The OIE Ad hoc Group on bovine spongiform encephalopathy met at the OIE Headquarters from 20 to 22 September 2000.

The members of the OIE Ad hoc Group and other participants are listed in Appendix I. Dr A. Thiermann was appointed chairman of the Ad hoc Group.

Dr T. Chillaud, Head of the Information and International Trade Department, welcomed the participants on behalf of Dr J. Blancou, Director General of the OIE. In his introductory address to the meeting, he pointed out that there had been changes to the presentation of the 2000 edition of the International Animal Health Code (the Code), one consequence of which was the renumbering of the articles of the chapter on bovine spongiform encephalopathy (BSE), without of course altering the content. He also called the attention of participants to the chapter concerning BSE in the 2000 edition of the Manual of Standards for Diagnostic Tests and Vaccines (in preparation), which provides information on the new diagnostic methods available.

The members of the Ad hoc Group examined the terms of reference established for their meeting according to the comments emanating from the 68th General Session, the specific issues raised by the World Health Organization and the documents received from the United States of America (USA) (see Appendix II).

The existence of the category of ‘countries provisionally free from BSE where at least one indigenous case has been reported’ was challenged by the USA, leading to their proposal to modify radically the content of the adopted BSE Chapter.

The Group reviewed the history of the drafting of the chapter on BSE, which has been an iterative process. It concluded that the existing provisions, although complex, had the advantage of encouraging declaration of the first case, on the understanding that a risk analysis was a key element prior to determination of the status of a country with regard to BSE.

The provisionally free category was designed as an intermediate step on the path to declaration of a ‘free country’ for countries categorised as countries with a high or a low incidence (providing a defensible ‘pathway’ between categories as in the Code Appendices on epidemiological surveillance systems for rinderpest and contagious bovine pleuropneumonia).
The *Ad hoc* Group, whilst not wishing to change the current structure of the chapter, acknowledged that an explanatory diagram showing the relationship and progression from high incidence status to free status would probably improve comprehension of the Chapter.

On the basis of available scientific information, the *Ad hoc* Group provided answers (see Appendix III) to each of the other questions resulting from the contribution of the United States of America or listed in the terms of reference. Taking into account these answers, the Group prepared revised draft Articles 2.3.13.1. to 2.3.13.6. for the BSE *Code* (see Appendix IV), and a revised draft *Code* Appendix 3.8.3. on the surveillance and monitoring systems for BSE (see Appendix V).
Appendix I

MEETING OF THE OIE AD HOC GROUP ON
BOVINE SPONGIFORM ENCEPHALOPATHY

Paris, 20-22 September 2000

List of Participants

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Note: Points 1 to 6 result from the discussion on BSE during the 68th General Session (May 2000).

1. Countries with a population of less than one million bovines aged 24 months

The Delegates of several countries (Austria, Estonia, Portugal and Slovenia) pointed out that the definition given for the category "BSE provisionally free countries or zones where at least one indigenous case has been reported", in which the limit is set at one case of BSE per million for cattle aged over 24 months, poses a problem for countries with less than one million bovines in this age bracket; from the point of view of these Delegates, such countries can never fall into this category.

The question put to the Ad hoc Group is therefore to know whether the definition should be modified to take into account countries with fewer than one million bovines aged over 24 months. If so, a revised wording of the definition will have to be proposed.

2. Risk materials classified by age

The Delegate of Portugal made reference to new scientific data that should be used to consider replacing ‘6 months’ by ‘12 months’ in point 2 a) of Article 3.2.13.15. (Now Article 2.3.13.22.). The Ad hoc Group is asked to verify that the new scientific data and to consider whether indeed this allows for such an amendment to be made.

3. New post-mortem diagnostic tests and surveillance

Dr Vallat pointed out that the new rapid diagnostic tests that can be used post mortem appear to offer new possibilities which the Ad hoc Group on BSE should study with a view to enriching the chapter and the accompanying Appendix, particularly in the field of surveillance. In this spirit, the Delegate of Switzerland suggested that point 4) of Article 3.2.13.1. (now Article 2.3.13.1.) should refer to targeted surveillance.

The Ad hoc Group is therefore requested to reflect on the possibility of taking into account new immunodiagnostic methods for BSE in the chapter on this disease and/or the Appendix, given that the question of the validation of these methods would have to be discussed by the Standards Commission.

