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[SANCO/10264R5/2006 part 2 BSE]

Appendix XIII

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community position:
The Community welcomes the work done by the Code Commission and can support this proposal however it has introduced some written comments below to be considered or reflected on and taken on board during the next code Commission meeting in September 2006.

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) gelatine 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;

Community written comment:
Based on the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow. the Community can only support the inclusion of protein-free tallow with a maximal 0,15% insoluble impurities to the list under Article 2.3.13.1, point 1) if no SRM is used for the production of tallow and that the animals of which the raw material has been derived, have passed ante- and post mortem inspection.

   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, ~~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~~ passed 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.;

Community position:
The Community welcomes the decision to keep the age limit awaiting the outcome of ongoing research and pathogenesis studies before assessing the modification of the

current age criteria for de-boned muscle meat of cattle as defined in Article 2.3.13.1, point g).

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. Countries should review the risk assessment annually to determine whether the situation has changed.

Community written comments:
In case the situation changes over the year the member countries should review but also be obliged to provide this documentation. This should be clearly specified. The surveillance results should be part of this documentation.

The Community proposes the following:
"1. the outcome of a risk assessment, based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective. Countries should review the risk assessment annually to determine whether the situation has changed . It the latter case, countries have to provide the documentation, including the surveillance results. In that case a review of the risk assessment is needed."

Furthermore the Community recommends that the risk assessment should be carried out by an international expert panel. The European Community wants to emphasize the importance that OIE start establishing the working method for future categorisation in order to initiate the categorisation process as soon as the Code Chapter is agreed.

a) Release assessment

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

~~i) the presence or absence of animal TSE agents the BSE agent in the country, *zone* or *compartment* and, if present, evidence regarding their its 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 ruminants 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.~~

~~The results of any surveillance and other epidemiological investigation into the disposition of the *commodities* identified above (especially surveillance for BSE conducted on the cattle population) relevant to the above should be taken into account in carrying out the assessment.~~

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

Community written comment:
The Community cannot support the deletion of surveillance in point (i). If a risk assessment is to be based on solid data, it is natural to incorporate the surveillance data. There is no reason to omit this reference, since a BSE risk assessment should be based, at least partly, on surveillance data.

ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

iii) imported *meat-and-bone meal* or *greaves*;

iv) imported cattle, sheep and goats;

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 intended for *in vivo* use in cattle.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

Community written comments:
When using the concept of zone or compartment in addition to a country, it is also important to assess the flow of animals and other potentially contaminated commodities between zones in the country, it is not totally clear if the term "imported" in a) iii), iv), v), vi) and vii) also includes trade or movements within a country from another zone. It should be clearly stated that, when performing a risk assessment for a zone, the term import also includes movements from other zones.

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~~ cattle being exposed to the BSE agent, 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 up 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.

Community written comments:
Apart from the approval of the laboratory the test methodology should also be approved.
The Community proposes to replace "approved laboratories" by "approved laboratories and approved method" under point 4) of Article 2.3.13.2.

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.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above)~~ ~~demonstrates non-negligible~~ fails to demonstrate negligible risk, the country should conduct Type A 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~~ if the following conditions ~~be~~ are 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~~ specific measures have been taken for the relevant period of time defined below to manage ~~all risks~~ each identified risk;

2. the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met;

Community written comments:
It should be specified what kind of surveillance will be required if the relevant point target has been met for countries with a negligible BSE risk.

In addition there should be a more stringent surveillance programme for countries with cases reported in their past to asses the effectiveness of the measures taken in the past. Therefore the Community proposes to modify Article 2.3.13.3. point 2 as follows:

"2) EITHER

a) if there has been no indigenous case of BSE, the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met, or

b) if there has been an indigenous case of BSE, the country has demonstrated that Type A surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met.

3. EITHER:

a) there has been no *case* of BSE~~,~~ or, ~~any~~ if there has been a *case*, every *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 neither *meat-and-bone meal* ~~or~~ nor *greaves* derived from ruminants has ~~not~~ been fed to ruminants;

Community written comments:

Experience within the European Community pointed out the risk of cross-contamination when applying a restricted ruminant to ruminant feed ban. The Community proposes to modify Article 2.3.13.3.., point 3a) ii) as follows:

"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 mammals has not been fed to ruminants;"

OR

b) ~~the last indigenous *case* of BSE was reported more than 7 years ago~~ if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; ~~any indigenous *case* of BSE was born more than 8 years ago~~; and

Community written comments:

The Community can support the proposed change under Article 2.3.14.3. point 3 b) . It is far more relevant to take into account the date of birth rather than the date of reporting. The Community can support the modification from " born more than 8 years " into born more than 11 years".

