
USA Comments in blue font

Article 1.6.5.

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

Report of a Member Country which applies for recognition of status,
under Chapter 11.4. of the Terrestrial Code

Please address concisely all the following topics under the headings provided to describe the actual situation and procedures currently applied in the country explaining how this complies with the Terrestrial Code.

Please use the terminology defined in the OIE Terrestrial Code and Terrestrial Manual.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages.

Any annex should be provided in one of the OIE official languages.

1. INTRODUCTION

Provide a general description of the husbandry and slaughtering practices in the country.

2. VETERINARY SYSTEM

a) Describe how the Veterinary Service of the country complies with the provisions of Chapters 1.1., 3.1. and 3.2. in the Terrestrial Code.

b) Describe how Veterinary Services supervise, control and maintain all BSE-related activities.

c) Provide maps, figures and tables wherever possible.

d) Provide information on any OIE PVS evaluation conducted in your country and follow-up steps within the PVS Pathway and highlight the results relevant to BSE and the susceptible species.

e) Provide a description of the structure (including number and distribution) and role of private veterinary profession in BSE surveillance and control.

3. BSE RISK STATUS REQUIREMENTS

Article 11.4.2. of the Terrestrial Code Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country or zone. This document is the means whereby a claim for negligible risk (Article 11.4.3.) or controlled risk (Article 11.4.4.) can be made to the OIE.

The document comprises the following:

– Section 1 – Risk assessment (see Section Point 1 of Article 11.4.2.)

– Section 2 – Other requirements of Points 2 to 4 of Article 11.4.2.

– Awareness programme

– Compulsory notification and investigation
Diagnostic procedures and methods

Section 3 – BSE Surveillance and monitoring systems (Point 4 of Article 11.4.2. and Articles 11.4.20. to 11.4.22.)

Section 4 – BSE history of the country or zone (Articles 11.4.3. and 11.4.4.).

N.B. Where, during the completion of this questionnaire, the submitting Veterinary Service provides documentation regarding the legislation under which it is mandated, it should provide the content of any legal act described (in one of the three official languages of OIE), as well as the dates of official publication and implementation. Submitting countries should follow the format and numbering used in this document and address concisely the following topics.

SECTION 1: RISK ASSESSMENT (see point 1 of Article 11.4.2.)

Introduction

The first step in determining the BSE risk status of the cattle population of a country or zone is to conduct a risk assessment (reviewed annually), based on Sections 2 and 3 and Chapter 4.3. of the Terrestrial Code, identifying all potential factors for occurrence of classical BSE and their historic perspective. Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country or zone of origin should be provided.

Documentation guidelines

This section provides guidance on the data gathering and presentation of information required to support the risk entry and exposure assessments in respect of:

Entry assessment:
1) The potential for the entry of the classical BSE agent through importation of meat-and-bone meal or greaves (including of non-ruminant origin).
2) The potential for the entry of the classical BSE agent through the importation of potentially infected live cattle.
3) The potential for the entry of the classical BSE agent through the importation of potentially infected products of ruminant origin.

Exposure assessment:
4) The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production.
5) The potential for the exposure of cattle to the classical or atypical BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin.

In each of the five areas of entry and exposure assessment that follow, the contributor is guided in terms of the question, the rationale and the evidence required to support the country or zone status claim.

Entry assessment

1) The potential for the entry of the classical BSE agent through importation of meat-and-bone meal or greaves

Question to be answered: Has meat-and-bone meal, greaves, or feedstuffs containing either, been imported within the past eight years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of meat-and-bone meal, greaves or feedstuffs containing either meat-and-bone meal or greaves, is necessary to assess the risk of entry of classical BSE agent. Meat-and-bone meal and greaves originating in countries of undetermined or controlled BSE risk pose a higher likelihood of entry than that from negligible risk countries.

