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REPORT OF THE MEETING OF THE BUREAU OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 28 June to 2 July 2004

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The Bureau of the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Bureau) met at the OIE Headquarters from 28 June to 2 July 2004.

The members of the Bureau and other participants are listed in Appendix I. The Agenda adopted is given in Appendix II.

Dr D. Wilson, Head of the International Trade Department, welcomed the members of the Bureau on behalf of the Director General, Dr B. Vallat, and recalled the extensive work programme for the Code Commission resulting from discussions at the 72nd General Session, particularly on foot and mouth disease (FMD), avian influenza and a simplified categorisation system for bovine spongiform encephalopathy (BSE).

The Bureau took the opportunity to review the currency of all chapters and appendices in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*), and the texts which remained *under study* from previous discussions. Topics which the Bureau considered should be updated as a priority were listed in the future work programme. After cross-checking against the 2004 edition of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*), the Bureau removed the term (under study) from texts for enzootic bovine leucosis, equine viral arteritis and small ruminant semen.

The Bureau examined various draft and revised *Terrestrial Code* chapters and appendices, and comments received on them. The outcome of this part of the Bureau's work is presented as appendices to this report, with insertions and amendments to existing *Terrestrial Code* text and previously circulated drafts being shown as double underlined text, and with text proposed for deletion in strikeout.

Member Countries are strongly encouraged to comment on all aspects of the report. Comments need to reach the OIE Headquarters by 26 November 2004 in order to be considered at the next Code Commission meeting in January 2005.

A. TEXTS FOR MEMBER COUNTRY COMMENT

1. Chapter 1.1.1. General definitions

The Bureau did not revise the definition for 'emerging disease' because it considered that the proposal received from the United States of America (USA) did not significantly improve the current text.

A revised definition for *buffer zone* is at Appendix III.

The Bureau decided not to develop a definition for 'fallen stock' but to explain more clearly the use of the term in the BSE surveillance Appendix.

The Bureau recommended that the Central Bureau revise, without changing the scientific content or intent, the *Terrestrial Code* text as necessary to introduce the latest approaches to zone/region and compartment, and OIE listed diseases, as determined by the OIE International Committee.

2. Section 1.2. Obligations and ethics in international trade

The Bureau decided not to include the comments from the USA in paragraphs 5) and 6) of Article 1.1.1.2 because some of the comments reflected Member Countries' existing SPS obligations, and others did not take account of the need in some circumstances to act urgently on unverified reports.

3. Chapter 2.3.3. Bovine tuberculosis

The Bureau noted that the Scientific Commission for Animal Diseases was organising an *ad hoc* Group of experts to examine the proposed revised bovine tuberculosis chapter, in the light of Member Countries' comments and discussion at the General Session. The *ad hoc* Group would address both animal health and public health aspects. The Bureau proposed Dr W-A. Valder for membership of the *ad hoc* Group.

4. Chapter 1.3.5. Zoning, regionalisation and compartmentalisation

The Bureau did not add the additional text to Article 1.3.5.1 as suggested by the USA because the definitions of the two concepts already contained such text.

5. Chapter 2.1.1. Foot and mouth disease

The Bureau did not agree that a time limit should be placed on epidemiological linkages to a confirmed or suspected outbreak (Article 2.1.1.1), as proposed by the Southern Cone countries of South America. The Bureau believed that any linkages to a confirmed or suspected outbreak should be investigated whenever antibodies, including colostral antibodies, are found and cannot be linked to vaccination of the animal or its dam.

The USA's comment re 'shipped' was not adopted because veterinary certification cannot certify as to future events. Similar comments regarding the inclusion of issues covered in horizontal articles on import/export procedures were not adopted because such references would need to be made in all disease chapters and it was expected that certifying veterinarians would routinely refer to the relevant horizontal chapters.

The request from the Republic of South Africa for more testing safeguards to be included in Articles 2.1.1.14, 2.1.1.15 and 2.1.1.18 was unable to be addressed, in the absence of details as to the type of testing proposed and the species to be tested. The Bureau responded in a similar manner to the proposal from the Southern Cone countries of South America regarding comments on trade in meat under Articles 2.1.1.20 and 2.1.1.21, because the identified deficiencies which would require risk analysis for these commodities were not specified.

The Bureau proposed that paragraph 2) of Article 2.1.1.21 be deleted because a free country or zone has now been defined as one in which there is no evidence of virus circulation.

The proposed modifications are at Appendix IV.

6. Section 2.9. Bee diseases

The Bureau reviewed Member Countries' comments arising from the General Session discussion on the diseases of bees, and decided to ask the European Union (EU) to propose an expert(s) to draft a new chapter on the small hive beetle *Aethina tumida* (based on the current chapter on the *Tropilaelaps* mite), with a supporting document, prior to the Director General of the OIE establishing an *ad hoc* Group.

An *ad hoc* Group will be tasked with reviewing Member Countries' comments regarding feral populations and compartmentalisation, and the reference to haplotypes of *Varroa* mite in Article 2.9.5.1.

7. Section 3.9. Antimicrobial resistance

After consideration of comments from the EU, the Bureau of the Code Commission changed the title of the appendix to 'Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals' to better reflect the content and to be consistent with OIE terminology regarding risk analysis.

As a result of the complexity of comments received on the text and the specialist expertise required to address them, the Bureau decided to refer all other comments to the Biological Standards Commission.

8. Chapter 2.1.13. Classical swine fever

The Bureau of the Code Commission considered Member Countries' comments and the General Session discussion on classical swine fever (CSF) and reiterated its view that points b), c), d) and f) of paragraph 2 of Article 2.3.13.4 should be deleted and point g) of paragraph 2 of that Article be modified as those measures were not essential in order for a free country to maintain its status. The proposed modifications are at Appendix V.

The Bureau awaits advice from the Scientific Commission for Animal Diseases regarding commodities which could be safely traded regardless of the CSF status of the exporting country.

9. Chapter 2.3.13. Bovine spongiform encephalopathy

For this chapter, the Bureau of the Code Commission produced two alternative versions, taking into account comments received from Member Countries. Part a) contains a proposed new chapter with a simplified categorisation system while Part b) proposes a revised current chapter.

