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 do not contain brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age, all of which have been removed in a hygienic manner.

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 does not contain the tissues listed in point 1) of Article 2.3.13.19., all of which have been removed in a hygienic manner;

3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have been removed in a hygienic manner;

4) the *meat products* destined for export are derived from deboned meat and do not 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, all of which have been removed in a hygienic manner;

5) 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;

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

7) 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;

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

9) the affected cattle as well as:

a) if these are females, [their last] all their progeny born within 2 years prior to, [or] and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and

b) all cattle which, during their first year of life, were reared [together] with the affected cattle during [the] their first year of [their] life, and, [in both situations,] which [may have] investigation showed consumed the same potentially contaminated feed [as that which the affected cattle consumed] during that period [the first year of their life], or

c) where the results of an investigation are inconclusive, all cattle [either] born in the same herd as, and within 12 months of the birth of, the affected cattle [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] when slaughtered or at death, are 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) From cattle originating from a country or zone with a high BSE risk, that were at the time of slaughter over 6 months of age, 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 derived protein products [derived therefrom]. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle originating from a country or zone with a moderate BSE risk, that were at the time of slaughter over 6 months of age, 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, distal ileum, skull, vertebral column and derived protein products [derived therefrom]. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

3) From cattle, originating from a country or zone with a minimal BSE risk, that were at the time of slaughter over 30 months of age, 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 and spinal cord, skull, vertebral column and derived protein products [derived therefrom]. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities 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)] 3 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 $\log_{10}$ LD_{50}/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.

[ ] deleted

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 bovine spongiform encephalopathy (BSE) has at least two goals: to determine whether BSE is present in the country, and, if present, to monitor the extent and evolution of the epizootic, thus aiding control measures and monitoring their effectiveness.

The cattle population of a country or zone not free from BSE, will comprise the following sub-populations in order of decreasing size:

1) cattle not exposed to the infective agent;

2) cattle exposed but not infected;

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

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

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

   c) the smallest number will show clinical signs of disease.

Surveillance programmes should be determined by, and commensurate with the outcome of the risk assessment referred to in Article 2.3.13.2. and should take into account the diagnostic limitations associated with the above sub-populations and the relative distributions of infected animals among them.

Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While surveillance should focus on this sub-population, investigation of other sub-populations using the new diagnostic techniques may provide a more accurate picture of the BSE situation in the country or zone. A surveillance strategy may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below.

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger

numbers of cattle identified in Article 3.8.4.3. Any shortfall in the first two sub-populations should be addressed by the sampling of normal cattle over 30 months of age at slaughter. 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.

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 consistent [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 this population and, within this pop, cattle over 30 months of age, but younger cattle should not be ignored.] 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.

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE [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.

Table 1. Minimum number of annual investigations of [animals] cattle showing clinical signs [compatible]-consistent 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 3.8.4.3.

Examination of targeted cattle [not] displaying clinical signs not necessarily [compatible with] indicative of BSE

Cattle that have died or have been killed for reasons other than routine slaughter [(including 'fallen' stock and emergency slaughter)] should be examined. This population will include cattle which have died on farm or in transit, 'fallen stock', and stock sent for emergency slaughter.

Many of these cattle may have exhibited some of the clinical signs listed in Article 3.8.4.2. which were not recognised as being compatible with BSE. Experience in countries where BSE has been identified indicates that this population is the second most appropriate population to target in order to detect BSE.

[Surveillance needs to focus on animals over 30 months of age.]

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.]

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.

[ ] deleted