Evidence required:

a) Documentation, based on official statistics, to support claims that meat-and-bone meal (including of non-ruminant origin), greaves or feedstuffs containing either meat-and-bone meal or greaves have not been imported, OR
b) Documentation, based on official statistics, on annual volume, by country of origin, of meat-and-bone meal (including of non-ruminant origin), greaves or feedstuffs containing them imported during the past eight years.

c) Documentation describing the species composition of the imported meat-and-bone meal, greaves or feedstuffs containing them.

d) Documentation, from the Veterinary Service of the country of production, providing information that the method used to reduce BSE infectivity complies with Article 11.4.19.

2) The potential for the entry of the classical BSE agent through the importation of potentially infected live cattle

Question to be answered: Have live cattle been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:
– the BSE status of the country or zone of origin;
– dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;
– age of animals imported for slaughter;
– the effective implementation of the ban on feeding of ruminants with meat-and-bone meal and greaves derived from ruminants in the country or zone of origin before the birth of the imported animals.

Evidence required:

a) Documentation, based on official statistics, to support claims that live cattle have not been imported, OR

b) Documentation including tables on the country or zone of origin and volume of imports and providing evidence of compliance with the requirements of Articles 11.4.6. to 11.4.9.

3) The potential for the entry of the classical BSE agent through the importation of potentially infected products of ruminant origin

Question to be answered: What products of ruminant origin have been imported within the past seven years? This includes all products of bovine origin that are not considered as safe commodities in Article 11.4.1., in particular, products listed in points 1 a), v), vi) and vii) of Article 11.4.2.

Rationale: The likelihood of entry is dependent on:
– the BSE status of the country or zone of origin and whether these products contain tissues known to contain BSE infectivity (Article 11.4.13.);
– dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;
– age at slaughter.

Evidence required:

a) Documentation on the country or zone of origin and volume of imports of all products of ruminant origin that are not considered as safe commodities in Article 11.4.1.

b) Documentation providing evidence of compliance with the requirements of Chapter 11.4.

Exposure assessment

4) The origin of ruminant carcasses, by-products and slaughterhouse/abattoir waste, the parameters of the rendering processes

Question to be answered: How have ruminant carcasses, by-products and slaughterhouse/abattoir waste been processed over the past eight years?
Rationale: The overall risk of BSE in the cattle population of a country or zone is proportional to the potential for recycling and amplification of the infectivity through rendering practices. For the risk assessment to conclude that the cattle population of a country or zone is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting meat-and-bone meal could retain BSE infectivity.

The rendering is a process by which non edible animal by-products and slaughter waste, including bones and fallen stock, are transformed into meat-and-bone meal.

Evidence required:

a) Documentation describing the collection and disposal of fallen stock, non-edible animal by-products, and materials condemned as unfit for human consumption. If your country manages by-products derived from imported cattle differently, provide documentation.

b) Documentation describing the definition, collection and disposal of material listed in Article 11.4.14.

c) Documentation describing the rendering industry and process and parameters used to produce ruminant meat-and-bone meal and greaves.

d) Documentation describing monitoring and enforcement of the above.