The Bureau urges Member Countries to examine these two approaches and to send comments to the Central Bureau.

a) New BSE chapter with a simplified categorisation system

Recalling the support from the OIE International Committee at the 72nd General Session for a simplified categorisation system for BSE, the Bureau of the Code Commission drafted a new text reflecting this approach. The new text (Appendix VI) is submitted to Member Countries for comment.

The following criteria were the basis for formulating the new text:

i) the recommendations from the *ad hoc* Group meeting of April 2004 for a three category approach; the report of the meeting is at Appendix VII;

ii) proposals from Member Countries – the EU, the USA, Australia, New Zealand, Japan, South Africa, Korea and Argentina – for a new approach;

iii) the shift in emphasis agreed by the OIE International Committee towards commodity-specific recommendations;

iv) the linkage between risk assessment outcomes and surveillance, and the ability to be categorised as negligible BSE risk with or without mitigating measures; and

v) the recommendations of the *ad hoc* Group regarding the factors relevant to a risk assessment and the safety of certain commodities.

Articles were consolidated as necessary to address a three category approach but changes to existing recommendations were minimised. In the explanation below, 'current Article' refers to the 2004 edition of the *Terrestrial Code.*

Article 1 was not modified with regard to specific commodities because of the absence of any new scientific information on the risks presented. With the respect to tallow, this approach reflects the position of the BSE *ad hoc* Group. The Bureau understands that the results of an investigation into whether or not the BSE agent may be present in tallow will soon be released. In addition, while the *ad hoc* Group believed that the information available indicated that 'bovine blood and blood by-products' would be safe (subject to stunning being carried out in accordance with the current Article 2.3.13.14), the Bureau awaits further concrete scientific information before making recommendations on their use.

Article 2 was modified, taking into consideration the recommendations of the *ad hoc* Group on the factors important to release and exposure assessments.

A new Article 3 addressing a category named *'negligible BSE risk without mitigating measures'* was drafted by merging current Articles 2.3.13.3 and 2.3.13.4 describing free and provisionally-free categories, and taking into consideration the recommendations of the *ad hoc* Group and comments received from Member Countries. Recommendations regarding the destruction of progeny were retained for a country or zone/compartment which had reported a case of BSE more than 7 years ago; however, the Bureau was of the view that, in the light of the lack of evidence for vertical transmission, these recommendations should be dispensed with from this article and the new Article 4.

The new Article 4 addressing a category named *'negligible BSE risk with mitigating measures'* incorporates the current Articles 2.3.13.5 and 2.3.13.6 describing minimal and moderate risk categories, and includes the concept of 'high BSE risk' in its recommendations. In this exercise, the Bureau took into consideration the recommendations of the *ad hoc* Group and comments received from Member Countries.

In order to have a single middle category, the Bureau considered it necessary not to differentiate risk levels for commodities on the basis of BSE incidence rate. In this regard, the Bureau agreed with the *ad hoc* Group's proposal that because of the difficulty of estimating accurately the prevalence of BSE infection and the relative lack of importance of prevalence in relation to rendering commodities safe, a broad second category be created with no arbitrary distinctions. Australia recommended an emphasis on risk assessment and disease management rather than on disease incidence in drawing up new categories. The USA also supported a risk-based rather than prevalence-based approach to categorisation. The Bureau considered that this approach did not reduce the importance of surveillance in categorising countries or zones/compartments.

A new Article 5 *'undetermined* BSE *risk'* was created for those countries or zones/compartments which, by not conducting a risk assessment or surveillance, could not be categorised in either of the above categories but which could still trade safely in certain commodities under specified conditions.

In accordance with the proposed 'three category system', the articles dealing with commodities have been redrafted to address the risk posed by the combination of the commodity and the source country or zone/compartment.

A new Article 6 is essentially unchanged from the current Article 2.3.13.8 which dealt with imports from free countries or zones.

A new Article 7 dealing with cattle from a country or zone/compartment posing a negligible BSE risk with mitigating measures resulted from a merger of the existing recommendations in current Articles 2.3.13.10 and 2.3.13.11.

The existing recommendations for the import of cattle from a country or zone with a high BSE risk were incorporated unchanged in new Article 8 addressing cattle from a country or zone/compartment with an undetermined BSE risk.

On the recommendation of the *ad hoc* Group, recommendations for post-mortem inspection were added to new Articles 9, 10 and 11 to address the need to certify to certain tissues having been removed in a manner to avoid contamination.

The new Article 10 is a combination of current Articles 2.3.13.14 and 2.3.13.15. The recommendations regarding the age for the removal of specified risk materials were based on expert advice regarding pathogenesis studies and epidemiological analysis.

The new Article 11 was modified from the current Article 2.3.13.16, taking into account the recommendations of the *ad hoc* Group, and in order to adapt it for Member Countries in which animal identification and traceability are not required. The Bureau did not believe that such systems would play a significant role in further mitigating any BSE risk posed by the exported commodity.

The recommendation for the removal of the entire intestine was reconsidered, and in view of comments from the USA, Thailand, Taiwan, Korea, Canada and Japan and advice from an expert, the Bureau now proposes that the current Article 2.3.13.18 (new Article 13) be modified to require the exclusion from trade of the distal ileum only.

The substance of the remainder of the articles is unchanged. The Bureau considered that the recommendations in the current Article 2.3.13.22 are substantially incorporated into new Article 2 and proposes deletion of this article.

b) Proposed revision of the current BSE chapter

The Bureau took Member Countries comments into account in revising the current BSE chapter.

In the absence of new scientific information on the risks presented, Article 2.3.13.1 was not modified with respect to specific commodities. This approach on tallow reflects the position of the BSE *ad hoc* Group. The Bureau understands that the results of an investigation into whether or not the BSE agent may be present in tallow will soon be released. In addition, while the *ad hoc* Group believed that the information available indicated that 'bovine blood and blood by-products' would be safe (subject to stunning being carried out in accordance with Article 2.3.13.14), the Bureau awaits further concrete scientific information before making recommendations on their use.

Article 2.3.13.2 was modified, taking into consideration the recommendations of the *ad hoc* Group on the factors important to release and exposure assessments.

