BSE.

– Countries which have imported products of ~~animal~~ bovine origin from countries with 'classical' BSE~~s~~ are more likely to experience 'classical' BSE.

– Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

– Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: What products of animal origin have been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

– ~~the species of origin of the animal products and~~ whether these products contain tissues known to contain BSE infectivity (Article 11.4.14.);

– country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of ~~geographical~~ the BSE risk;

– feeding and management of the ~~*animals*~~ cattle in the country of origin;

– use ~~to which~~ of the *commodity*~~.~~ ~~has been put as apart from representing risk of developing clinical *disease*,~~ tThe *slaughter*, rendering and recycling ~~in~~ as *meat-and-bone meal* of imported ~~*animals*~~ cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;

~~– species;~~

~~– dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;~~

– age at *slaughter*.

Annex XXI (contd)

Evidence required:

– Documentation on the country of origin of imports. ~~This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.~~

– Documentation describing origin~~s, species~~ and volume of imports.

= Documentation confirming that these products do not contain tissues listed in Article 11.4.14.

– Documentation describing the end use of imported ~~animal~~ bovine products, and the disposal of waste.

– Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.27.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ~~ruminant~~ bovine origin

Assumptions:

– That the consumption by bovines of *meat-and-bone meal* or *greaves* of ~~ruminant~~ bovine origin plays the only significant role in BSE transmission.

– That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ~~ruminant~~ bovine origin.

– Safe commodities as listed in Article 11.4.1. ~~Milk and blood~~ are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.4.3. and 11.4.4.)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ~~ruminant~~ bovine origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.4.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

~~– BSE has a long *incubation period* and insidious onset of signs, so *cases* may escape detection.~~

~~– Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.~~

~~– Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.~~

~~– BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.~~

– BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.4.19.

Annex XXI (contd)

– BSE agent is present at much higher titres in central nervous system ~~and reticulo-endothelial~~ tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past eight years?

Rationale: If potentially infected ~~*animals*~~ cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilised in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

– Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

– Documentation describing the definition and disposal of specified risk material, if any.

– Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

– Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

– Documentation describing monitoring and enforcement of the above.

Article 11.4.29.

Conclusions of the risk assessment

The overall risk of 'classical' BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity. 'Atypical' BSE is considered to occur at a similar low rate in all cattle populations. Both have ~~and~~ the potential for recycling and amplification of the infectivity through livestock feeding practices. ~~For~~ tThe *risk assessment* should ~~to~~ conclude whether ~~that the cattle population of a country or *zone* is free from BSE risk, it should have demonstrated that~~ appropriate measures have been taken to manage any risks identified.

- - - - - - - - - - - - - -

— Text deleted.

---

[1] See point 4) of Article 11.4.21.

[2] See point 3) of Article 11.4.21.

[3] See point 2) of Article 11.4.21.

[4] See point 1) of Article 11.4.21.