

OIE-TAHC-JANUARY 2005 REPORT

PROPOSED THREE CATEGORY VERSION

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 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 ~~(excluding hides and skins from the head)~~;
  - d) gelatin and collagen prepared exclusively from hides and skins ~~(excluding hides and skins from the head)~~;
  - 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 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;
  - 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 the following *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*.
  - a) cattle;
  - b) *fresh meat* and *meat products*;
  - e) gelatin and collagen prepared from bones or from hides and skins from the head;
  - d) tallow and tallow derivatives, other than protein-free tallow as defined above;
  - e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

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

## Article 2

The BSE risk status of the cattle population of a country, *zone* or *compartment* ~~can only~~ 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 the following 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/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 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 Articles 3.8.4.2. and 3.8.4.3.;
  - 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.
  - 5) ~~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;~~

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 3

#### Negligible BSE risk without commodity-specific risk mitigation ~~mitigating~~ measures

Commodities from the cattle population of a country, ~~zone or compartment~~ pose a negligible risk of transmitting the BSE agent without the need to apply commodity-specific risk mitigation ~~mitigating~~ measures, should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2, has been conducted in order to identify the historical and existing risk factors and the country ~~it~~ has been demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage ~~any~~ all risk identified;
- 2) the country has demonstrated that Type B a level of surveillance and monitoring which complies with the requirements of in accordance with Appendix 3.8.4. is in place, ~~and~~

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 54) of Article 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 54) of Article 2 have been complied with for at least 7 years; and
  - ii) it has been demonstrated, thorough an appropriate level of control and audit, that for at least 8 years the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; banned and the ban has been effectively enforced for at least 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 4

#### Negligible BSE risk with commodity-specific risk mitigation ~~mitigating~~ measures

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent due to the application of additional commodity-specific risk mitigation measures, should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2, has been conducted in order to identify the historical and existing risk factors, and ~~it~~ the country has been not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage ~~any~~ all risks identified;
- 2) the country has demonstrated that level of Type A surveillance and monitoring which complies with the requirements of in accordance with Appendix 3.8.4. is in place; ~~and~~

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 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; ~~and either~~ at least one of the following two conditions applies:
- i) the criteria in points 2) to 54) of Article 2 are complied with, but have not been complied with for 7 years; ~~or~~
  - ii) it ~~cannot be~~ has not been demonstrated that for at least 8 years controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years; ~~has not been fed to ruminants;~~

OR

- b) there has been an the last indigenous *case* of BSE ~~was~~ reported more than 7 years ago, the criteria in points 2) to 45) of Article 2 are complied with, and it can be demonstrated, through an appropriate level of control and audit that a ban on feeding ruminants *meat-and-bone meal* and *greaves* derived from ruminants is have not been fed to ruminants effectively enforced, but ~~either~~ at least one of the following two conditions applies:
- i) the criteria in points 2) to 54) of Article 2 have not been complied with for 7 years; ~~or~~
  - ii) ~~the ban on feeding ruminants with~~ 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 has not been effectively enforced 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 ;

OR

- e) the last indigenous *case* of BSE has been reported less than 7 years ago, and:
- i) the criteria in points 2) to 54) of Article 2 have been complied with for at least 7 years;
  - ii) ~~the ban on feeding ruminants with *meat and bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 8 years;~~
  - 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 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 6

When importing from a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

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

the presentation of an *international veterinary certificate* attesting that the country or *zone/compartment* complies with the conditions in Article 3.

#### Article 7

When importing from a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation measures ~~mitigating measures~~, *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 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 2) c) iii) of Article 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 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 9

When importing from a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

for fresh meat and meat products from cattle (other than that listed in point 1) of Article 1)

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

- 1) the country, *zone* or *compartment* complies with the conditions in Article 3;
- 2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate.

#### Article 10

When importing from a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

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

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

- 1) the country, *zone* or *compartment* complies with the conditions in Article 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 ~~(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* do not contain:
  - a) the tissues listed in Article 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 with these tissues.

#### Article 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 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* for at least 8 years;
  - 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* ~~are derived from deboned meat and~~ do not contain:
  - a) the tissues listed in Article 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 ~~these tissues~~.

#### Article 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 4 and 5 should not be traded between countries.

#### Article 13

- 1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 4 and 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 Articles 4 ~~and 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.
- 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 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 14

*Veterinary Administrations of importing countries* should require:

for gelatin and collagen prepared from bones ~~or from hides and skins from the head~~ 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 without commodity-specific risk mitigation ~~mitigating~~ measures; or
- 2) a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation ~~mitigating~~ measures; and
  - a) skulls and vertebrae (except tail vertebrae, ~~and hides and skins from the head~~) 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 15

*Veterinary Administrations of importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 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 without commodity-specific risk mitigation ~~mitigating~~ measures, or
- 2) a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation ~~mitigating~~ measures, and it originates from cattle which have been subjected to ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 13.

#### Article 16

*Veterinary Administrations of importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 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 without commodity-specific risk mitigation ~~mitigating~~ measures; or
- 2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

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