However in view of the long incubation period of BSE, it is not possible to precisely assess the impact of any control measure before several years. Simulation studies have been performed in France and Denmark to estimate the pattern of the BSE epidemic

and indicate clear differences pending on the demography of the cattle population. This should be taken into account in future reviews.

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 neither *meat-and-bone meal* ~~and~~ nor *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~~ if the following conditions ~~be~~ are 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 measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time ~~to manage all risks identified 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~~ has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target~~, in accordance with Table 1,~~ is met;

Community written comments:
The level of surveillance needed after reaching the target points of type A surveillance should be specified but there is also a need for more clarity on the regime that is required after the points target of type B surveillance is met.

The Community cannot agree that a country with a controlled risk after having reached the target points for type A surveillance can implement a lower level of surveillance awaiting to fulfil the requirements for the negligible risk status. Therefore the Community proposes to impose for countries posing controlled BSE risk that a type A surveillance should be maintained at least seven years preceding the date when the country meets the criteria for a negligible risk status. This would ensure that countries with a controlled risk can only receive the negligible risk status, where no SRM removal is required, following an increased surveillance programme immediately prior to the change of risk status.

3. EITHER

a) there has been no *case* of BSE, or, ~~any~~ if there has been a *case*, every *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 neither *meat-and-bone meal* ~~and~~ nor *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;

Community written comments:

Experience within the European Community pointed out the risk of cross-contamination when applying a restricted ruminant to ruminant feed ban. The Community proposes to modify Article 2.3.13.4., point 3a) ii) as follows:

"ii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from mammals 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 neither *meat-and-bone meal* ~~and~~ nor *greaves* derived from ruminants ~~have not~~ has 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 referred to in Article 2.3.13.3.

Community written comments*:
Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present in the age cohorts born before the risk management measures were taken for the appropriate period of time, assurances should be given to exclude those animals and products derived thereof from trade. In practice, those animals and products derived should be excluded from trade from countries with a negligible BSE risk status. The possibility of cases born just after the implementation of the feed ban should be considered and should not always, based on the situation and an assessment, constitute a reason to question the negligible risk status. The Community took note of the intention of the TAHSC to look into this issue in the second half of 2006.

The Community proposes the following:

"For cattle from countries with a negligible BSE risk where any indigenous case of BSE was detected, 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. 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 2.3.13.3. point 3,b,iii);

3. 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 or after the date of birth of the last indigenous case if born after the date of the feed ban ."

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 referred to 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~~ where there has been 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~~ was effectively enforced.

Community written comments:

The current wording in point 3) referring to indigenous cases could be misinterpreted that only countries with indigenous cases should comply with point 3). In addition the possibility of cases born just after the implementation of the feed ban should be considered. The Community proposes to clarify as follows:

"3) 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 or after the date of birth of the last indigenous case if born after the date of the feed ban .."

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 referred to in Article 2.3.13.3.;

2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate~~.

Community written comments*:

The Community proposes to amend Article 13, point 1) as follows:

Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present born before the risk management measures were taken, assurances should be given to exclude those animals and products derived from trade. The Community took note of the intention of the TAHSC to look into this issue in the second half of 2006.

The Community proposes:

"point 3: In countries with negligible BSE risk where there have been indigenous cases, the cattle from which the fresh meat and meat products were derived passed ante-mortem and post-mortem inspections, and 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 enforced."

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 referred to in Article 2.3.13.4.;

2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~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 were derived 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~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 2 of 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*.~~

Community written comments:

The Community feels that for control reasons the harvesting of mechanically recovered meat should not only be extended to the skull or vertebral column of bovine animals of any age but should also be extended to all bovine bones.

In view of this the Community suggest replacing article 11 point 2 c with:

'4) b) mechanically separated meat from all bones from cattle of all ages,'

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* are derived:

   a) ~~are not suspect or confirmed BSE *cases*~~;

   b) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

   c) ~~were subjected to~~ passed 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~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 3 of 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.

Community written comments:

Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present born before the risk management measures were taken, assurances should be given to exclude those animals from trade. Therefore the Community proposes the following:

"In countries with a negligible BSE risk, ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products derived from cattle born before the date from which the ban on the feeding of ruminants with meat-and-bone meal and

greaves derived from ruminants had been enforced 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 derived protein products~~. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Community written comments:
In their opinion of 27-28 November 2000 the Scientific Steering Committee recommend that the entire intestine of bovine animals of all ages should be removed as specified risk material whenever it is not highly unlikely that the slaughtered animals are infected. On previous occasions (the minutes of the ad hoc Group meeting in 2004) the experts did not consider that there were sufficient new data to recommend a change from its previous recommendation to remove tonsils and intestine from cattle of all ages due to the presence of lymphoid tissue throughout the intestines. The Community would like to be informed of the scientific data which supports the premise to limit the removal to the distal ileum.