Revised text submitted by the EU and Canada on Article 2.3.13.3 (and on Articles 2.3.13.4, 2.3.13.5, 2.3.13.12 and 2.3.13.16 for Canada) was not adopted as it was not considered to significantly improve the existing risk mitigation.

A comment from Australia and Canada regarding the age cut-off in Articles 2.3.13.5 and 2.3.13.6 was not adopted as the *ad hoc* Group believed that an age of 24 months was the usual cut off point for animal census data; if the ages were aligned at 24 months, the *ad hoc* Group considered that the prevalence cut-off limits for the categories would need to be adjusted.

The wording of paragraph 2) c) of Article 2.3.13.6 was clarified.

On the recommendation of the *ad hoc* Group and in light of comments from Canada, recommendations for post-mortem inspection were added to Articles 2.3.13.13, 2.3.13.14, 2.3.13.15 and 2.3.13.20 to address the need to certify to certain tissues having been removed in a manner to avoid contamination.

A Japanese recommendation that meat-and-bone meal be banned even from BSE-free countries was not adopted as it was considered to be excessive for exporting countries not affected by BSE.

The age cut-off for mechanically separated meat from skull and vertebral column in Article 2.3.13.16 was changed from 6 to 12 months on the recommendation of the *ad hoc* Group and for consistency with Article 2.3.13.18.

The current recommendation to remove the entire intestine was reconsidered by the Bureau, and in view of comments from the USA, Thailand, Taiwan, Korea, Canada and Japan and advice from an expert, the Bureau now proposes that Article 2.3.13.18 be modified to require the exclusion from trade of the distal ileumonly.

The Bureau considered that the recommendations in Article 2.3.13.22 are substantially incorporated into Article 2.3.13.2 and proposes deletion of this Article.

The proposed modifications (Appendix VIII) are submitted to Member Countries for comment.

c) Appendix 3.8.4 on surveillance and monitoring systems for BSE

The Bureau noted that the *ad hoc* Group had examined comments on the appendix submitted by Member Countries in making its recommendations. The Bureau endorsed the comments of the *ad hoc* Group regarding the BSE surveillance appendix and is submitting revised text for the comment of Member Countries (Appendix IX).

d) Appendix 3.6.3 on transmissible spongiform encephalopathy agents inactivation procedures

The Bureau modified Appendix 3.6.3 in accordance (Appendix X).

10. Chapter 2.1.9. Bluetongue

The Bureau noted that the report of the *ad hoc* Group on Bluetongue had been circulated for the information of Member Countries during the 72nd General Session; this report is at Appendix XI. Extensive comments received from the EU (available on the EU Website at http://europa.eu.int/comm/food/international/organisations/oie_en.htm) were examined by the Bureau.

The Bureau was not aware of any information to contradict the conclusions of the recent OIE Bluetongue Conference regarding the infective period for bluetongue, and did not make any changes to the article. The Bureau noted that an appendix on surveillance for bluetongue was being developed by the Scientific Commission for Animal Diseases and the EU comments on surveillance would be taken into account by that Commission.

The Bureau noted the concerns expressed by the EU that there was insufficient scientific evidence on the safety of vaccinated animals to support the position that such animals could be moved without additional measures. The EU also commented on the likely competence of *Culicoides* species.

11. General principles of animal health surveillance

The Bureau received from the Scientific Commission for Animal Diseases a revised proposed *Terrestrial Code* appendix on the general principles of animal health surveillance. The appendix was revised by the Scientific Commission for Animal Diseases in the light of Member Countries' comments and is presented unchanged as clean text for further comment at Appendix XII, prior to being proposed for adoption at the 73rd General Session.

12. Chapter 2.1.14. Avian influenza

The Bureau considered how best to progress the development of this chapter. It noted that an appendix on surveillance for avian influenza was being developed by an *ad hoc* Group under the Scientific Commission for Animal Diseases, and Member Country comments on that subject would be taken into account by that Commission.

The Bureau will ask the Director General to form an *ad hoc* Group to address issues relating to the definition of the disease and to make recommendations regarding the commodity-specific risks posed by highly pathogenic notifiable avian influenza (HPNAI) and low pathogenic notifiable avian influenza (LPNAI). The Bureau is of the view that the *ad hoc* Group should combine expertise in avian influenza (animal and public health) with regulatory experience.

The Bureau expects that the January 2005 meetings of the two Commissions will be used to utilise the outputs of the two *ad hoc* Groups mentioned above to develop a surveillance appendix and a modified chapter for adoption by Member Countries at the 73rd General Session.

13. Issues under study in 2003 edition of the *Terrestrial Code*

The Bureau reviewed the 2003 edition of the *Terrestrial Code* for issues marked as *under study*. The following actions were taken for the articles listed below. Other articles containing *under study* will be referred to experts for advice.

a) Enzootic bovine leukosis

The Bureau noted that the 2004 edition of the *Terrestrial Manual* includes virological tests (including a PCR) for enzootic bovine leukosis and, as a result, decided to remove the *under study* from paragraph 3 of Article 2.3.4.3 in the 2004 edition of the *Terrestrial Code*.

b) Equine viral arteritis

The Bureau noted that the 2004 edition of the *Terrestrial Manual* includes a prescribed virus isolation test for equine viral arteritis and, as a result, decided to remove the *under study* from Articles 2.5.10.2, 2.5.10.4 and 2.5.10.5 in the 2004 edition of the *Terrestrial Code*.

c) Small ruminant semen

The Bureau noted that the 2004 edition of the *Terrestrial Manual* includes prescribed serological tests for bluetongue and, as a result, decided to remove the *under study* from Article 3.2.2.2 of the 2004 edition of the *Terrestrial Code*.

14. Working Groups on Animal Production Food Safety and Animal Welfare

The Bureau endorsed the reports of the two Working Groups and is circulating them for the information and comment of Member Countries. The reports are at Appendices XIII and XIV.

15. Future work programme

A table summarising planed future activities for the Code Commission is at Appendix XV.

16. Traceability

The Bureau again requested Member Countries to submit proposals and draft texts on traceability. The Bureau is of the view that the OIE needs to develop guidelines on traceability now rather than in response to an animal or public health crisis. These guidelines must be developed in coordination with the Codex Alimentarius Commission and the process will be followed by the Working Group on Animal Production Food Safety.