4. Definition of the category "country or zone with a low incidence of BSE"

The Delegate of Italy discussed the interpretation to be given to the last paragraph of the definition of a ‘country or zone with a low incidence of BSE’. He thought that the text, as written, could erroneously appear to mean that even a country where no case had appeared could be classified in this category.

The Ad hoc Group is therefore requested to clarify this point.

5. Buffaloes

The Delegate of Nepal raised the fundamental question for his country and many other African and Asian countries—are buffaloes bovines? Dr Vallat expressed the view that the text only covered bovines in the strict sense of the term and suggested that the question of buffaloes, which had never been broached, be put to the Ad hoc Group.
6. Provisions on BSE status

The Delegate of Mexico mentioned the contribution that his country, Canada and the United States of America were prepared to make between the General Session and next September to the provisions concerning status.

The proposals referred to above will be submitted to the Ad hoc Group if they reach the Central Bureau in time for the meeting.

7. Review of BSE in small ruminants

Following the WHO Consultation on Animal TSEs and Public Health: Epidemiology, Risk and Research Requirements, which was held in Geneva (Switzerland) from 1 to 3 December 1999, the WHO wrote to the OIE to request “that a priority review of BSE in small ruminants” be conducted through the Code Commission.

The views of the Ad hoc Group on this matter are thus required, specifying whether the Code chapter on BSE should include provisions on small ruminants.

8. Hypothetical third route of transmission

This new item is added to take into account the contents of a fax sent on 27 July 2000 by Dr Maura Ricketts, Senior Medical Advisor on TSEs, Animal and Food-Related Public Health Risks, Department of Communicable Disease Surveillance and Control, WHO, to Dr J. Blancou, stating “as you know, we have continuing interest in BSE as a zoonotic disease, and read with interest several news stories suggesting that there was a third route for the transmission of TSE among cattle populations. Also, with the recently announced born-after-ban BSE case in the UK in 1996, we have noticed that the concept of a third method of transmission of BSE has become a part of many otherwise standard news stories on the subject, yet WHO is unaware of any evidence supporting a newly recognized route of transmission. Therefore, on behalf of WHO, we would like to request OIE to convene a working group to review available evidence and provide a statement on this matter.”
ISSUES DISCUSSED WITHIN THE AD HOC GROUP ON
BOVINE SPONGIFORM ENCEPHALOPATHY

The Ad hoc Group examined the comments emanating from the 68th General Session and the specific issues raised by the World Health Organization (WHO) as well as the documents received later from the United States of America (USA). The Group examined the chapter adopted during the General Session taking into consideration recent epidemiological findings and the limits of existing scientific information, incorporating the principles of risk analysis in developing practical recommendations for dealing with international trade without compromising human or animal health.

Issue 1: Describe the scientific basis for creating five categories of BSE country status

On the basis of the existing scientific information and OIE principles for disease status categorisation, the original chapter identified three categories (free, low incidence and high incidence). While the OIE precedent of categorisation by disease incidence alone was a natural course to follow, several aspects of bovine spongiform encephalopathy (BSE) (length of the incubation period, absence of pre-clinical tests to detect infected animals, absence of ante-mortem diagnostic tests to investigate suspected animals) demanded additional criteria for categorisation, leading successive Ad hoc Groups to incorporate consideration of risk factors in the process. This is consistent with the current OIE approach to categorisation (see Chapter 2.2.2. on Aujeszky's disease adopted during the 68th General Session).

Incorporating the assessment of risk factors meant creating an additional category (provisionally free), as most countries in the world could not be assigned to any of the original three categories.

In respect of OIE precedents (brucellosis, tuberculosis, etc.), free status does not deny the presence of cases. The introduction of a 'provisionally free' category encourages notification of first cases.

In response to numerous country comments requesting a clear distinction between provisionally free countries with and without cases, the previous Ad hoc Group recommended the text to further sub-divide this category (into provisionally free without cases and provisionally free with indigenous cases).

The Group stresses that while the names of categories reflect traditional OIE terminology (i.e. mainly based on incidence), the current categorisation process emphasises the assessment of risk factors and their management as well as the quality of surveillance.