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 and vertebral column ~~and derived protein products~~. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Community written comments:
In the opinions of the former Scientific Steering Committee it was considered that the intestines and tonsils of bovine animals should be considered a risk at any age and therefore be removed in all cattle. For the rest of SRM the SSC took, according to the opinion, an extremely cautious approach and although it was considered extremely unlikely to have detectable infectivity below an age of 30 months being the half of the mean incubation period in field BSE cases (60 months), the exceptional finding of BSE cases in younger animals lead to an age limit of 12 months. This age limit was considered by the SSC as a considerable reassurance of non-infectivity.
The recent conclusions from the recent EFSA opinion on SRM, published in May 2005, stated that following a cautious approach and taking into account the appearance of infectivity in central nervous system (CNS) at ¾ of the incubation period and the age of BSE cases in young animals (less than 35 months old, 0.06 % of total of BSE cases), a cut-off at 21 months would give the highest safety margin. If the rare BSE cases found in very young animals (4 cases in 40 Million tested since 2001) are not taken into account, a cut-off at 30 months would represent a "considerable but not an absolute safety margin with respect to detectable infectivity". There is no scientific basis to raise the age limit for removal of tonsils and intestines. In addition EFSA recommends further work on the epidemiological data to evaluate the likelihood of infectivity in SRM derived from young animals.
The Community reserves its position on the 30 month age limit pending the further work by the EFSA.

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 and vertebral column ~~and derived protein products~~. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatine 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:

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk and ~~come~~ are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

   a) skulls from cattle over 30 months of age at the time of slaughter ~~and vertebrae (except tail vertebrae)~~ have been excluded;

Community written comments:
On 18 January 2006 the European Food Safety Authority adopted an opinion on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE risk". The Community can support this amendment for countries with a controlled BSE risk. Nevertheless the Community recommends that the OIE examine in more detail the different processes used in the production of collagen and gelatine and proposes that the OIE lays down much more detailed requirements for the safe processing of these products. In particular for gelatine all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4% with a pH 12.5) for a period of at least 20 days with a sterilisation step of 138 to 140 degrees centigrade during four seconds. The gelatine must be extracted by\heating one or several times in succession, followed by purification by means of filtration and sterilisation.
For collagen the raw material must be subjected to a treatment involving washing, pH adjustment using acid or alkali, followed by one or more rinses, and then filtration and extrusion.

   b) the bones have been subjected to a process which includes all of the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) ~~prolonged~~ acid or alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating);

OR

3. they originate from a country, *zone* or *compartment* posing an undetermined BSE risk and are derived

from cattle which have passed ante-mortem and post-mortem inspections; and that

a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;

b) the bones have been subjected to a process which includes all of the following steps:

i) pressure washing (degreasing),

ii) acid demineralisation,

iii) acid or alkaline treatment,

iv) filtration,

v) sterilisation at ≥138°C for a minimum of 4 seconds,

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

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:

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk, ~~it originates come~~ are derived from cattle which ~~been subjected to~~ have passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 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. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. they are derived from tallow meeting the conditions referred to in Article 2.3.13.15; or

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

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~~—~~ text deleted

APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Community written comments:

The Community can support the improvement made to the surveillance Appendix and in particular the requirement to test all clinical suspects in addition to animals of other risk groups. However at the General Session in May 2005 it was agreed that countries were allowed to use the full BSurvE model on the countries own data as an alternative to the Terrestrial Code Appendix 3.8.4. The Community would welcome some clarification.

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 (clinical suspects);

   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 or emergency slaughter, or downer cattle);

Community written comments:
The terminology "downer cattle" might be confused with "fallen stock". The Community proposes to clarify and to reword Article 3.8.4.1., point 4 b) as follows

"b) cattle over 30 months of age that are unable to rise or to walk without assistance (downer cattle); cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (emergency slaughter);"

The same applies for article 3.8.4.2. point 2.

   c) cattle over 30 months of age which are found dead or killed 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.

6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 3.8.4.2.

Description of cattle subpopulations

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

   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.~~ The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

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 or killed 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)~~ documented records or reliable estimates of ~~concerning~~ the age distribution of ~~it's~~ the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*. ~~The application of the following procedure will allow the detection of BSE at a 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.~~

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 should be designed 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~~ the design prevalence for Type A or Type B surveillance ~~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:

a) cattle population numbers stratified by age;

b) the number of cattle tested for BSE stratified by age and by subpopulation.