17. Zoning/regionalisation and compartmentalisation

Noting that the OIE had been requested by members of the WTO SPS Committee to develop guidelines on these concepts to aid implementation by Member Countries, the Bureau of the Code Commission requests OIE Member Countries to submit guidelines with practical examples. The Director General of the OIE may then convene an *ad hoc* Group to draft proposals for the Code Commission.

.../Appendices

Appendix I

MEETING OF THE BUREAU OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 28 June-2 July 2004

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Appendix II

MEETING OF THE BUREAU OF THE OIE

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 28 June-2 July 2004

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Agenda

1. General definitions (Chapter 1.1.1)
2. Obligations and ethics in international trade (Section 1.2)
3. Guidelines for reaching a judgement of equivalence of sanitary measures (Chapter 1.3.7)
4. Zoning and regionalisation (Chapter 1.3.5)
5. Foot and mouth disease (Chapter 2.1.1 and Appendix 3.8.6)
6. Bovine spongiform encephalopathy (Chapter 2.3.13)
7. Bovine tuberculosis (Chapter 2.3.3)
8. Classical swine fever (Chapter 2.1.13)
9. Diseases of bees (Section 2.9)
10. Semen and embryo related matters (Sections 3.2 and 3.3)
11. Antimicrobial resistance (Section 3.9)
12. Avian influenza (Chapter 2.1.14)
13. Bluetongue (Chapter 2.1.9)
14. General principles and surveillance systems (Section 3.8)
15. Animal production food safety
16. Animal welfare
17. Other

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Appendix III

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

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Buffer zone

means a zone established ~~within, and~~ along the border of~~,~~ an *infected zone* using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or a *free zone*. These measures may include, but are not limited to, vaccination.

Vaccinated animals must be recognisable by a specific permanent mark. The vaccines used must meet standards defined in the *Terrestrial Manual.*

The *buffer zone* should have an intensified degree of disease surveillance and control.

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Appendix IV

CHAPTER 2.1.1.

FOOT AND MOUTH DISEASE

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Article 2.1.1.4.

FMD free zone where vaccination is not practised

An FMD free zone where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. The FMD free zone ~~must~~ should be separated from the rest of the country, if infected, and, if relevant, from neighbouring infected countries by a ~~*surveillance*~~ *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus ~~must~~ should be implemented. A country in which an FMD free zone where vaccination is not practised is to be established should:

1) have a record of regular and prompt animal disease reporting;

2) send a declaration to the OIE stating that it wishes to establish an FMD free zone where vaccination is not practised and that:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV infection has been found during the past 12 months;

   c) no vaccination against FMD has been carried out during the past 12 months;

   d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 2.1.1.8.;

3) supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.6. is in operation in the FMD free zone where vaccination is not practised;

4) describe in detail:

   a) regulatory measures for the prevention and control of both FMD and FMDV infection,

   b) the boundaries of the FMD free zone, and the ~~*surveillance*~~ *buffer zone*,

   c) the system for preventing the entry of the virus into the FMDV free zone (in particular if the procedure described in Article 2.1.1.8. is implemented),

   and supply documented evidence that these are properly implemented and supervised.

The free zone will be included in the list of FMD free zones where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

Appendix IV (contd)

Article 2.1.1.5 .

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. ~~Vaccination of zoo animals, animals belonging to rare species or breeds, or animals in research centres as a precaution for conservation purposes is an example of implementation of such a zone.~~ The free zone where vaccination is practised ~~is~~ should be separated from the rest of the country, if infected, and, if relevant, from neighbouring infected countries by a *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus ~~must~~ should be implemented.

Vaccination of zoo animals, animals belonging to rare species or breeds, or animals in research centres as a precaution for conservation purposes is an example of implementation of a FMD free zone where vaccination is practised.

A country in which an FMD free zone where vaccination is practised is to be established should:

1) have a record of regular and prompt animal disease reporting;

2) send a declaration to the OIE that it wishes to establish an FMD free zone where vaccination is practised, where there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that surveillance for FMD and FMDV in accordance with Appendix 3.8.6. is in operation;

3) supply documented evidence that the vaccine used complies with the standards described in the *Terrestrial Manual*;

4) describe in detail:

   a) regulatory measures for the prevention and control of both FMD and FMDV circulation,

   b) the boundaries of the FMD free zone where vaccination is practised and the *buffer zone* if applicable,

   c) the system for preventing the entry of the virus into the FMD free zone (in particular if the procedure described in Article 2.1.1.8. is implemented),

   and supply evidence that these are properly implemented and supervised;

5) supply documented evidence that it has a system of intensive and frequent surveillance for FMD in the FMD free zone where vaccination is practised.

The free zone will be included in the list of FMD free zones where vaccination is practised only after the submitted evidence has been accepted by the OIE.

If a country that has an FMD free zone where vaccination is practised wishes to change the status of the zone to FMD free zone where vaccination is not practised, a waiting period of 12 months after vaccination has ceased or 12 months after the last *outbreak*, whichever is later, is required and evidence must be provided showing that FMDV infection has not occurred in the said zone during that period.

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Article 2.1.1.8.

Transfer of FMD susceptible animals from an infected zone to a free zone within a country

Live animals from FMD susceptible species can only leave the infected zone if moved by mechanised transport to the nearest designated abattoir located in the *buffer zone* or the *surveillance zone* for immediate slaughter. In the absence of an abattoir in the *buffer zone* or the *surveillance zone*, live FMD susceptible animals can be transported to the nearest abattoir in a free zone for immediate slaughter only under the following conditions:

1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the animals were kept in the *establishment* of origin for at least 3 months prior to movement;

3) FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;

4) the animals must be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before loading, directly from the *establishment* of origin to the abattoir without coming into contact with other susceptible animals;

5) such an abattoir is not approved for the export of *fresh meat*;

6) ~~all products obtained from the animals must be considered infected and treated in such a way as to destroy any residual virus in accordance with Appendix 3.6.2.;~~ all products obtained from the animals and any products coming into contact with them must be considered infected and treated in such a way as to destroy any residual virus in accordance with Appendix 3.6.2.;

7) *vehicles* and the abattoir must be subjected to thorough cleansing and *disinfection* immediately after use.

