# Annex 7

# **USA COMMENTS**

# DRAFT CHAPTER 1.8.**APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY**

# Article 1.8.1.

## Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of the cattle (*Bos indicus* and *Bos taurus*) population of a country or *zone* is determined on the basis of a *risk assessment* that evaluates the risk of BSE agents (classical and atypical) being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE *cases*.

In this chapter, “BSE” refers to both classical and atypical forms~~, unless specified otherwise~~.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by OIE Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the “Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries" (available on the OIE website).

Each element of the core document of the dossier provided to the OIE, should be clearly and concisely addressed with an explanation, where relevant, of how each one complies with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

‒ The history of occurrence and management of BSE *cases* in the country or *zone* (Article 1.8.2.)

‒ Legislation (Article 1.8.3.)

‒ Veterinary system (Article 1.8.4.)

‒ BSE risk assessment (Article 1.8.5.)

‒ BSE surveillance (Article 1.8.6.).

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in the dossier. The dossier and all of its annexes should be provided in one of the OIE official languages.

# Article 1.8.2.

## History of occurrence and management of BSE cases in the country or zone

Describe the history of occurrence and management of BSE *cases* by providing the following documentary evidence:

1) If a *case* of BSE has ever been diagnosed in the country or *zone*, indicate the total number of BSE *cases*, and:

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a) Provide a table of aggregated data on all *cases* of BSE encountered in the country or *zone*, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;

b) For the past eight years, provide a table to indicate, for each *case*, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous *case* of classical BSE.

2) If there have been *cases* of BSE, confirm that they were excluded from the *feed* chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

# Article 1.8.3.

## Legislation

Provide a table listing all relevant legislation, regulations, *Veterinary Authority* directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

# Article 1.8.4.

## Veterinary system

The quality of the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members (Article 3.1.1.). It also supports an evaluation of the BSE risk status ~~of the cattle population~~ of a country or *zone*.

1) Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2.

2) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.

3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.

4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsmen; private *veterinarians*; *veterinary paraprofessionals*; transporters; workers at livestock *markets*, auctions and *slaughterhouses/abattoirs*; and other relevant non-governmental stakeholders in the control of BSE.

5) Describe the official cattle identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate if there are any industry associations or organisations involved in cattle identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

# Article 1.8.5.

## BSE risk assessment

### 1. Entry assessment

As described in Article 11.4.2., an entry assessment evaluates the likelihood that the classical BSE agent has been introduced into thecountry or *zone* through the importation of *commodities.*

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For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

The *commodities* to be considered in the entry assessment are:

‒ Cattle.

‒ Ruminant-derived protein meal.

‒ *Feed* (not intended for pets) that contains ruminant-derived protein meal.

‒ Fertilizers that contain ruminant-derived protein meal.

‒ Any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.~~, e.g. over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~posing a controlled or undetermined BSE risk.~~

#### a) For each *commodity* listed above indicate if they were imported in the preceding eight years, and if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country* or *zone* and whether or not they are consistent with, or provide an equivalent level of assurance with, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: cattle may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into *feed* for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place and their results to monitor or track imported *commodities* to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

#### b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

### 2. Exposure assessment

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated *feed*, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

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As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported *commodities* (classical BSE)oras a result of the presence of BSE agents (classical or atypical BSE) in the indigenous cattle population of the country or *zone*.

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e. longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e. to determine the period of time to be attested in point 2 of Articles 11.4.6., 11.4.7., 11.4.9., 11.4.12. and 11.4.13.).

As indicated in point 1b) of Article 11.4.2., the first step in the exposure assessment involves an evaluation of the impact of livestock industry practices on preventing cattle from being fed ruminant-derived protein meal and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle from being fed ruminant-derived protein meal.

#### a) Livestock industry practices.

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices with a particular emphasis on feeding practices; disposal of dead ~~stock~~ animals and waste from slaughtered animals; rendering; and production, distribution and storage of *feed* that may lead to cattle being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in Section *b)* *An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or *zone*.