This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

Community written comments*:

The Community is aware and acknowledge that not the same surveillance criteria might apply to countries with or without a BSE risk.

The Community strongly support the amendment is the last phrase in Article 3.8.4.3. just above point i.e.
"All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested".
In addition, the assessment of the surveillance programme should also take into account the number of clinical suspects identified in the country during previous years. The clinical suspects should be documented.
The Community asks the TAHSC to clarify if the Community understanding is correct.

1. Type A surveillance

   The application of Type A surveillance will allow the detection of BSE around a design prevalence[1] of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. ~~Maintenance (~~Type B~~)~~ surveillance

   The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

   Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 2.3.13.3) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

   Type B surveillance may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 2.3.13.4), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

   ~~For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk', 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] DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

1. Selecting the points target

The ~~desired~~ surveillance points target ~~is~~ should be selected from Table 1, which shows target points for adult cattle populations of different sizes. ~~A country's~~ The size of the adult cattle population ~~size~~ of a country, *zone* or *compartment* 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~~

Points targets for country, *zone* or *compartment* ~~with 0 cases, 95% confidence~~		
Adult cattle population size (24 months and older)	**Type A surveillance**	**Type B surveillance**
≥ 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

~~DP is the maximum possible prevalence or "design prevalence".~~

Community written comments:
The categories are very broad, especially for the smaller populations. This will have negative consequences for countries just above the limit for one category. For example a country with 410 000 adult cattle will be obliged to collect twice as many points as a country with 390 000 adult cattle. It would be better to split in more categories for the smaller populations.

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*.

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

Community written comments:
The Community suggests the following wording in accordance with the definitions of the subpopulations as mentioned in Article 3.8.4.1. and 3.8.4.2.:

'If a country, zone or compartment determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'emergency slaughter' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

~~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 slaughter[1]	**Fallen stock[2]**	**Casualty slaughter[3]**	**Clinical suspect[4]**
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).

Community written comments:
The Community suggests aligning the terminology in the table with the definitions under Article 3.8.4.1. and 3.8.4.2.

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Appendix XXX

APPENDIX 3.6.5

GENERAL GUIDELINES FOR THE DISPOSAL OF DEAD ANIMALS

Community speaking position:
The Community supports this proposal.

Introduction

The mass disposal of dead animals associated with an animal disease outbreak is often subject to intense public and media scrutiny thereby obligating the *Veterinary Administration* of a Member Country to not only conduct disposal operations within acceptable scientific principles to destroy the causative pathogen but also to address public and environmental concerns.

The guidelines in this Appendix are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and be attainable with the resources available. The guidelines should also be applied in conjunction with the procedures described for the humane killing of animals in Appendix 3.7.6.

Strategies for the disposal of dead animals (entire animals or parts thereof) should be prepared well in advance of any emergency. Major issues related to the disposal of dead animals include the number of animals involved, biosecurity concerns over the movement of infected or exposed animals, people and equipment, environmental concerns, and the psychological distress experienced by farmers and animal handlers.

Regulations and jurisdiction

The legislation regulating animal health and the organisation of the *Veterinary Administration* should give the *Veterinary Services* the authority and the legal powers to carry out the activities necessary for the efficient and effective disposal of dead animals. Cooperation between the *Veterinary Service* and other relevant government bodies is necessary to developing a coherent set of legal measures for the disposal of dead animals in advance of any emergency. In this context the following aspects should be regulated:

- Right of entry to an establishment for the *Veterinary Services* and associated personnel;
- Movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead animals to another location for disposal;
- The obligation on the involved farmer and animal handlers to cooperate with the *Veterinary Services*;
- Any need to transfer the ownership of animals to the *Competent Authority;*
- The determining of the method and location of disposal, and the necessary equipment and facilities, by the V*eterinary Services*, in consultation with other involved authorities including national and local governmental organisations competent for the protection of the environment,;

Should the chosen option for the disposal of dead animals be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Preparedness

The mass killing and disposal of animals in the event of a disease outbreak or disposal of animals in the event of natural disasters such as floods, usually must proceed with the minimum delay. The success is determined by the structures, policies and infrastructure established in advance:

- *Technical preparedness* – standard operating procedures (including documented decision-making processes, training of staff); a relationship with industry is essential to obtain compliance with animal health policies - farmer associations, commodity representatives, animal welfare organisations, support structures such as security services, relevant government agencies, the media and consumer representatives

- *Financial preparedness* - a compensation or insurance mechanism; access to emergency funding; access to personnel through agreements with private veterinarians;

- *Communication plan* - Information sharing with officials involved in the outbreak, affected farmers, professional organizations, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

- *Resources* –The management of resources should address such items as personnel, transport, storage facilities, equipment (such as mobile handling facilities for animals, disinfection equipment), fuel, protective and disposable material and logistical support.