Animals moved into a free zone for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 2.1.1.11.

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Article 2.1.1.20.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for *fresh meat* of cattle ~~bovines~~ (excluding feet, head and viscera)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

1) have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

Appendix IV (contd)

2) have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.1.1.21.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary Administrations* should require:

for *fresh meat* or *meat products* of pigs and ruminants other than bovines

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which:

1) have been kept in the country or zone since birth, or have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

~~2) have not been vaccinated;~~

3) have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

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Appendix V

CHAPTER 2.1.13.

CLASSICAL SWINE FEVER

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Article 2.1.13.4.

Country or zone free of CSF in domestic and wild pigs

1) Historically free status

A country or zone may be considered free from the disease in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.1.13.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from CSF in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.1.13.2. and when:

a) it is a notifiable disease;

~~b) domestic pigs are properly identified when leaving their *establishment* of origin with an indelible mark giving the identification number of their herd of origin; a reliable tracing back procedure is in place for all pigs leaving their *establishment* of origin;~~

~~c) the feeding of swill is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;~~

~~d) animal health regulations to control the movement of *commodities* covered in this Chapter in order to minimise the risk of introduction of the infection into the *establishments* of the country or zone have been in place for at least 2 years;~~

AND EITHER

e) where a *stamping-out policy* without vaccination has been practised for CSF control, no *outbreak* has been observed in domestic pigs for at least 6 months; or

f) ~~where a *stamping-out policy* combined with vaccination has been practised, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no *outbreak* has been observed in domestic pigs for at least 12 months; or~~

~~g)~~ where a vaccination strategy has been adopted, with or without a *stamping-out policy*, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no *outbreak* has been observed in domestic pigs for at least 12 months;

Appendix V (contd)

AND

h) CSF infection is not known to occur in the wild pig population and monitoring of wild pigs indicates that there is no residual infection.

• • •

— text deleted

Appendix VI

PROPOSED SIMPLIFIED VERSION

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the exporting country or zone/compartment:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins (excluding hides and skins from the head);

   d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat).

2) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the exporting country or zone/compartment:

   a) cattle;

   b) *fresh meat* and *meat products*;

   c) gelatin and collagen prepared from bones or from hides and skins from the head;

   d) tallow and tallow derivatives, other than protein-free tallow as defined above;

   e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

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

Article 2

The BSE risk status of the cattle population of a country or zone/compartment can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

Appendix VI (contd)

a) Release assessment

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

i) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

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

iii) imported live animals;

iv) imported animal feed and feed ingredients;

v) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 13 and may have been fed to cattle;

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

b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

i) the presence or absence of animal TSE agents in the country or zone/compartment and, if present, their prevalence based on the outcomes of surveillance;

ii) prevalence of infection of animals with TSE agents in the country or zone/compartment, including the surveillance and other epidemiological investigations on which the determination is based;

iii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

iv) the use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

v) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3;

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

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4; records of the number and results of investigations should be maintained for at least 7 years;

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

Article 3

Negligible BSE risk without mitigating measures

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

1) a risk assessment, as described in point 1) of Article 2, has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER:

a) there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:

i) the criteria in points 2) to 5) of Article 2 have been complied with for at least 7 years; and

ii) it has been demonstrated that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

b) the last indigenous *case* of BSE was reported more than 7 years ago; and

i) the criteria in points 2) to 5) of Article 2 have been complied with for at least 7 years; and

ii) 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; and

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 4

Negligible BSE risk with mitigating measures

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

1) a risk assessment, as described in point 1) of Article 2, has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER

a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed; and either:

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

ii) it has not been demonstrated that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

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

i) the criteria in points 2) to 5) of Article 2 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;

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed ;

OR

c) the last indigenous *case* of BSE has been reported less than 7 years ago, and:

i) the criteria in points 2) to 5) of Article 2 have been complied with for at least 7 years;

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

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 5

Undetermined BSE risk

The cattle population of a country or zone/compartment poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 6

When importing from a country or zone/compartment posing a negligible BSE risk without mitigating measures, *Veterinary Administrations* should require:

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

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

Appendix VI (contd)

Article 7

When importing from a country or zone/compartment posing a negligible BSE risk with mitigating measures, *Veterinary Administrations* should require:

for cattle

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

1) the country or zone/compartment complies with the conditions in Article 4;

2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 2) c) iii) of Article 4;

3) in the case of a country or zone/compartment with an indigenous case, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 8

When importing from a country or zone/compartment with an undetermined BSE risk, *Veterinary Administrations* should require:

for cattle

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

1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2) all BSE *cases*, as well as:

   a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

   b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

   c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 9

When importing from a country or zone/compartment posing a negligible BSE risk without mitigating measures, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

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

1) the country or zone/compartment complies with the conditions in Article 3;

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

Article 10

When importing from a country or zone/compartment posing a negligible BSE risk with mitigating measures, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

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

1) the country or zone/compartment complies with the conditions in Article 4;

2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate;

3) cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* do not contain:

   a) the tissues listed in Article 13,

   b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

   all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 11

When importing from a country or zone/compartment with an undetermined BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

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

Appendix VI (contd)

1) the cattle from which the *fresh meat* and *meat products* originate:
   a) are not suspect or confirmed BSE *cases*;
   b) have not been fed *meat-and-bone meal* or *greaves* for at least 8 years;
   c) were subjected to ante-mortem and post-mortem inspections;
   d) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
2) the *fresh meat* and *meat products* are derived from deboned meat and do not contain:
   a) the tissues listed in Article 13,
   b) nervous and lymphatic tissues exposed during the deboning process,
   c) mechanically separated meat from the skull and vertebral column,

   all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 12

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country or zone/compartment defined in Articles 4 and 5 should not be traded between countries.

Article 13

1) From cattle of any age originating from a country or zone/compartment defined in Articles 4 and 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle that were at the time of slaughter over 30 months of age originating from a country or zone/compartment defined in Articles 4 and 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 14

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones or from hides and skins from the head and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

1) a country or zone/compartment posing a negligible BSE risk without mitigating measures; or

2) a country or zone/compartment posing a negligible BSE risk with mitigating measures; and

   a) skulls and vertebrae (excluding tail vertebrae, and hides and skins from the head) have been excluded;

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

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

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

      or to an equivalent process in terms of infectivity reduction.