Issue 2: Hypothesis of spontaneous BSE cases

The hypothesis regarding spontaneous BSE cases was discussed but was not taken into account in defining the category of 'provisionally free country or zone where at least one indigenous case has been reported'. It is only after conducting a risk assessment and demonstrating management of the risk factors identified that a country can be included in this category (see Article 2.3.13.4.).

Issue 3: Country provisionally free with indigenous cases

A country that continues to experience indigenous cases for several years without exceeding one case per million cannot be categorised as a 'provisionally free country where at least one indigenous case has been reported', unless it demonstrates that all criteria in Article 2.3.13.4. have been met. The Ad hoc Group disagrees with the assertion of the USA that additional cases necessarily mean 'repeated exposure occurred and could be continuing to occur', as a country could not remain in the category without demonstrating 'that appropriate measures have been taken for the relevant period of time to manage any risk identified' by the risk assessment process (see point 1 of Article 2.3.13.4.). While the Ad hoc Group recognises the possibility that 'repeated exposure occurred and could be continuing to occur' may be the case, the Group considers that alternate hypotheses are plausible:
Appendix III (contd)

1) in the case of a country which has evolved from low incidence to provisional freedom status by complying with point 2)b of Article 2.3.13.4., such cases could be ascribed to animals with incubation periods exceeding seven years;

2) in the case of a country that has been previously free or provisionally free without indigenous cases, the occurrence could be ascribed to imported animals whose identification has been lost or which have incurred accidental exposure (animals exported on a temporary basis, etc.).

The category of 'provisionally free country or zone where at least one indigenous case has been reported' is intended primarily as a transitional stage for countries previously categorised as low incidence countries that have managed the risk factors identified by the risk assessment, and thus are moving towards the status of disease freedom. The occurrence of rare indigenous cases (i.e. less than one per million) that can be convincingly explained by the recognised epidemiology of the disease should not necessarily result in the country status reverting to the low incidence category.

Issue 4: Justification of the difference between low incidence and high incidence countries

The justification was already given in 1998 (reference: Appendix III of the report of the meeting of the OIE Ad hoc Group on BSE dated June-July 1998):

'This limit can be justified by the following arguments:

1) it is based on historical data (countries that have reported indigenous cases are clearly divided into two groups);

2) the two log difference between the lower and the upper limits represents a statistically valid difference.'

A country with an annual incidence rate greater than, or equal to, one case per million and less than, or equal to one hundred cases per million that fails to meet all the criteria listed in Article 2.3.13.1. is categorised as a high incidence country (see Article 2.3.13.6.).

Issue 5: Specified risk materials

The recommendations addressing specified risk materials have been formulated for each category in order to make the risk management measures proportionate to the estimated level of risk. The recommendations are based on two principal factors:

1) the gradient in prevalence of BSE infected animals among the BSE categories;

   based on the definition for each category, there is a significant difference in the prevalence of infected animals between each category, as evidenced by actual statistical data;

2) the gradient in the level of detectable infectivity among the tissues which comprise the list of specified risk materials.

Within infected animals, there is a gradient of detectable infectivity among individual specified risk materials. Initially, the risk estimations were based on data obtained from published information on scrapie. Later, it was shown that this represented the worst case scenario, as data from naturally occurring clinical BSE cases demonstrated that infectivity is confined almost exclusively to the central nervous system (CNS) (reference: Table in page 11 of the document entitled "Opinion of the Scientific Steering Committee on the Human Exposure Risk (HER) via food with respect to BSE adopted on 10 December 1999", which can be viewed on, or downloaded from, the following Web page: http://europa.eu.int/comm/food/fs/sc/ssc/out67_en.html).

Therefore, based on current evidence of infectivity of tissues from natural BSE cases and experimental pathogenesis studies, there is a scientific argument for considering the removal of some non CNS tissues (such as tonsils, thymus and spleen) from the list of specified risk materials.
The Ad hoc Group questions why the removal of bones and lymph nodes is required in point 1 of Article 2.3.13.16., while these are not listed among the specified risk materials in point 1 of Article 2.3.13.22.

**Issue 6: Meat-and-bone meal**

The issue of potential cross contamination of cattle feed with feed that is intended for other species (pigs or poultry) and contains meat-and-bone meal is not dealt with in the Code, as the effectiveness of a ruminant feed ban has to be addressed at the national level. There is no scientific evidence supporting the ban of feeding pigs and poultry with meat-and-bone meal derived from ruminants.

