for *fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate.

Article 2.3.13.15.

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

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

3) cattle from which the meat or *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 (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* destined for export have neither been contaminated by, nor contain either brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age.

Article 2.3.13.16.

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

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

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

3) ante-mortem inspection is carried out on all bovines;

4) cattle from which the meat or *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;

5) the *fresh meat* and *meat products* destined for export have neither been contaminated by, nor contain, brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age.

Article 2.3.13.17.

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

for *fresh meat* and *meat products* from cattle

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

1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

2) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and has neither been contaminated by, nor contains the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process;

3) the *meat products* destined for export are derived from deboned meat and

have neither been contaminated by, nor contain the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals;

4) a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;

5) ante-mortem inspection is carried out on all bovines;

6) the cattle from which the meat or *meat products* destined for export originate:

   a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

   b) are not the progeny of BSE suspect or confirmed females; and either:

      i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced; or

      ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;

   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;

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

8) the affected cattle as well as:

   a) if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

   b) all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which

the affected cattle consumed during the first year of their life,

if alive in the country or zone, are slaughtered and completely destroyed.

Article 2.3.13.18.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from countries with a minimal, moderate or high BSE risk should not be traded between countries.

Article 2.3.13.19.

1) 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, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column, and protein products derived therefrom, from cattle over 6 months of age originating from countries with a high BSE risk. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) 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:

   a) brains, eyes, spinal cord, distal ileum, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter aged over 6 months;

   b) brains, eyes and spinal cord, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a minimal BSE risk has been reported, that were at the time of slaughter aged over 30 months.

   Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using the commodities listed in points a) and b) above should also not be traded.

Article 2.3.13.20.

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 bones came from:

1) a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk; or

2) a country or zone with a moderate BSE risk; and

   a) skulls and vertebrae (excluding 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 > 138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.21.

Veterinary Administrations of *importing countries* should require:

for tallow (other than protein-free tallow as defined in Article 2.3.13.8.) 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 BSE free or provisionally free country or zone; or

2) a country or zone with a minimal BSE risk, and

   a) if prepared by fat melting, it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2)b) of Article 2.3.13.19.;

   b) if prepared by rendering, (under study); or

3) a country or zone with a moderate BSE risk; and

   a) if prepared by fat melting, it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2)a) of Article 2.3.13.19.;

   b) if prepared by defatting of bones:

      i) skulls and vertebral columns from cattle over 6 months of age have been excluded; or

      ii) it has been processed using a method that reduces the infectivity by at least 5 log10 LD50/g (processes under study);

   c) if prepared by rendering, (under study).

Article 2.3.13.22.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.8.) 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 BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk;

OR

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

Article 2.3.13.23.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:

1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;

2) the age of the donor animals;

3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

4) precautions to avoid contamination during collection of tissues;

5) the process to which the material will be subjected during manufacture;

6) the amount of material to be administered;

7) the route of administration.

APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

The surveillance strategy applied for bovine spongiform encephalopathy (BSE) should be determined by, and commensurate with the outcome of the risk assessment referred to in Article 2.3.13.2. Surveillance and risk assessment are part of an iterative process and inform each other.

Surveillance for BSE has at least two goals: one is to determine whether BSE is present in the country, and the other, once the disease has been detected, is to monitor the evolution of the epizootic, direct control measures and monitor their effectiveness.

A surveillance strategy may need to combine several methods of investigation.

Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the *Manual*.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.6. on surveillance and monitoring of animal health. Recommended strategies for selecting the part of the population for testing are described below.

Article 3.8.4.2.

Examination of cattle displaying clinical signs compatible 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. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals with compatible clinical signs. Surveillance should primarily focus on cattle over 30 months of age, but younger cattle should not be ignored.

Table 1 indicates the minimum number of clinical cases that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. As this sampling is not random, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction.

Article 3.8.4.3.

Examination of targeted cattle not displaying clinical signs compatible with BSE

Cattle that have died or have been killed for reasons other than routine slaughter (including 'fallen' stock and emergency slaughter) should be examined. Surveillance needs to focus on animals over 30 months of age.

Table 1. ***Minimum number of annual investigations of animals showing clinical signs compatible with BSE required for effective surveillance according to the total cattle population over 30 months of age***

Total cattle population over 30 months of age	**Minimum number of samples to examine**
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336

10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

Article 3.8.4.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter is a means of 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.

Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Article 3.8.4.5.

Within each of the above sub-populations, 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.