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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.

Article 2.3.13.2.

The BSE status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

- 1) the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:
 - a) the potential for introduction and recycling of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin;
 - b) importation of *meat-and-bone meal* or *greaves* potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;
 - c) importation of animals or embryos/oocytes (other than cattle embryos described in Article 2.3.13.8.) potentially infected with a TSE;
 - d) epidemiological situation concerning all animal TSE in the country or zone;
 - e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;

- f) 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;
- 2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;
- 3) compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;
- 4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;
- 5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.

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

Article 2.3.13.3.

BSE free country or zone

The cattle population of a country or zone may be considered free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
 - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:

- i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
- ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- c) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years and the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years.

Article 2.3.13.4.

BSE provisionally free country or zone

The cattle population of a country or zone may be considered as provisionally free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) either:
 - a) there has been no *case* of BSE; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or
 - ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not

been complied with for 7 years.

Article 2.3.13.5.

Country or zone with a minimal BSE risk

The cattle population of a country or zone may be considered as presenting a minimal BSE risk should the country or zone comply with the following requirements:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) EITHER:
 - a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants is effectively enforced, but:
 - i) the criteria in points 2) to 5) of Article 2.3.13.2. have not been complied with for 7 years; or
 - ii) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has not been effectively enforced for 8 years;

OR

- b) the last indigenous *case* of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*), and:
 - i) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 8 years;
 - ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years;
 - iii) the affected cattle as well as:
 - if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and
 - all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

- where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle

if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Article 2.3.13.6.

Country or zone with a moderate BSE risk

The cattle population of a country or zone may be considered as presenting a moderate BSE risk if:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;
- 2) the BSE incidence rate has been:
 - a) if based only on surveillance in accordance with Article 3.8.4.2., greater than or equal to, one indigenous *case* per million and less than or equal to, one hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or
 - b) if based on surveillance in accordance with Article 3.8.4.2., Article 3.8.4.3. and Article 3.8.4.4., greater than, or equal to, one indigenous case per million and less than, or equal to, two hundred indigenous cases per million within the cattle population over 24 months of age in the country or zone calculated over the past 12 months; or
 - c) less than one indigenous *case* per million for less than four consecutive 12-month periods (*Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.*);
- 3) the affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to, 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 with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,

if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Countries and zones where the BSE incidence rate has been less than one indigenous *case* per million within the cattle population over 24 months of age during each of the last four consecutive

12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones with a moderate BSE risk.

Article 2.3.13.7.

Country or zone with a high BSE risk

The cattle population of a country or zone may be considered as presenting a high BSE risk if it cannot demonstrate that it meets the requirements of another category.

Article 2.3.13.8.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

- 1) *milk and milk products*;
- 2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
- 3) ~~protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;~~
- 4) dicalcium phosphate (with no trace of protein or fat);
- 5) hides and skins;
- 6) gelatin and collagen prepared exclusively from hides and skins.

Article 2.3.13.9.

When importing from a BSE free country or zone, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in Article 2.3.13.8.

the presentation of an *international veterinary certificate* attesting that the country or zone complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

Article 2.3.13.10.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for 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) 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 the progeny of BSE suspect females.

Article 2.3.13.11.

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

for 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) 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) 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 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.

Article 2.3.13.12.

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

for 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) 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 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.

Article 2.3.13.13.

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

for 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 feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 3) all affected cattle as well as:
 - a) if these are females, all their progeny born within 2 years prior to, 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 with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,

if alive in the country or zone, when slaughtered or at death, are completely destroyed;

- 4) 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 2.3.13.14.

When importing from a BSE provisionally free country or zone, *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 2.3.13.4. 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 do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been removed in a hygienic manner.

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 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, all their progeny born within 2 years prior to, 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 with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,

if alive in the country or zone, 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. 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. 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. 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 $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,
 or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.21.

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 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 3 of Article 2.3.13.19., or

- 3) a country or zone with a moderate BSE risk, and 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 of Article 2.3.13.19.

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.

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