e) Documentation, in the form of the following table, on the audit findings in rendering plants processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (e.g. fish, poultry, pig, horse), related to the prohibition of the feeding to ruminants of meat-and-bone meal and greaves. The sampling aims to detect whether material of non-ruminant origin could have been contaminated with ruminant material.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the eight years for which effectiveness is claimed)</th>
<th>Type of renderers</th>
<th>Number of plants in (A) inspected under Competent Authority supervision</th>
<th>Number of inspections in (B) in total</th>
<th>Total number of plants in (B) with infractions</th>
<th>Total number of plants in (B) inspected under Competent Authority supervision with sampling</th>
<th>Total number of plants in (E) with positive test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A)</td>
<td>(B)</td>
<td>(C)</td>
<td>(D)</td>
<td>(E)</td>
<td>(F)</td>
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</tr>
<tr>
<td>Year 1</td>
<td>Material of ruminant origin (or mixed species)</td>
<td>(e.g.: &lt; or = to A)</td>
<td>(e.g.: &gt; or = to B)</td>
<td>(e.g.: &lt; or = to B)</td>
<td>Not applicable for the purpose of the dossier</td>
<td>Not applicable for the purpose of the dossier</td>
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<tr>
<td>Only material of non-ruminant origin</td>
<td>(e.g.: &lt; or = to A)</td>
<td>(e.g.: &gt; or = to B)</td>
<td>(e.g.: &lt; or = to B)</td>
<td>(e.g.: &lt; or = to B)</td>
<td>(e.g.: &lt; or = to B)</td>
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<tr>
<td>Year 2, etc.</td>
<td>Material of ruminant origin (or mixed species)</td>
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<td></td>
<td>Not applicable for the purpose of the dossier</td>
<td>Not applicable for the purpose of the dossier</td>
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<td>Only material of non-ruminant origin</td>
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</tbody>
</table>
f) Documentation, in the form of the following table, on each rendering plant above processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (e.g. fish, poultry, pig, horse) with infractions, specifying the type of infractions (columns D and F of the table above) and the method of resolution.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the eight years for which effectiveness is claimed)</th>
<th>Type of renderers</th>
<th>Plant ID</th>
<th>Nature of infraction</th>
<th>Method of resolution</th>
<th>Follow-up results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>Material of ruminant origin (or mixed species)</td>
<td>ID 1</td>
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<td>ID 2</td>
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<td>ID 3, etc.</td>
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<td></td>
<td>Only material of non-ruminant origin</td>
<td>ID 1</td>
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<td>ID 3, etc.</td>
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<tr>
<td>Year 2, etc.</td>
<td>Material of ruminant origin (or mixed species)</td>
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<tr>
<td></td>
<td>Only material of non-ruminant origin</td>
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</tbody>
</table>

5) The potential for the exposure of cattle to the classical and atypical BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin

*Question to be answered:* Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (Articles 11.4.3. and 11.4.4. in the Terrestrial Code)?

*Rationale:* The overall risk of BSE in the cattle population of a country or zone is proportional to the level of known or potential exposure to BSE infectivity. If cattle have not been fed products of ruminant origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk. Where *meat-and-bone meal* is utilised in the production of any *cattle livestock* feed, the risk of cross-contamination exists.

In the case of countries applying for negligible risk status, it will be required to demonstrate that the ruminant feed ban has been effective for at least eight years.

Feed mills are processing plants where different feed ingredients are mixed and processed together to produce compound feed for animals. This should include on-farm feed producers that keep cattle.

*Evidence required:*

a) Documentation describing the feed industry, including repartition between feed mills producing feed for ruminant only, feed for non-ruminant only and feed for both.

b) Documentation describing methods of animal feed production, including details of ingredients used, and the extent of use of *meat-and-bone meal* (including of non-ruminant origin) in any livestock feed.

c) Documentation describing the use of imported *meat-and-bone meal* and *greaves* (including of non-ruminant origin), including the feeding of any animal species.
d) Documentation describing the use made of *meat-and-bone meal* and *greaves* produced from ruminants, including the feeding of any animal species.

e) Documentation on the measures taken to control cross-contamination of ruminant feedstuffs with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding.

f) Documentation, in the form of the following table, on the audit findings in feed mills processing feed for ruminant only, for non-ruminant only and for both, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*. The sampling aims to detect whether material of ruminant origin could have contaminated feed intended to ruminant.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the eight years for which effectiveness is claimed)</th>
<th>Type of feed mill</th>
<th>Number of feed mills in (A) inspected under Competent Authority supervision</th>
<th>Number of inspections in (B) in total</th>
<th>Total number of feed mills in (B) with infractions</th>
<th>Total number of inspected feed mills in (B) with sampling</th>
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</tr>
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<tbody>
<tr>
<td>(A)</td>
<td>(B)</td>
<td>(C)</td>
<td>(D)</td>
<td>(E)</td>
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</tr>
<tr>
<td>Year 1</td>
<td>For ruminant only</td>
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<td></td>
<td>For non-ruminant only</td>
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<td>Not applicable for the purpose of the dossier</td>
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<td>For both</td>
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<td>Year 2, etc.</td>
<td>For ruminant only</td>
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<td></td>
<td>For non-ruminant only</td>
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<td>Not applicable for the purpose of the dossier</td>
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<td></td>
<td>For both</td>
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</table>