Therefore the Ad hoc Group does not propose any changes to the existing Chapter.

**Issue 7: Countries with an adult cattle population of less than one million head**

The Delegates of several countries (Austria, Estonia, Portugal and Slovenia) pointed out that the definition given for the category "BSE provisionally free countries or zones where at least one indigenous case has been reported", in which the limit is set at one case of BSE per million for cattle aged over 24 months, poses a problem for countries with less than one million bovines in this age bracket; from the point of view of these Delegates, such countries can never fall into this category.

To address these concerns, the Ad hoc Group recommends that the maximum allowed incidence be expressed in millions of cattle years. For example, if the adult cattle population is 500,000, the incidence can not exceed one case every 24 months.

**Issue 8: Low incidence countries without indigenous cases**

In the context of the categorisation process, the absence of reported cases does not necessarily mean real zero incidence. Therefore the Ad hoc Group maintains its previous position that a country with no reported cases but that does not comply with all the criteria listed in Article 2.3.13.3. should be categorised as a country with a low incidence of BSE.

**Issue 9: Risk materials classified by age (point 2 a) of Article 2.3.13.22.)**

The Delegate of Portugal has not to date provided scientific evidence to justify replacing '6 months' by '12 months' in point 2a) of Article 2.3.13.22. and the review of current material presented on the EC/SCC web site has failed to reveal such evidence.

**Issue 10: New post-mortem diagnostic tests and surveillance**

The new diagnostic tests already available (one western blot and two ELISAs) can only be used, like immunohistochemistry, on dead animals. However, they have the advantage over immunohistochemistry of allowing faster examination of a large number of samples.

To take into account this scientific advance, as well as the experience of several Member Countries in the surveillance of this disease, the Ad hoc Group approved the proposal put forward by the Delegate of Switzerland during the 68th General Session to modify point 4 of Article 2.3.13.1. to refer to targeted surveillance.

Appendix 3.8.3. was also amended in the interest of improving surveillance by adding to existing provisions targeted surveillance of 'fallen stock' and emergency slaughtered stock. The animals included in this targeted surveillance are in addition to the numbers recommended in Table 1 of the Appendix. The text on random sampling of clinically normal cattle was modified to emphasise its very low level of epidemiological sensitivity.
Appendix III (contd)

The introduction to the Appendix was simplified because the chapter on BSE in the 2000 edition of the Manual of Standards for Diagnostic Tests and Vaccines (in preparation) provides information on the new diagnostic methods available.

**Issue 11: Buffaloes**

The Ad hoc Group stated that it had no scientific data on BSE infection of buffaloes (Bubalus spp., Syncerus sp.). Although no case had been reported to date in buffaloes, the fact that many genera belonging to the family Bovidae (including Bison sp.) are susceptible to transmissible spongiform encephalopathy led the Ad hoc Group to believe that buffaloes are probably also susceptible. Prior to trading in buffaloes and products of buffalo origin, one should conduct a risk analysis using the same principles as those described in the BSE Chapter.

In response to the query of the Delegate of Nepal, the Ad hoc Group added an introductory phrase in Article 2.3.13.1. of the chapter on BSE to emphasise that it deals only with BSE in cattle (Bos taurus and B. indicus).

**Issue 12: Review of BSE in small ruminants**

The opinion of the Ad hoc Group on this issue is that any demonstration of the presence of the BSE agent in small ruminants, or even any evidence suggesting that BSE is actually present in small ruminant populations should be examined by an Ad hoc Group.

A working group on this subject has been formed by the European Commission. The OIE should follow the progress of this group's work, and decide, if necessary, to convene an Ad hoc Group.

The Ad hoc Group considers that it is currently inappropriate to create a special chapter to deal with an event that for the moment remains pure conjecture.
CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this chapter are intended to manage the risks associated with the presence of the BSE agent in cattle (Bos taurus and indicus) only.