##### i) Demographics of the cattle population and production systems.

Describe the composition of the cattle population and how the cattle industry is structured in the country or *zone* considering the types of production ~~systems, including all that apply,~~ such as dairy, beef rearing~~, feedlot, fattening~~ and beef finishing, and the farming systems, such as intensive, extensive, semi intensive, transhumant, pastoral, agropastoral, and mixed-species farming. The description should include the number and size of farms in each type of production system.

##### ii) Feeding practices.

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). Where animal-based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertilizers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e. cattle of any age which were found dead or were killed on a farm, during transportation, at livestock *markets* or auctions, or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at *ante mortem* inspections or any other materials derived from or that incorporate ruminant protein are applied to land where cattle graze or where forage is harvested for feeding to cattle. Where such fertilizers or composted materials are used, provide information on the extent and frequency of use.

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Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with *feed* meant for non-ruminant species or that ruminant *feed* is not likely to be cross-contaminated with *feed* intended for non-ruminants that may contain rendered products of ruminant origin.

##### iii) Slaughtering and waste management practices.

Describe the practices for fallen stock including cattle euthanised as part of a BSE surveillance programme under Article 11.4.18.~~that occur on farm, during transport, at livestock~~ *~~markets~~* ~~or auctions or prior to~~ *~~slaughter~~*, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe the places where cattle are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other [*Competent Authority*](http://www.oie.int/index.php?id=169&L=0&htmfile=glossaire.htm#terme_autorite_veterinaire) and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at *ante mortem* inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

##### iv) Rendering practices.

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal *feed*. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

‒ the source and types of raw materials handled;

‒ whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;

‒ whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;

‒ the parameters of the rendering process (time, temperature, pressure, etc.);

‒ the type and intended end use of rendered products produced. If available, provide the amount of rendered products produced annually by type and intended end use;

‒ if materials derived from imported cattle are managed differently, describe the process.

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Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programs, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

##### v) Feed production, labelling, distribution and storage.

Where rendered products are used as ingredients in the production of animal *feed* the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle *feed* or as a result of cattle *feed* being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether or not facilities producing *feed* for ruminant or non-ruminant livestock as well as pets are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of facilities producing *feed*, indicating for each facility:

‒ ~~excluding those listed in Article 11.4.1bis.,~~ whether or not rendered ruminant products, excluding those listed in Article 11.4.1bis., were used as ingredients in *feed* for ruminants, non-ruminants and pets;

‒ whether or not each facility was dedicated to manufacturing *feed* for a particular species or manufactured *feed* for multiple species including ruminants.

Where facilities manufactured *feed* for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during *feed* manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programs, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

##### vi) Conclusions for livestock industry practices.

‒ Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?

‒ Clearly and concisely describe the rationale leading to the conclusion reached.

‒ Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimatio*n.

‒ Where the likelihood estimate is non-negligible, proceed to *Section b) An evaluation of BSE specific mitigation measures*.

#### b) An evaluation of BSE specific risk mitigation measures.

For those countries that have reported classical BSE *cases* in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in their cattle population. These countries, together with others whose livestock industry practices would have been conducive to recycling may have implemented specific measures, such as through a legislated *feed* ban to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

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##### i) The nature and scope of a feed ban.

Indicate if there is a ban on feeding ruminants with protein meal derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

##### ii) Commodities with the greatest BSE infectivity.

Indicate whether or not any of those *commodities* listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

‒ Describe how they are disposed or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.

‒ Describe any measures in place that ensure *slaughter* waste declared as unfit for human consumption that is rendered is not cross-contaminated with these *commodities*.

‒ Describe whether these *commodities* from fallen stock and animals condemned at *ante mortem* inspection are excluded from rendering and how this is done.

‒ Where these *commodities* are not excluded from fallen stock or *slaughter* waste declared as unfit for human consumption, describe the final disposal of this waste, and how it is handled and processed.