**g)** Documentation, in the form of the following table, on each feed mill processing feed for ruminant only, for non-ruminant only and for both, with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution.

<table>
<thead>
<tr>
<th>Year (information should be provided for each of the eight years for which effectiveness is claimed)</th>
<th>Type of feed mills</th>
<th>Feed mills ID</th>
<th>Nature of infraction</th>
<th>Method of resolution</th>
<th>Follow-up results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>For ruminant only</td>
<td>ID 1</td>
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<td></td>
<td>ID 2</td>
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<td>ID 3, etc.</td>
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<td></td>
<td>For non-ruminant only</td>
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<td>ID 3, etc.</td>
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<td>For both</td>
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<td>ID 2</td>
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<td>ID 3, etc.</td>
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<tr>
<td>Year 2, etc.</td>
<td>For ruminant only</td>
<td>ID 1</td>
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<td>ID 2</td>
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<td></td>
<td>ID 3, etc.</td>
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<tr>
<td>For non-ruminant</td>
<td>ID 1</td>
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</tbody>
</table>
h) Documentation explaining why, in light of the findings displayed in the preceding four tables (of Sections 4 and 5), it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin.

i) Documentation of husbandry practices (multiple species farms) which could lend themselves to cross-contamination of cattle feed with meat-and-bone meal and greaves destined to other species.

SECTION 2: OTHER REQUIREMENTS (see points 2 to 4 of Article 11.4.2.)

1) Awareness programme (see point 2 of Article 11.4.2.)

Questions to be answered:

– Is there an awareness programme?
– What is the target audience?
– What is the curriculum and how long has it been in place?
– Is there a contingency and/or preparedness plan that deals with BSE?

Rationale:

An awareness programme is essential to ensure detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses.

Evidence required:

a) Documentation indicating when the awareness programme was instituted and its continuous application and geographical coverage.

b) Documentation on the number and occupation of persons who have participated in the awareness programme (veterinarians, producers, workers at auctions, slaughterhouses/abattoirs, etc.).

c) Documentation of materials used in the awareness programme (the manual, supportive documents, or other teaching materials).

d) Documentation on the contingency plan.

2) Compulsory notification and investigation (see point 3 of Article 11.4.2.)

Questions to be answered:

– What guidance is given to veterinarians, producers, workers at auctions, slaughterhouses/abattoirs, etc. in terms of the criteria that would initiate the investigation of an animal as a BSE suspect? Have these criteria evolved?
– What were the date and content of the legal act making notification of BSE suspects compulsory?
– What are the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspect?

Rationale:

In order to ensure an appropriate detection and follow-up of any BSE cases, a solid legislation on BSE control and eradication should be in place.

The socio-economic implications associated with BSE require that there be incentives and/or obligations to notify and investigate suspect cases.

Evidence required:
a) Documentation on the date of official publication and implementation of compulsory notification, including a brief description of incentives and penalties.

b) Documentation on the manual of procedures for investigation of suspect animals and follow-up of positive findings.

3) Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system (see point 4 of Article 11.4.2.)

**Questions to be answered:**

- Are the diagnostic procedures and methods those described in Chapter 2.4.6. of the *Terrestrial Manual*?

- Have these diagnostic procedures and methods been applied through the entire surveillance period?