Article 15

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 1) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a country or zone/compartment posing a negligible BSE risk without mitigating measures, or

2) a country or zone/compartment posing a negligible BSE risk with mitigating measures, and it originates from cattle which have been subjected to ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 13.

Article 16

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 1) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) they originate from a country or zone/compartment posing a negligible BSE risk without mitigating measures; or

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

Appendix VII

Original: English
April 2004

REPORT OF THE MEETING OF THE OIE AD HOC GROUP TO REVIEW THE BOVINE SPONGIFORM ENCEPHALOPATHY CHAPTER IN THE OIE *TERRESTRIAL ANIMAL HEALTH CODE*

Paris, 15-16 April 2004

The OIE *ad hoc* Group to review the bovine spongiform encephalopathy (BSE) chapter in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) met at the OIE Headquarters from 15 to 16 April 2004.

The members of the *ad hoc* Group and other participants are listed in Appendix A. The Agenda adopted is given in Appendix B.

On behalf of Dr B. Vallat, Director General of the OIE, Dr D. Wilson, Head of the OIE International Trade Department, welcomed the participants and thanked them for their willingness to work on some essential issues. He recalled the discussions on BSE at the 2003 General Session regarding a simplification of the BSE-risk categorisation system while retaining its scientific base, and noted the comments from Member Countries, both of which should form the basis of the *ad hoc* Group's discussions. The OIE's task and hence that of the *ad hoc* Group was to give an indication to the International Committee in May 2004 as to directions the experts think the simplified BSE-risk categorisation system should go, with a detailed text perhaps available for adoption in 2005.

The *ad hoc* Group discussed the simplification of the BSE-risk categorisation in the *Terrestrial Code*. The *ad hoc* Group's proposals are at Appendix C.

The *ad hoc* Group reviewed some other aspects of the BSE chapter and surveillance appendix in the *Terrestrial Code*, on the basis of the latest scientific information and comments from Member Countries. Amendments proposed by the *ad hoc* Group are at Appendix D.

The *ad hoc* Group recommended that it meet again after the General Session to review the comments from Member Countries on its proposals for BSE-risk categorisation.

.../Appendices

Appendix VII (contd)

Appendix A

MEETING OF THE OIE AD HOC GROUP
TO REVIEW THE BOVINE SPONGIFORM ENCEPHALOPATHY CHAPTER IN THE
OIE *TERRESTRIAL ANIMAL HEALTH CODE*

Paris, 15-16 April 2004

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Appendix B

**MEETING OF THE OIE AD HOC GROUP
TO REVIEW THE BOVINE SPONGIFORM ENCEPHALOPATHY CHAPTER IN THE
OIE *TERRESTRIAL ANIMAL HEALTH CODE***

Paris, 15-16 April 2004

Adopted Agenda

1. Update on significant scientific advances on BSE and its relationship with other TSE's
2. Proposals for revision of BSE-risk categories in the 2003 *Terrestrial Animal Health Code* chapter
3. Proposals for revision of the other aspects of the 2003 *Terrestrial Animal Health Code* chapter on BSE
4. Proposals for revision of the BSE surveillance Appendix in the 2003 *Terrestrial Animal Health Code*

Appendix VII (contd)

Appendix C

PROPOSED BOVINE SPONGIFORM ENCEPHALOPATHY CATEGORISATION SYSTEM

The *ad hoc* Group believed that the purpose of a bovine spongiform encephalopathy (BSE) categorisation system was to enable and encourage appropriate risk mitigation measures (based on a risk assessment as described in Article 2.3.13.2) to be applied to commodities for trade so that they would present a negligible risk to the importing country.

The *ad hoc* Group believed that the use of three categories offered the best science-based practicable approach to the epidemiology of BSE, with an emphasis on the safety of commodities for trade rather than on a pragmatic classification of country status. It believed that a change in emphasis would be best achieved through an expanded list of conditions for safe trading of commodities.

In this context, the *ad hoc* Group believed that it was appropriate to emphasize the use of surveillance as specified in Appendix 3.8.4. to supplement data provided by risk assessments.

The *ad hoc* Group proposed the following three categories:

a) **Category 1 - *negligible BSE risk* or *negligible BSE risk without mitigating measures***

A country or zone/compartment where a combination of surveillance and risk assessment confirms that commodities need no risk mitigation measures to present a negligible risk of transmitting the BSE agent.

b) Category 2 - *controlled BSE risk* or *negligible BSE risk with mitigating measures*

A country or zone/compartment where a combination of surveillance and risk assessment confirms that the risk factors present are being mitigated, and that commodities present a negligible risk of transmitting the BSE agent due to the application of additional commodity-specific risk mitigation measures. The general and commodity-specific risk mitigation measures applied are commensurate with the risk factors identified and are subject to regular review, based on the latest scientific information.

c) Category 3 - *undetermined BSE risk*

A country or zone/compartment not complying with the requirements of Category 1 or 2.

The *ad hoc* Group proposed a broad second category with no arbitrary distinctions, due to the difficulty of estimating accurately the prevalence of BSE infection and the relative lack of importance of prevalence in relation to rendering commodities safe. A country or zone/compartment in this category would need to demonstrate:

- an effective ruminant to ruminant feed ban;
- routine ante-mortem and post-mortem veterinary inspection;
- SRM removal and destruction to reinforce the effectiveness of the feed ban;
- completion and regular review of a risk assessment in accordance with Article 2.3.13.2;
- implementation of a surveillance programme (in accordance with Appendix 3.8.4) to supplement data provided by the risk assessment;
- routine examination and notification of clinical cases;
- access to adequate laboratory capacity;
- implementation of an awareness programme in accordance with Article 2.3.13.2.

Appendix VII (contd)

Appendix C (contd)

The third category still offered the opportunity for trade in certain commodities for those Member Countries where the required risk assessment and/or surveillance were not within their capabilities at the time. In order to qualify for category 2, a country or zone/compartment in category 3 would need to demonstrate that all criteria for category 2 had been in place for an appropriate period of time.