‒ Describe whether or not all these processes and methods are subject to approval and oversight by the *Veterinary Services* or other *Competent Authority*.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

##### iii) Parameters of the rendering process.

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

##### iv) Cross-contamination.

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other *Competent Authority*.

##### v) Awareness programme under the scope of the feed ban.

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

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##### vi) Monitoring and enforcement of the feed ban.

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

‒ official oversight from the *Veterinary Authority*, other *Competent Authority* or a third party;

‒ training and accreditation programmes for inspectors;

‒ the planned frequency of inspections, the procedures involved including manuals and inspection forms;

‒ sampling programmes and *laboratory* testing methods used to check the level of compliance with the *feed* ban and cross-contamination;

‒ options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years using tables as appropriate:

‒ planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance and how they may have impacted the programme;

‒ number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not cross contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;

‒ the types of infractions (non-compliance) that occurred and corrective actions undertaken;

‒ any infractions (non-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

##### vii) Conclusions for the evaluation of BSE specific risk mitigation measures.

‒ In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:

‒ the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials cross contaminated by them, may have entered the animal feed chain;

‒ the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;

‒ the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived protein meal.

‒ Given the evaluation of BSE specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the cattle population has been exposed to either classical or atypical BSE negligible or non-negligible?

‒ Clearly and concisely describe the rationale leading to the conclusion reached.

‒ Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.

‒ Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

### 3. Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to classical BSE.

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As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

*‒ commodities* listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;

*‒* the rendering process does not destroy infectivity of the BSE agent(s);

*‒* the ruminant-derived protein meal is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived protein meal as an ingredient;

*‒* one or more animals that ingest contaminated *feed* become infected;

*‒* the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;

*‒ commodities* listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

#### a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:

##### i) Age at exposure.

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

##### ii) Production type.

‒ Calves reared as replacement animals for the breeding *herd*.

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle *feed*, it is highly likely that some level of recycling would occur.

‒ Feedlot cattle.

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

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Considering that mature cattle are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle *feed*.

##### iii) The impact of livestock industry practices or the implementation of measures under a *feed* ban.

When evaluating the potential for the recycling of the BSE agents in the cattle population where an infraction (non-compliance) has occurred that may have led to *feed* being ~~cross-~~contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

#### b) Conclusions for the consequence assessment.

Where the outcome of the evaluation of livestock industry practices or the evaluation of BSE specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the cattle population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

### 4. Risk estimation

### As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal.

#### a) Provide a summary of the entry and exposure assessments and the conclusions reached.

#### b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.

#### c) ~~When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly~~ Indicate the period of time for which it can be considered that the risk of BSE agents being recycled in the cattle population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.

# Article 1.8.6.

## BSE surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme together with an overview of the range and progression of clinical signs that cattle affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle population where ~~disease~~ BSE is more likely to be detected~~, if it is actually present~~.

The Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 3 of Article 11.4.18. have been effectively implemented.

For the purposes of *surveillance*, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

Animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the disease spectrum (i.e. from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE *surveillance* and include those animals described in points 2a) to 2d) of Article 11.4.18.

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### 1. Awareness and training programmes (point 3a) of Article 11.4.18.)

Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

#### a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.

#### b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group by those involved in caring for livestock, as well as the protocols for sample collection and submission by *veterinarians* and animal health technicians).

#### c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographic coverage for these activities.

#### d) Provide a description including examples of materials used in the awareness programme including training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist).

#### e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.

#### f) Provide details of any contingency or preparedness plan for BSE.

### 2. Compulsory notification (point 3b) of Article 11.4.18.)

To ensure the reporting and further investigations of any animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the BSE spectrum, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

a) Indicate the date of implementation of any supporting legislation and associated policies making notification of BSE compulsory. Indicate if a definition for a "BSE suspect" exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.

b) Describe the supportive measures in place for notification of animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the BSE spectrum, such as incentives, compensations or penalties.

#### c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters, workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria for reporting animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the BSE spectrum. What mechanisms are in place to ensure that these guidelines reach those stakeholders?