**Rationale:**
The OIE only recognises for the purpose of this submission samples that have been tested in accordance with the *Terrestrial Manual*.

**Evidence required:**

a) Documentation as to the approved laboratories where samples of cattle tissues from the country or zone are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).

b) Documentation of the diagnostic procedures and methods used and their compliance with Chapter 2.4.6. of the *Terrestrial Manual*.

c) Documentation that the diagnostic procedures and methods have been applied through the entire surveillance period.

**SECTION 3: BSE SURVEILLANCE AND MONITORING SYSTEMS** (see point 4 of Article 11.4.2.)

**Questions to be answered:**

- Does the BSE surveillance programme comply with the guidelines in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*?

- What were the results of the investigations?

**Rationale:**
Articles 11.4.20. to 11.4.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

**Evidence required:**

1) Documentation that the samples collected are representative of the distribution of the cattle population in the country or zone, including by age and subpopulations as described in Article 11.4.21.

2) Documentation of the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified).
3) Documentation of the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.4.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of point 1 of Article 11.4.21. At least three of the four subpopulations should be sampled.

4) Documentation, based on the following table, of all clinically suspect cases notified complying with the definition in point 1 of Article 11.4.21.

<table>
<thead>
<tr>
<th>Laboratory identification number</th>
<th>Age</th>
<th>Description of observed clinical signs</th>
<th>Point of detection (farm, market channels, slaughterhouse)</th>
<th>Final diagnosis</th>
</tr>
</thead>
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</table>

5) Documentation according to the following table that the number of target points applicable to the country or zone and its BSE surveillance requirements (type A or type B surveillance as a result of the risk assessment of section 1) are met as described in Articles 11.4.21. and 11.4.22.

<table>
<thead>
<tr>
<th>SUMMARY TABLE FOR BSE SURVEILLANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year: (complete a separate table for each year of surveillance)</td>
</tr>
<tr>
<td>Surveillance subpopulations</td>
</tr>
<tr>
<td>Routine slaughter</td>
</tr>
<tr>
<td>Samples</td>
</tr>
<tr>
<td>&gt;1 and &lt;2 years</td>
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<tr>
<td>&gt;2 and &lt;4 years</td>
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<td>&gt;4 and &lt;7 years</td>
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<tr>
<td>&gt;7 and &lt;9 years</td>
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<tr>
<td>&gt;9 years</td>
</tr>
<tr>
<td>Subtotals</td>
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<tr>
<td>Total points</td>
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</tbody>
</table>

6) Indicate the number of adult cattle (over 24 months of age) in the country or zone.

SECTION 4: BSE HISTORY OF THE COUNTRY OR ZONE (see Articles 11.4.3. and 11.4.4.)

Questions to be answered:

– Has BSE occurred in the country or zone?
– How has it been dealt with?

Rationale:

The categorisation of a country or zone in as either negligible or controlled risk is dependent upon, the outcome of the risk assessment described in Section 1, compliance with the provisions described in Section 2, the results of surveillance described in Section 3, and the history of BSE in the country or zone. This section provides the opportunity to describe the BSE history in the country or zone.
Evidence required:

1) Documentation of whether a case of BSE has ever been diagnosed in the country or zone.

   In the case of positive BSE findings:

2) Documentation on the numbers of BSE cases (classical and atypical), the origin of each BSE case in respect to the country or zone. Indicate the birth date and place of birth.

3) Indicate the most recent year of birth of the classical BSE cases.

4) Documentation that:
   – the case(s), 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 could not rule out consumption of 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 or zone, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

4 COMPLIANCE WITH THE TERRESTRIAL CODE

The Delegate of the Member Country applying for a BSE risk status must submit documentary evidence that the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. of the Terrestrial Code have been properly implemented and supervised.

5. RECOVERY OF BSE RISK STATUS

Member Countries applying for recovery of BSE risk status of a country or zone should comply with the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. of the Terrestrial Code and provide detailed information as specified in this questionnaire.