The *ad hoc* Group noted that risk mitigation measures in line with the current five categories (based primarily on differences in apparent prevalence of BSE infection) were not being implemented in practice. It believed that, with the three proposed categories being risk-based (with emphasis on a combination of risk assessment and surveillance), there would be less opportunity for subjective interpretation.

The *ad hoc* Group will develop procedures for countries or zones/compartments moving from categories presenting a higher risk to those of lower risk. These procedures will be based on the outcomes of a risk assessment, and the quantity and duration of surveillance, to confirm compliance with the requirements of the lower risk category.

The *ad hoc* Group agreed that the *Terrestrial Code* should contain a list of commodities presenting a negligible likelihood of transmitting the BSE agent, either without any restrictions being applied or as a result of the application of risk mitigation measures. Accordingly, it proposed the following modifications to Article 2.3.13.1, subject to a revised categorisation system being adopted:

"*Veterinary Administrations* should authorise trade:

1) without BSE related restrictions and from all categories of countries or zones/compartments regardless of their BSE status, in:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins (excluding hides and skins from the head);

   d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

2) without BSE related restrictions from category 1 countries or zones/compartments, in all other commodities;

3) with BSE related restrictions, from categories 2 and 3 countries or zones/compartments, in:

   a) for cattle under 30 months of age, boneless beef (muscle meat) from cattle subject to ante-mortem and post-mortem veterinary inspection and stunning conducted in accordance with Article 2.3.13.15;

   b) for cattle over 30 months of age, boneless beef (muscle meat) from cattle subject to ante-mortem and post-mortem veterinary inspection and stunning conducted in accordance with Article 2.3.13.15, and with removal of all SRMs (in accordance with Article 2.3.13.19) in a hygienic manner;

   c) for cattle of all ages, heart, liver and kidneys, and products made exclusively from these tissues, from cattle subject to ante-mortem and post-mortem veterinary inspection and stunning conducted in accordance with Article 2.3.13.15;

d) for cattle of all ages, bovine-derived tissues (other than those designated in Article 2.3.13.18), not intended for use in food or feed, cosmetics, pharmaceuticals including biologicals, or *in vivo* medical devices;

4) subject to the additional prescribed conditions relating to the BSE status of the cattle population of the *exporting country* or zone, from category 2 countries or zones/compartments, in:

a) cattle;

b) bone-in *fresh meat* and *meat products*;

c) gelatin and collagen prepared from bones;

d) tallow and tallow derivatives, and dicalcium phosphate."

Appendix VII (contd)

Appendix D

PROPOSED MODIFICATIONS TO OTHER ASPECTS OF THE OIE *TERRESTRIAL ANIMAL HEALTH CODE* CHAPTER AND APPENDIX ON BOVINE SPONGIFORM ENCEPHALOPATHY

The *ad hoc* Group proposed some modifications to other aspects of the *Terrestrial Code* chapter and appendix on BSE, to better address the risk factors and to harmonise with the latest scientific information on BSE.

The *ad hoc* Group believed that references to an effective feed ban and the need for accurate record keeping should be included in Article 2.3.13.2.

The *ad hoc* Group proposed clearer wording for the paragraph addressing the 'on-going awareness programme'.

The *ad hoc* Group discussed the BSE risks associated with the *in vivo* use of medical devices and with the use of bovine-derived tissues in industry (e.g. for the manufacture of bone china, soap, etc.) and proposed some changes to the release assessment in Article 2.3.13.2 to address such risks.

The *ad hoc* Group was not aware of new information questioning the safety of 'protein free tallow'. Therefore, at this stage, the *ad hoc* Group did not believe that it was justified to propose a change to the text on tallow in the BSE chapter of the 2003 *Terrestrial Code*.

The *ad hoc* Group believed that the general approach should be that SRMs be removed from cattle in country or zone categories other than 'free' and 'provisionally free', as described in Article 2.3.13.19.

The *ad hoc* Group believed that the information available indicated that 'bovine blood and blood by-products' would be safe, subject to stunning being carried out in accordance with Article 2.3.13.15.

The *ad hoc* Group believed that, for the practical implementation of Article 2.3.13.3, the OIE should not recommend in c) ii) merely that 'the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned' (although this would be the science-based position) but that the feeding to ruminants of any *meat-and-bone meal* and *greaves* be banned, unless (in practice) bovine SRM removal and destruction requirements are in place. This was due to concerns over multiples streams of raw materials which may not have been separated adequately in feed manufacturing premises and over the presence of ruminant-derived *meat-and-bone meal* in the intestines of pigs and poultry at slaughter.

In point 2)b) of Article 2.3.13.4, the *ad hoc* Group recommended that feed cohorts be included in the definition to address cases where several are imported from the same herd and may have been exposed to the same contaminated feed in the exporting country. The *ad hoc* Group believed that the Canadian proposal for testing birth and feed progeny at the time of their death could yield valuable additional data but should not be compulsory.

The *ad hoc* Group noted that, in Article 2.3.13.5, the 24 months age cut off was not consistent with Table 1 in Appendix (30 months), but it believed that 24 months was the usual cut off point for census data; if the ages are aligned at 24 months, the *ad hoc* Group considered that the prevalence cut-off limits for the categories may need to be adjusted.

The *ad hoc* Group also recommended that the Code Commission clarify text in Article 3.8.4.1 regarding sub-populations, and address some apparent inconsistencies between the reference in that article to the need to sample from more than one sub-population and the references in Article 2.3.13.6 to the various sub-populations to be sampled.

Appendix VII (contd)

Appendix D (contd)

The *ad hoc* Group also recommended that 'and post-mortem inspection' be added in Articles 2.3.13.14 and 2.3.13.15 to ensure a general minimum standard of hygiene at plants.

The *ad hoc* Group also recommended that, in point 5) of Article 2.3.13.16, the cut off age could be increased to 12 months as an effective feed ban was in place. It also recommended that points 2) to 4) of Article 2.3.13.17 be harmonised with the age cut offs in Article 2.3.13.19 by moving all to 12 months.

The *ad hoc* Group did not consider that there were sufficient new data to recommend a change from its previous recommendation to remove tonsils and intestine from cattle of all ages from moderate and high risk countries or zones, due to the presence of lymphoid tissue throughout the intestines.