- *Heavy equipment* – including trucks, tractors, bulldozers, and front-end loaders.

Critical elements

The list of critical elements, which has not the pretension to be complete, needs to be taken into account in planning and implementation.

- *Timeliness* - early detection of new infections, immediate killing of infected animals and rapid removal of the dead animals with inactivation of the pathogen are important. Spread of the pathogen from the dead animals and their surroundings should be blocked as soon and as effectively as possible.

- *Occupational health and safety* - Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposing dead animals. Special attention should be given to zoonotic aspects. Workers should be sufficiently protected against infection with protective clothing, gloves, face masks, spectacles, vaccination, anti viral medicines, regular health checks.

- *Pathogen inactivation* - the disposal procedure should be selected to result in inactivation of the pathogen.

- *Environmental concerns* - different methods of the disposal of dead animals have different effects on the environment. For instance pyre burning will produce smoke and smells; burial might lead to gas production and also a risk of contamination of air, soil, surface and sub surface water.

- *Availability of capacity* - An assessment of capacities of different methods of disposal should be made prior to any emergency. Temporary storage of dead animals in cold stores may relieve a lack of processing capacity.

- *Inadequate funding*

- *Public reaction*

- *Acceptance by farmers* - Farmers will be sensitive to the safety measures taken to prevent spread of the disease by disposal method selected and the transport of the dead animals to the disposal site. Adequate compensation of owners for the loss of animals or for burial or burning sites will improve acceptability.

- *Equipment* - Equipment used in the disposal of dead animals can transfer infection to other premises. The cleaning and disinfection of the outside surfaces of equipment such as cranes, containers and trucks, and the departure of vehicles from the farm should receive special attention. Trucks transporting dead animals should be leak proof.

- *Wildlife* - When disposing of dead animals, full attention should be given to preventing scavengers gaining access to dead animals, which might cause spread of disease.

Practical considerations

- *Selection of disposal site* – sufficient top soil to cover the site; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites.

- *Selection of contractors for transport* – availability; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.

- *Logistical preparedness for the appropriate technology* – availability of fuel (wood, old tyres); sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to minimise the spread of infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (eg vaccination) of personnel; rendering capacity at rendering plants; arms and ammunition, additional cold storage and holding facilities at rendering plants and abattoirs.

- *Procedures and policies for disposal of other possibly contaminated products* – manure, eggs; milk; non-animal products; animal feed.

- *Wildlife* –need to address risk posed; expertise availability for capture/culling of wildlife.

Recommended methods for the disposal of dead animals

The method(s) chosen should be based on local conditions and circumstances.

Some of the methods below may require on-farm pre-processing prior to transportation of dead animals to central facilities for rendering or incineration. Preprocessing could include the grinding of dead animals which can be transported in sealed containers, or be subjected to fermentation or freezing.

- *Rendering* - This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. The availability of the capacity should be determined in advance.

- *Incineration in a dedicated facility* – In such a facility, whole dead animals or parts of animals can be completely burned and reduced to ash, often in conjunction with other substances (such as municipal waste, hazardous waste or hospital waste). Effective inactivation of pathogens, including spores, occurs. Fixed facility incineration is wholly contained and has some advantages from the environmental viewpoint as the exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber.

- *Rendering and incineration* - These may be combined for improved security and to provide additional fuel for furnaces in facilities used for other purposes such as in cement kilns and electricity generation plants.

- *Air curtain incineration* – This process fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times for example in a burn-pit. The equipment can be mobile and, because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens.

- *Pyre burning* - This open system of burning dead animals is a well established procedure that can be conducted on site with no requirement for transportation of animal material. However, it takes an extended period of time and has no way of verifying pathogen inactivation, and there may be particulate dissemination from incomplete combustion. Further, because the process is open to view, there may be a lack of acceptance by the public.

- *Composting* - Composting is a natural ~~biological~~ decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients. However some viruses and spore forming bacteria, such as *Bacillus anthracis*, and other pathogens such as *Mycobacterium tuberculosis* may survive.

- *Trench burial* - In this method, whole dead animals are buried and covered by soil. Burial is an established procedure which may be conducted on site. It may not inactivate all pathogens. In some circumstances, dead animals may be disposed of by *mounding* whereby they are covered by a layer of soil above ground.

