

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

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 Administrations* 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) gelatin and collagen prepared exclusively from hides and skins;
 - e) protein-free tallow (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 30 months of age or less, 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 were subject to ante-mortem and post-mortem inspections and were not suspect or confirmed BSE *cases*; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;
 - 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 Administrations* 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*.

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

Article 2.3.13.2.

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* (which is reviewed annually), based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective:

a) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced into the cattle population from a pre-existing TSE in the indigenous ruminant population or via *commodities* potentially contaminated with a TSE agent, through a consideration of the following:

- i) the presence or absence of animal TSE agents in the country or *zone* or *compartment* and, if present, their prevalence based on the outcomes of surveillance;
- ii) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
- iii) imported *meat-and-bone meal* or *greaves*;
- iv) imported live animals;
- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;
- vii) imported products of ruminant origin for *in vivo* use in cattle.

Surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the cattle population) relevant to the 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 exposure of the BSE agent to cattle, 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 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 Appendix 3.8.4.;

- 3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
- 4) the examination in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

When the *risk assessment* (which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates non-negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* (which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

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

- 1) a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified;
- 2) the country has demonstrated that Type B surveillance in accordance with Appendix 3.8.4. is in place;
- 3) EITHER:
 - a) there has been no *case* of BSE, or any *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 2.3.13.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

- b) the last indigenous *case* of BSE was reported more than 7 years ago; and
 - i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; and
 - iii) all BSE *cases*, as well as:
 - all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- 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.

Article 2.3.13.4.

Controlled BSE risk

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

- 1) a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified;
- 2) the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. is in place;
- 3) EITHER
 - a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2) to 4) of Article 2.3.13.2. 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 reported, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that *meat-and-bone meal* and *greaves* derived from ruminants have not been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;
 - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

- iii) all BSE *cases*, as well as:
 - all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- 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.

Article 2.3.13.5.

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 2.3.13.6.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in point 1) of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.

Article 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

- 1) the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
- 2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.4.;
- 3) in the case of a country, *zone* or *compartment* with an indigenous *case*, 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 had been effectively enforced.

Article 2.3.13.8.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

for cattle

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 the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
 - b) 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
 - c) 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 enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
 - 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 2.3.13.9.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

- 1) the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;
- 2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate.

Article 2.3.13.10.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

- 1) the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
- 2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate;
- 3) cattle from which the *fresh meat* and *meat products* destined for export originate 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* do not contain:
 - a) the tissues listed in Article 2.3.13.13.,
 - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.11.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

- 1) the cattle from which the *fresh meat* and *meat products* originate:
 - a) are not suspect or confirmed BSE *cases*;
 - b) have not been fed *meat-and-bone meal* or *greaves*;
 - c) were subjected to ante-mortem and post-mortem inspections;
 - d) 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* do not contain:
 - a) the tissues listed in Article 2.3.13.13.,
 - 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,

all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.12.

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 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Article 2.3.13.13.

- 1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., 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, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities 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 2.3.13.4., 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, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities 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 2.3.13.5., 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, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of importing countries should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

- 1) a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) a country, *zone* or *compartment* posing a controlled BSE risk; and
 - a) skulls and vertebrae (except tail vertebrae) have been excluded;
 - b) the bones have been subjected to a process which includes all the following steps:
 - i) pressure washing (degreasing),
 - ii) acid demineralisation,
 - iii) prolonged alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,
 or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.15.

Veterinary Administrations of importing countries should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

- 1) a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) a country, *zone* or *compartment* posing a controlled BSE risk, and it originates from cattle which have been subjected to ante-mortem and post-mortem inspection and has not been prepared using the tissues listed in point 2 of Article 2.3.13.13.

Article 2.3.13.16.

Veterinary Administrations of importing countries should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

- 1) they originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM
ENCEPHALOPATHY

Article 3.8.4.1.

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 2.3.13.2. 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;
 - 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, emergency slaughter or downer cattle);

- c) cattle over 30 months of age which are found dead 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*. All countries should sample at least three of the four subpopulations. This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

Article 3.8.4.2.

Description of cattle subpopulations

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

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 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, particularly cattle over 30 months of age, is the one exhibiting the highest prevalence. The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.

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 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 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 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 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).

Within each of the above subpopulations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.

When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implication. Authorities must find ways to overcome these difficulties.

Article 3.8.4.3.

1) Implementation of type A surveillance

In order to implement efficiently a surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. The application of the following procedure will allow the detection of BSE prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.

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 country should design its surveillance strategy 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 appendix were obtained by applying the following factors to a statistical model:

- a) a prevalence of one case per 100,000 of the adult cattle population;
- 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 clinical 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.

2) Maintenance (type B) surveillance

For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk', surveillance should continue at a reduced maintenance level.

In order to implement efficiently a maintenance surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. The application of the following procedure will allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.

Maintenance surveillance should focus on the higher prevalence subpopulations (especially clinical suspects). The number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, *zone* or *compartment's* BSE status (to a maximum of 7 years).

Article 3.8.4.4.

1) Selecting the points target

The desired surveillance points target is selected from Table 1, which shows target points for adult cattle populations of different sizes. A country's adult cattle population size 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. The target depends on the design prevalence chosen by the country.

Table 1 Points targets for different adult cattle population sizes in a country, *zone* or *compartment* which has not identified any BSE cases

Target points for country, zone or compartment with 0 cases, 95% confidence		
Adult Cattle Population Size (24 months and older)	DP¹ 1/100,000	DP¹ 1/50,000
≥ 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

¹ DP is the maximum possible prevalence or “design prevalence”.

2) 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 Appendix 3.8.1. 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, countries should sample at least three of the four subpopulations.

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.

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

Surveillance subpopulation			
Routine slaughter¹	Fallen stock²	Casualty slaughter³	Clinical suspect⁴
Age ≥ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

¹ See point 4) of Article 3.8.4.2.

² See point 3) of Article 3.8.4.2.

³ See point 2) of Article 3.8.4.2.

⁴ See point 1) of Article 3.8.4.2.

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

Article 3.8.4.5.

To monitor the evolution of BSE in a country, zone or compartment once it is detected

To monitor the evolution of BSE in a country, *zone* or *compartment* once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and policies for the removal of specified risk materials.

APPENDIX 3.6.3.

PROCEDURES FOR THE REDUCTION OF INFECTIVITY OF
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS

Article 3.6.3.1.

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.
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