#### d)Describe the reporting framework for animals that ~~lie on the continuum~~ show ~~symptoms~~ signs of the BSE spectrum for evaluation. Has this framework evolved over time and, if so, how?

### 3. Laboratory testing (point 3c) of Article 11.4.18.)

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

#### a) If BSE samples are submitted to a *laboratory* in the country or *zone* for testing provide an overview of how many are involved in testing BSE samples, how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.

# Annex 7 (contd)

#### b) If the BSE samples are not submitted to a *laboratory* in the country or *zone* for testing or suspicious or positive samples are referred to a *laboratory* outside the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

#### c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e. negative, positive and inconclusive)?; and what test would be undertaken if discordant results between primary and secondary tests arise (e.g. primary positive result followed by a secondary negative result)?

#### 4. Evaluation procedures and protocols to identify and report potential candidates for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up with epidemiological investigation BSE positive findings (point 3d) of Article 11.4.18.)

Because the incidence of BSE is likely to be very low in Member Countries it is important that *surveillance* efforts focus on subsets of the cattle population where disease is more likely to be detected~~, if it is actually present~~. Hence, those animals described in points 2a) to 2d) of Article 11.4.18. must be targeted for BSE *surveillance*.

Considering that BSE is a progressive disease and that animals to be included in the *surveillance* programme may arise at the farm, the *slaughterhouse/abattoir*, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification and reporting of animals potentially ~~lying on the continuum~~ showing ~~symptoms~~ signs of the clinical BSE spectrum (e.g. by the farmer, *animal handler*, *veterinarian*, etc.), (2) the criteria to determine which of these reported animals need to be tested for BSE (e.g. the criteria used by the *veterinarian* that allows the discrimination of reported animals subject to laboratory testing), (3) the collection and submission of samples for testing in a laboratory, and (4) a follow-up epidemiological investigation for BSE positive findings.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

a) List the common cattle disorders with clinical signs compatible with BSE in the country or *zone*. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g. dairy, beef) and by age group.

b) Describe the procedures and protocols in place for reporting animals potentially ~~lying on the continuum~~ showing ~~symptoms~~ signs of the clinical BSE spectrum (those described in points 2a) to 2d) of Article 11.4.18.) to the *Competent Authority*. For example, these procedures and protocols may include the steps that a farmer may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

c) Describe the procedures and protocols in place for the investigation of reported animals potentially ~~lying on the continuum~~ showing ~~symptoms~~ signs of the BSE spectrum (those described in points 2a) to 2d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the *herd* are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

 **RATIONALE:** Accuracy.

d) Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition.

# Annex 7 (contd)

e) Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the cattle identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from.

f) Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results.

g) Provide a summary table for each of the preceding eight years (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2a) to 2d) of Article 11.4.18.).

|  |
| --- |
| Table 1.  |
| Year: \_\_\_\_\_ |
| Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority  |
| Clinical presentation (see point 2 of Article 11.4.18.) | Number of reported animals  | Number of animals subjected to BSE testing |
| (A) Cattle displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment |  |  |
| (B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs  |  |  |
| (C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history |  |  |
| (D) Cattle found dead (fallen stock) with an appropriate supporting clinical history  |  |  |

### 5. Animals subjected to laboratory testing

#### a) Provide in Table 2, for each of the preceding eight years, details of all animals counted in Table 1 that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

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| --- |
| Table 2. Details of the animals that were subjected to laboratory testing. |
| Year notified | Laboratory identification number or individual identification number  | Age(in months) at first detection | Type of production system (dairy, beef, mixed, etc.) | Description of observed clinical signs  | Clinical presentation (A, B, C or D) | Final diagnosis (if BSE, specify the strain)  | For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth) |
|  |  |  |  |  |  |  |  |

# Annex 7 (contd)

# Article 1.8.7.

## Recovery of BSE risk status

Following the occurrence of an indigenous *case* of classical BSE in an animal born within the preceding eight years in a country or *zone* with a negligible BSE risk status ~~of a country or~~ *~~zone~~*, the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.

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