- *Biogas production* - This is a closed system of anaerobic fermentation which would require for the disposal of dead animals or their parts prior mechanical and thermal treatment of the input material (such as the liquid product of rendering plants). This process may not inactivate all pathogens.

- *Alkaline hydrolysis* – This method uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of bones and teeth. This residue (2% of the original weight of the animal) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

- *Bio-refining* - this is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurised vessel. The waste material is treated at 180°C at 12 bar pressure for 40 minutes, heated by the indirect application of steam kj, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. The process inactivates all microbiological agents.

- *Dead animal disposal at sea* - International Conventions define the conditions to be met for the disposal of dead animals at sea.

Guidelines for decision-making for the disposal of dead animals

Strategies for dead animal disposal require preparation well in advance of an emergency in order to maximize the efficiency of the response. Major issues related to dead animal disposal can include the number of animals involved, bio-security concerns over movement of infected and exposed animals, people and equipment, environmental concerns, and the extreme psychological distress and anxiety experienced by producers and emergency workers.

The disposal of large numbers of dead animals will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the

environment, local economies, producers, and the livestock industry. Decision makers need to understand the economic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of dead animal disposal technologies and must reflect a balance between the scientific, economic, and social issues at stake. Timely slaughter, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question:

Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety; community concerns; international acceptance; transport availability; industry standards; cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.

Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, must total 100.

Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor, (eg 1 = the worst possible fit, and 10 = the best fit).

Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg V = F x U)

Step 5 -By adding the Balanced Values to a sum for each disposal option, it is possible to compare the suitability of disposal options by numerically ranking the sums of the Balanced Values for each disposal option. The largest sum would suggest that disposal option as the best balanced choice.

An example of the use of this process follows in Table 1. In this example rendering achieved the highest sum and would be considered as the best balanced choice and the most suitable disposal option for the factors considered.

Appendix XXX (contd)

Table 1: **Decision Making Process**

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial		Commercial Landfill	
	Weight	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Factors															
Operator Safety	20	7	140	4	80	8	160	3	60	7	140	8			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	8	120	5	75	4	60	4			
Impact on Environment	10	10	100	8	80	3	30	10	100	3	30	3			
Reaction of the Public	10	10	100	7	70	1	10	9	90	3	30	4			
Transport Availability	5	1	5	1	5	8	40	5	25	3	15	8			
Acceptable to Industry	5	7	35	7	35	7	35	7	35	6	30	7			
Cost	5	4	20	1	5	6	30	9	45	8	40	9			
Risk to Wildlife	5	10	50	10	50	5	25	4	20	5	25	5			
Capacity to Meet Requirements	5	5	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	650	sum	535	sum	595	sum	515	sum		sum	

Appendix XXXI

APPENDIX 3.8.5.

FACTORS TO CONSIDER IN CONDUCTING THE BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT RECOMMENDED IN CHAPTER 2.3.13.

Community written comments:
The Community supports this proposal but would like the written comments below taken on board in the next working group meeting.

Article 3.8.5.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country, *zone* or *compartment* is to conduct a risk assessment (reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence, their historical perspective and the risk management measures which have been adopted to prevent cattle from becoming infected:

1) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present:

a) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

b) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

c) imported *meat-and-bone meal* or *greaves*;

d) imported cattle, sheep and goats;

e) imported animal feed and feed ingredients;

f) 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;

g) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

2) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, through a consideration of the following, to assess the likelihood of exposure of cattle to the BSE agent:

a) the epidemiological situation concerning BSE in the country or *zone*;

b) the potential for 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;

c) the origin and use of bovine, caprine or ovine carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

d) 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;

e) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance.

The following guidelines are intended to assist *Veterinary Services* in conducting such a risk assessment.

Article 3.8.5.1.(bis)

The presence or absence of the BSE agent in the indigenous ruminant population

Assumptions:

- While cattle pose the only demonstrated risk, and must be regarded as the best "indicator species" for the presence of BSE in a country, BSE has recently been demonstrated in a goat and there is potential for it to also be present in sheep.

- If a surveillance programme for BSE in cattle, as described in Appendix 3.8.4. is in place for an appropriate length of time and has failed to detect cases, it can be assumed that the disease is unlikely to be present in small ruminants.

- The BSE status of a country may change as more data become available; this may result from a change in status of any risk factor such as, for example, the detection of clinical disease, following active surveillance, or assessment of geographical BSE risk;

Question to be answered: Is a BSE surveillance programme as described in Appendix 3.8.4. in place? If so, for what period of time? Has BSE been identified in the country?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of BSE. The greater the surveillance effort, the greater the power of the information. Adequately targeted surveillance for BSE, such as described in Appendix 3.8.4., provides more powerful information than generic animal disease surveillance. Failure of an appropriate surveillance programme as described in Appendix 3.8.4., conducted for a period of 7 years (Article 2.3.13.3.) to detect a case of BSE indicates that either the agent was not released into the country, *zone* or *compartment*, or cattle were not exposed to the agent, or the production system was sufficiently stable to prevent the agents amplifying and recycling.

