CHAPTER 11.6.

BOVINE SPONGIFORM ENCEPHALOPATHY

EU position

The EU supports the adoption of the modified chapter.

Nevertheless, the EU would like to raise the fact that in implementing legislation on control and prevention of BSE, OIE Members should consider the field and practical constraints that may lead to a need for a more stringent application of regulations, e.g. larger ban on some raw material in order to avoid cross-contamination.

Moreover, the EU would like the OIE to consider some comments inserted below.

Article 11.6.1.

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.

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;

EU comments:

The EU would like to remind the Code Commission of its previous opinion on this point and to restate its position.

Based on the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow. the Community can only support the inclusion of protein-free tallow with a maximal 0,15% insoluble impurities to the list under Article 11.6.1, point 1) if no commodities as laid down in Article 11.6.14 are used for the production of tallow and that the animals of which the raw material has been derived, have passed ante- and post mortem inspection.

   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-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.6.14.;

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 11.6.2.

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. Members should review the *risk assessment* annually to determine whether the situation has changed.

   a) Release assessment

      Release 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 11.6.14. 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 release 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. 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 11.6.20. to 11.6.22.;

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 11.6.20. to 11.6.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

Article 11.6.3.

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 11.6.2., 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 11.6.20. to 11.6.22. 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 11.6.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit, including that of

cross contamination through feed of other mammalian origin, that for at least 8 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 11.6.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and

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 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. ~~To maintain negligible risk status, all imports of cattle should comply with requirements in Articles 11.6.7., 11.6.8. or 11.6.9., as relevant.~~

Article 11.6.4.

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 11.6.2., 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 11.6.20. to 11.6.22. 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 11.6.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, 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 11.6.2. have not been complied with for 7 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 8 years;

OR

b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 11.6.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

EU comment

The EU proposes a slight rewording as follows:

"b) there has been an indigenous case of BSE, the criteria in points 2 to 4 of Article 11.6.2. are being complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination through feed of other mammalian origin, that neither meat-and-bone meal nor greaves derived from ruminants is being 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 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. ~~To maintain controlled risk status, all imports of cattle should comply with requirements in Articles 11.6.7., 11.6.8. or 11.6.9., as relevant.~~

Article 11.6.5.

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 11.6.6.

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 11.6.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.6.3.

Article 11.6.7.

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 11.6.3.;

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.

EU comment

The EU wants to re-iterate its previous comment. The possibility of cases born just after the implementation of the feed ban should also be considered and should not always, based on the situation and an assessment, constitute a reason to question the negligible risk status.

The Community proposes the following:

"2. were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from mammals had been effectively enforced or after the date of birth of the last indigenous case if that indigenous case was born after the date of the implementation of the feed ban ."

This comment also applies to Article 11.6.8, point 3.

Article 11.6.8.

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 11.6.4.;

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 11.6.4.;

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 11.6.9.

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 2 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 11.6.10.

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 11.6.1.)

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 11.6.3.;

2. the cattle from which the *fresh meat* and *meat products* were derived, passed ante-mortem 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 11.6.11.

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 11.6.1.)

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 11.6.4.;

2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem 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 11.6.14.,

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

Article 11.6.12.

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 11.6.1.)

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-mortem 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 11.6.14.,

   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.

EU comment

The age limit for vertebral column should be aligned with the Article 11.6.14, point 3 (30 months).

Article 11.6.13.

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 11.6.3., 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 11.6.4. and 11.6.5. should not be traded between countries.

Article 11.6.14.

Recommendations on commodities that should not be traded

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., 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.

EU comment

The EU thanks the OIE to submit the question related to the justification to consider only the distal ileum as specified risk material to the SCAD.

2. From cattle that were at the time of *slaughter* over ~~30~~ 12 months of age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., 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~~,~~ and 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~~ 30 months of age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., 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 11.6.15.

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-mortem 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;

EU comment

The age limit for skulls should be aligned with the Article 11.6.14, point 2.

The Community proposes the following:

"a) vertebral columns from cattle over 30 months of age at the time of slaughter and skulls from cattle over 12 months of age 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 11.6.16.

Recommendations for the importation of tallow (other than as defined in Article 11.6.1.) 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-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.6.14.

EU comment

As article 11.6.14 has been modified, the words "points 1 and 2 should be deleted; the EU proposes the following wording:

"2. it originates from a country, zone or compartment posing a controlled BSE risk, is derived from cattle which have passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in Article 11.6.14."

Article 11.6.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.6.1.) 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 11.6.15.

Article 11.6.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.6.1.) 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 11.6.16.; or

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

Article 11.6.19.

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 11.6.20.

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 11.6.2. 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);

EU comment

The Community would propose the following amendment to point b) and c) for clarity reasons:

"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 showing abnormal clinical signs at ante-mortem inspection (casualty or emergency slaughter or downer cattle);

c) cattle over 30 months of age which are found dead on farm or during transport , or killed other than for human consumption (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 11.6.20. to 11.6.22.

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 11.6.21.

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. 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 11.6.2.), 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 11.6.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member ~~must~~ 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 7 years.

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

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

b) a confidence level of 95%;

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

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

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

f) 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:

g) cattle population numbers stratified by age;

h) 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 11.6.3.) 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 11.6.4.), 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.

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 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	**Type A surveillance**	**Type B surveillance**
>1,000,000	300,000	150,000
800,000-1,000,000	240,000	120,000
600,000-800,000	180,000	90,000
400,000-600,000	120,000	60,000
200,000-400,000	60,000	30,000
100,000-200,000	30,000	15,000
50,000-100,000	15,000	7,500
25,000 -50,000	7,500	3,750

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 7 consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

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 <2years			
0.01	0.2	0.4	N/A
Age ≥2 years and <4 years (young adult)			
0.1	0.2	0.4	260
Age ≥4 years and<7 years (middle adult)			
0.2	0.9	1.6.	750
Age ≥7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age ≥9 years (aged)			
0.0	0.1	0.2	45

Article 11.6.23.

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. Release assessment

   Release 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; ~~the status of the birth cohort of a *case* should be determined when investigating the implementation of feed bans~~ 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 11.6.24.

The potential for the release 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 11.6.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 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 8 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 risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

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 8 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 11.6.25.

The potential for the release 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 7 years?

Rationale: The release risks are 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 11.6.26.

The potential for the release 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 7 years?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.6.14.);

- 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.

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 8 years (see Articles 11.6.3. and 11.6.4.)?

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 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.6.28.

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 11.6.19.

- 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 8 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 utilized 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 11.6.29.

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 ~~must~~ should have demonstrated that appropriate measures have been taken to manage any risks identified.

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1 See point 4) of Article 11.6.21.
2 See point 3) of Article 11.6.21.
3 See point 2) of Article 11.6.21.
4 See point 1) of Article 11.6.21.

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