The bovine spongiform encephalopathy (BSE) status of a country or zone can only be determined on the basis of the following criteria:

1) the outcome of a risk [analysis] assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:
   a) consumption by cattle of meat-and-bone meal or greaves of ruminant origin;
   b) importation of meat-and-bone meal or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;
   c) importation of animals or embryos/ova potentially infected with a TSE;
   d) epidemiological situation concerning all animal TSE in the country or zone;
   e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;
   f) the origin of animal waste, the parameters of the rendering processes and the methods of animal feed production;

2) on-going education programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;

3) compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above and on selected subpopulations of higher risk animals, taking into account the guidelines in Appendix 3.8.3.; records of the number and results of investigations should be maintained for at least 7 years;

5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.

Standards for diagnostic tests are described in the Manual.

Article 2.3.13.2.

BSE free country or zone

A country or zone may be considered free of BSE if the following conditions are met:

1) a risk [analysis] assessment, as described in point 1) of Article 2.3.13.1., has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified;
Appendix IV (contd)

2) either:
   a) there has been no case of BSE; and either:
      i) the criteria in points 2) to 5) of Article 2.3.13.1. have been complied with for at least 7 years; or
      ii) the criteria in point 3) of Article 2.3.13.1. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants;

   OR

   b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle or bovine embryos/ova, and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:
      i) the criteria in points 2) to 5) of Article 2.3.13.1. have been complied with for at least 7 years; or
      ii) the criteria in point 3) of Article 2.3.13.1. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants;

   OR

   c) the last indigenous case of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.1. have been complied with for at least 7 years and the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years.

Article 2.3.13.3.

BSE provisionally free country or zone where no indigenous case has been reported

To be considered as a BSE provisionally free country or zone where no indigenous case has been reported, the country or zone should comply with the following requirements:

1) a risk assessment, as described in point 1) of Article 2.3.13.1., has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) either:
   a) there has been no case of BSE; and either:
      i) the criteria in points 2) to 5) of Article 2.3.13.1. are complied with, but have not been complied with for 7 years; or
      ii) it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.1. have not been complied with for 7 years;
b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle or bovine embryos/ova, and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.1. are complied with, but have not been complied with for 7 years; or

ii) it has been demonstrated that for at least 8 years no meat-and-bone meal or greaves have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.1. have not been complied with for 7 years.

Article 2.3.13.4.

BSE provisionally free country or zone where at least one indigenous case has been reported

To be considered as a BSE provisionally free country or zone where at least one indigenous case has been reported, the country or zone should comply with the following requirements:

1) a risk assessment, as described in point 1) of Article 2.3.13.1., has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) EITHER:

a) the last indigenous case of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.1. are complied with and the ban on feeding ruminants with meat-and-bone meal and greaves derived from ruminants is effectively enforced, but:

i) the criteria in points 2) to 5) of Article 2.3.13.1. have not been complied with for 7 years; or

ii) the ban on feeding ruminants with meat-and-bone meal and greaves derived from ruminants has not been effectively enforced for 8 years;

OR

b) the last indigenous case of BSE has been reported less than 7 years ago, the BSE incidence rate, calculated on the basis of indigenous case, has been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone*, and:

i) the ban on feeding ruminants with meat-and-bone meal and greaves derived from ruminants has been effectively enforced for at least 8 years;

ii) the criteria in points 2) to 5) of Article 2.3.13.1. have been complied with for at least 7 years;
Appendix IV (contd)

iii) the affected cattle as well as:

- if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

- all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life,

if alive in the country or zone, are slaughtered and completely destroyed.

* For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle years.

Article 2.3.13.5.

Country or zone with a low incidence of BSE

A country or zone may be considered as having a low incidence of BSE if:

1) a risk assessment, as described in point 1) of Article 2.3.13.1., has been conducted and the other criteria listed in Article 2.3.13.1. are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than, or equal to, one indigenous case per million and less than, or equal to, one hundred cases per million within the cattle population over 24 months of age in the country or zone; or

2) a risk assessment, as described in point 1) of Article 2.3.13.1., has been conducted and the other criteria listed in Article 2.3.13.1. are complied with, and the BSE incidence rate, calculated as specified in point 1) above, has been less than one indigenous case per million for less than four consecutive 12-month periods;

AND

3) the affected cattle as well as:

a) if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

b) all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life,

if alive in the country or zone, are slaughtered and completely destroyed.

Countries and zones where the BSE incidence rate, calculated over the past 12 months, has been less than one indigenous case per million within the cattle population over 24 months of age, but where a risk assessment, as described in point 1) of Article 2.3.13.1., has been conducted which demonstrates that at least one of the criteria to be recognised provisionally free from BSE is not complied with, shall be considered as countries or zones with a low incidence of BSE.
Article 2.3.13.6.