Evidence required: Documentation on awareness and surveillance programmes for BSE, their legal basis, scale, duration, and data generated.

Article 3.8.5.1. (tris)

The potential for the release of the BSE agent through meat-and-bone meal or greaves of local origin, or livestock feedstuffs potentially contaminated with them

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal* or *greaves* of local origin been used in livestock feedstuffs in the past? If so, where from which species and in what quantities? If so, what level of risk does this present?

Community written comments:
If meat-and-bone meal or greaves of local origin have been used in livestock feedstuffs in the past it is also interesting to know to which species, not only from which species. It is also interesting to know whether meat-and-bone meal of local origin have been used in feedstuffs for other animals and in that case if there have been any possible cross-contamination to livestock feedstuffs.

Rationale: Knowledge of the origin of *meat-and-bone meal* or *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent.

Evidence required:

- Documentation to support claims that *meat-and-bone meal* or *greaves* of local origin have not been used in livestock feedstuffs, OR

Community written comments:
Following the comment made under " question to be answered", the Community proposes to include:

"Documentation concerning prevention and control of potential cross-contamination."

- Where *meat-and-bone meal* or *greaves* of local origin have been used in livestock feedstuffs, documentation on annual volume.
- Documentation describing the composition (tissues used and species and class of stock) of the *meat-and-bone meal* or *greaves* of local origin.
- Documentation supporting why the rendering processes used to produce *meat-and-bone meal* or *greaves* of local origin would have inactivated, or significantly reduced the titre of the BSE agent, should it be present.
- Documentation describing the fate of locally-produced *meat-and-bone meal* and *greaves*.

Article 3.8.5.2.

The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves or livestock feedstuffs potentially contaminated with them

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal* or *greaves*, or feedstuffs containing either, been imported in the past? If so, when and where from and in what quantities? If so, what level of risk does the importation present?

Community written comments:
Regarding the destination of imported meat-and-bone meal, greaves or feedstuffs. It should be considered if imported meat-and-bone meal and greaves been used in

livestock feedstuffs or other feedstuffs including the possible cross-contamination of livestock feedstuffs.

Rationale: Knowledge of the origin of *meat-and-bone meal* or *greaves*, or feedstuffs containing either, is necessary to assess the risk of release of BSE agent.

Evidence required:

- Documentation to support claims that *meat-and-bone meal* or *greaves*, or feedstuffs containing either, have not been imported, OR
- Where *meat-and-bone meal* or *greaves,* or feedstuffs containing them, have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on dates of imports and annual volume, by country of origin, of *meat-and-bone meal* or *greaves,* or feedstuffs containing them, imported in the past.

Community written comments:
Following the comment made under " question to be answered", the Community proposes to include:

"- documentation describing the destination/use of imported meat-and-bone meal, greaves and feedstuffs.
- Documentation regarding to which species imported meat-and-bone meal, greaves or feedstuffs have been fed.
- Documentation concerning prevention and control of potential cross-contamination.."

- Documentation describing the composition (tissues used and species and class of stock) of the imported *meat-and-bone meal* or *greaves,* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal* or *greaves,* or feedstuffs containing them, would have inactivated, or significantly reduced the titre of the BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal*, *greaves* and feedstuffs.

Article 3.8.5.3.

The potential for the release of the BSE agent through the importation of bovine, caprine and ovine animals

Assumptions:

- Countries which have imported cattle from countries infected with BSE are more likely to experience BSE.
- Countries which have imported caprine and ovine animals from countries infected with BSE may be more likely to experience BSE, although this risk is largely hypothetical.

Community written comments:
In assessing this potential risk of imports of caprine and ovine animals from countries infected with BSE, the surveillance efforts of the country of origin should be taken into account in the evaluation.

- Animals imported for breeding may pose a greater risk than animals imported for slaughter because they are typically kept to a greater age than animals imported for slaughter.

- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: Have bovine, caprine or ovine animals been imported at any time since 1980? If so, what level of risk does the importation present?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;

- the *exporting country*'s policies with respect to the feeding to livestock of rations containing protein of animal origin;

- how imported ruminants were disposed of at the end of their productive life and whether their tissues could have been rendered into *meat and bone meal* or *greaves*;

- species of ruminant animals imported;

- factors such as production type (e.g. dairy versus meat breeds), geographic location and the potential influence of culturally unique husbandry practices which may give rise to differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

- age at slaughter or death;

- fate (rendered, incinerated, buried) and, if tested for BSE, the results.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of birth, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

Community written comments:

Regarding the country of origin of imports the BSE status of the exporting country should be included in this documentation.

- Documentation describing numbers, origins and species imported.
- Documentation describing the fate of imported animals, including their age at slaughter or death and, if tested for BSE, the results.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.4.

The potential for the release of the BSE agent through the importation of products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13.

Assumptions:

- Current scientific evidence strongly indicates that semen, embryos, muscle meat, gelatine, blood and blood products, protein-free tallow, hides and skins, and milk play no role in the transmission of BSE.

- Countries which have imported products of bovine, caprine or ovine origin containing or contaminated with tissues listed in Article 2.3.13.13. from countries with BSE are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: What products of bovine, caprine and ovine origin potentially containing or contaminated with tissues listed in Article 2.3.13.13. have been imported in the past? What level of risk does the importation present?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.13);
- dates and annual volumes of imports;
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- temperature, time and pressure parameters of processes used in the manufacture of the products;
- the *exporting country*'s policies with respect to the feeding to livestock of rations containing protein of animal origin;
- whether products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. may have been diverted from intended use and been rendered into *meat-and-bone meal* or *greaves*.

Evidence required:

- Documentation on the country of origin of imports of products potentially containing or contaminated with tissues listed in Article 2.3.13.13. This should identify the country of birth of bovine, caprine and ovine animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.5.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine, caprine or ovine origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of bovine, caprine and ovine origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin ever been fed to ruminants? If so, what level of risk does the practice present?

Rationale: If cattle have never been fed products potentially containing *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Evidence required: Documentation on feeding practices and feed bans, and measures to prevent cross-contamination of animal feed.

Community written comments:
It should also be assessed if there have been any possible cross-contamination to livestock feedstuffs. Therefore the Community proposes to add:

"and measures to prevent cross-contamination of animal feed <u>and control of these measures</u>. "

Article 3.8.5.6.

The potential for the release of the BSE agent through the importation of products of ruminant origin intended for *in vivo* use in cattle

Assumptions:

- TSEs have been demonstrated to be transmissible between animals iatrogenically, through the use of tissues containing potentially high levels of infectivity in the manufacture of vaccines in particular. Although such records relate specifically to the use in small ruminants of vaccines derived from brain or mammary tissue, the use of bovine brain for such purposes must also logically present a risk.

- International guidelines for the production of veterinary biological medicinal products recognise these risks, and aim to mitigate them by safe sourcing (as in Article 2.3.13.13) coupled, where necessary, by safe production methods.

Questions to be answered:

- Have veterinary biological medicinal products ever been imported from countries at risk of BSE?

- Would such products be manufactured by companies that guarantee compliance with international guidelines on the manufacture of veterinary medicinal products?

- Are individuals permitted to produce veterinary biological medicinal products that are not subject to national regulation, such as for use only within the herd or flock of origin, and is there potential for source materials to be derived from other countries?

Rationale:

- Scrapie has been demonstrated to be transmissible through the administration of vaccines against louping ill and against *Mycoplasma agalactiae*, which have been produced from ovine brain tissue and mammary tissue respectively. Parenteral inoculation of products containing such tissues, or organs such as the pituitary gland, is an effective means of transmitting infection. Similar risks could arise with regard to bovine derived vaccines which involved brain, spinal cord or pituitary gland.

Evidence required:

- Documentary evidence of national controls over the manufacture, importation and use of veterinary medicines.

- Specific documentation on products that contain, or have used bovine, ovine or caprine brain tissue as a substrate in manufacture.

Article 3.8.5.7.

The fate of tissues listed in Article 2.3.13.13, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- BSE has a long incubation period and insidious onset of signs, so cases may escape detection.
- Except for cases in the late *incubation period*, pre-clinical BSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- BSE may manifest in chronic disease or recumbency, and may be presented as fallen stock.
- Tissues listed in Article 2.3.13.13 (including tissues most likely to contain high titres of BSE infectivity) may be present in materials condemned as unfit for human consumption and may be rendered.
- BSE agent survival in rendering is affected by the method of processing. Rendering processes are described in Appendix 3.6.3.

Question to be answered: How has material containing tissues listed in Article 2.3.13.13 been processed in the past?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 3.8.5.8.

The overall risk of BSE in the cattle population of a country, *zone* or *compartment* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the risk assessment to conclude that the cattle population of a country, *zone* or *compartment* poses a negligible BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.