Country or zone with a high incidence of BSE

A country or zone may be considered as having a high incidence of BSE if:

1) a risk assessment, as described in point 1) of Article 2.3.13.1., has been conducted and the other criteria listed in Article 2.3.13.1. are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than one hundred case per million within the cattle population over 24 months of age in the country or zone; or

2) the BSE incidence rate, calculated over the past 12 months, has been greater than, or equal to, one case per million and less than, or equal to, one hundred cases per million within the cattle population over 24 months of age in the country or zone, and at least one of the criteria listed in Article 2.3.13.1. is not complied with.

...
APPENDIX 3.8.3.

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Surveillance for bovine spongiform encephalopathy (BSE) requires the laboratory examination of cattle brains or spinal cord from clinically suspect animals by histopathology and, if necessary, other methods described in the Manual (i.e. western blot, scrapie associated fibril examination and detection of abnormal PrP by immunohistochemistry). Since the histopathology of BSE is well described and remarkably consistent based on the experience of affected countries, histopathology alone is sufficient for BSE surveillance.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.5. on Surveillance and monitoring of animal health. [Options] Recommended strategies for selecting the part of the population for testing should include [in decreasing order of relevance]:

1. **Examination of native-born animals displaying clinical signs compatible with BSE**

   Screening the cattle population for animals displaying compatible clinical signs is the best approach for increasing the ability to detect BSE if it occurs. With this approach, animals displaying neurological signs or moribund cattle without signs of infectious or traumatic illness are candidates for examination of brain. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals with compatible clinical signs. Examination of the brains of these cattle may identify alternative diagnoses such as cerebral listeriosis, rabies or brain tumor. Surveillance should primarily focus on cattle over 24 months of age displaying behavioural and neurological signs lasting for at least 15 days and resistant to treatment. In countries where the incidence of progressive neurological diseases is low, surveillance may be extended to cattle over 4 years of age presenting clinical signs of progressive diseases.

   Table 1 indicates the minimum number of clinical cases that should be subjected to diagnostic tests according to the total native-born cattle population over 24 months of age. As this sampling is not random, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction.

   **Table 1. Minimum number of annual investigations of animals showing clinical signs compatible with BSE required for effective surveillance according to the total native-born cattle population over 24 months of age**

<table>
<thead>
<tr>
<th>Total native-born cattle population over 24 months of age</th>
<th>Minimum number of brains to examine</th>
</tr>
</thead>
<tbody>
<tr>
<td>500,000</td>
<td>50</td>
</tr>
<tr>
<td>700,000</td>
<td>69</td>
</tr>
<tr>
<td>1,000,000</td>
<td>99</td>
</tr>
<tr>
<td>2,500,000</td>
<td>195</td>
</tr>
<tr>
<td>5,000,000</td>
<td>300</td>
</tr>
<tr>
<td>7,000,000</td>
<td>336</td>
</tr>
<tr>
<td>10,000,000</td>
<td>367</td>
</tr>
<tr>
<td>20,000,000</td>
<td>409</td>
</tr>
<tr>
<td>30,000,000</td>
<td>425</td>
</tr>
<tr>
<td>40,000,000</td>
<td>433</td>
</tr>
</tbody>
</table>
Appendix V (contd)

2. Examination of selected subpopulations of higher risk animals

[Increases the ability to detect BSE if it is present.]

a) Higher risk animals include animals imported from countries or zones not free from BSE, animals which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE-affected cows and animals which have consumed feedstuffs potentially contaminated with other TSE agents;

b) Active surveillance programmes should target cattle that have died or have been killed for reasons other than routine slaughter (including 'fallen' stock and emergency slaughter).

Surveillance needs to [target mainly] focus on animals over 24 months of age.

[The efficiency of the surveillance is increased by a combination of the two above approaches.]

3. Random sampling of cattle brains

Random sampling of brains or spinal cords from normal cattle is not recommended. Since BSE is rare, even in countries with the highest incidence of disease, microscopic examination of brains from a random sample of the national cattle population is unlikely to detect a disease prevalence of 1 in 1,000,000 or more unless huge numbers of brains are examined.

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