The *ad hoc* Group indicated that progress in the European Union (EU) work on a statistically-valid surveillance programme for BSE would be monitored as a basis for reviewing and updating the appendix.

The *ad hoc* Group recalled that the purpose of the Appendix was to detect the presence of BSE and that it was therefore correct to:

– sample more than one sub-population;

– recognise that BSE is not unilaterally present in the first sub-population;

– propose a relative distribution of BSE among sub-populations;

– recognise that Table 1 is a highly optimistic interpretation based on the following (as described in Article 3.8.4.2)

  . concentration of all BSE within that sub-population,

  . an adult cattle mortality rate of 1%,

  . prevalence of central nervous system (CNS) signs of 1% within dying adult cattle.

The *ad hoc* Group proposed a modification to the second paragraph of Article 3.8.4.2 to clarify the use of Table 1, as follows:

> Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. The calculations assume a prevalence of one BSE clinically affected animal per one million adult cattle, a mortality rate not exceeding one percent per year in adult cattle, and a prevalence of central nervous system (CNS) signs not exceeding one percent within dying cattle. In countries where these assumptions do not apply, a different sampling rate needs to be used to reach the same conclusions.

The *ad hoc* Group believed that the above supports the adoption of a revised surveillance approach which:

– recognises the apparent distribution of BSE among the three sub-populations (based on initial EU findings);

– recognises the need for sampling of all sub-populations (except healthy cattle at slaughter unless sufficient samples cannot be derived from other sub-populations);

– recognises, on the basis of the EU CRL model or an equivalent examination of statistics derived from the sub-populations, the appropriate factors to be applied in the determination of the underlying prevalence of BSE in the cattle population.

Appendix VII (contd)

Appendix D (contd)

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

• • •

Article 2.3.13.2.

The BSE risk status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

   a) Release assessment

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

      i)a) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

      i)b) imported *meat-and-bone meal* or *greaves*;

      ii) imported live animals;

      iii) imported animal feed and feed ingredients;

      iv) imported products of ruminant ~~animal~~ origin for human consumption, which may have contained tissues listed in Article 2.3.13.19 and may have been fed to cattle;

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

   b) Exposure assessment

      Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle ~~susceptible animal species~~, through a consideration of the following:

      i)a) epidemiological ~~situation concerning all~~ the presence or absence of animal TSE agents in the country or zone and, if present, their prevalence based on the outcomes of surveillance;

      i)b) prevalence of infection of animals with TSE agents in the country or zone, including the surveillance and other epidemiological investigations on which the determination is based;

      ii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

      iii) the ~~origin and~~ use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

      iv) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3 ~~of neurological disease in adult cattle as well as fallen stock~~;

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

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;

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

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— text deleted

Appendix VIII

PROPOSED MODIFIED CHAPTER

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE status of the cattle population of the exporting country or zone/compartment:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins (excluding hides and skins from the head);

   d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat).

2) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE status of the cattle population of the exporting country or zone/compartment:

   a) cattle;

   b) *fresh meat* and *meat products*;

   c) gelatin and collagen prepared from bones or from hides and skins from the head;

   d) tallow and tallow derivatives, other than protein-free tallow as defined above;

   e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

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

Article 2.3.13.2.

The BSE risk status of the cattle population of a country or zone/compartment can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

Appendix VIII (contd)

a) Release assessment

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

i)a) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

i)b) imported *meat-and-bone meal* or *greaves*;

ii) imported live animals;

iii) imported animal feed and feed ingredients;

iv) imported products of ruminant ~~animal~~ origin for human consumption, which may have contained tissues listed in Article 2.3.13.18 and may have been fed to cattle;

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

b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle ~~susceptible animal species~~, through a consideration of the following:

i)a) ~~epidemiological situation concerning all~~ the presence or absence of animal TSE agents in the country or zone/compartment and, if present, their prevalence based on the outcomes of surveillance;

i)b) prevalence of infection of animals with TSE agents in the country or zone/compartment, including the surveillance and other epidemiological investigations on which the determination is based;

ii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

iii) the ~~origin and~~ use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iv) ~~implementation and enforcement of feed bans,~~ the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3 ~~of neurological disease in adult cattle as well as fallen stock~~;

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

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;

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

Article 2.3.13.3.

BSE free country or zone/compartment

The cattle population of a country or zone/compartment may be considered free of BSE, should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and either:

   a) there has been no *case* of BSE; and either:

      i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or

      ii) the criteria in point 3) of Article 2.3.13.2. 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* has been fed to ruminants;

   OR

   b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and ~~the affected cattle~~ all BSE *cases* as well as, if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed; and either:

      i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or

      ii) the criteria in point 3) of Article 2.3.13.2. 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* has been fed to ruminants;

   OR

   c) the last indigenous *case* of BSE was reported more than 7 years ago, and

      i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; and

Appendix VIII (contd)

ii) 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; and

~~iii) the affected cattle as well as:~~

- ~~if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~

- ~~all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~

- ~~where the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified and their movements controlled, and when slaughtered or at death, are completely destroyed.~~

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

BSE provisionally free country or zone/compartment

The cattle population of a country or zone/compartment may be considered as provisionally free of BSE, should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and either:

   a) there has been no *case* of BSE; and either:

      i) the criteria in points 2) to 5) of Article 2.3.13.2. 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 2.3.13.2. have not been complied with for 7 years;

OR

b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and ~~the affected cattle~~ all *cases* of BSE as well as, if these are females, all their progeny born within 2 years prior to or after clinical onset of the disease, if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.2. 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 2.3.13.2. have not been complied with for 7 years.

Article 2.3.13.5.

Country or zone/compartment with a minimal BSE risk

The cattle population of a country or zone/compartment may be considered as presenting a minimal BSE risk, should the country or zone/compartment comply with the following requirements:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER:

a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. 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 2.3.13.2. 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, and the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than two *cases* 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/compartment *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*, and:

Appendix VIII (contd)

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 2.3.13.2. have been complied with for at least 7 years;

~~iii) the affected cattle as well as:~~

- ~~if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~

- ~~all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, 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 affected cattle, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.~~

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 2.3.13.6.

Country or zone/compartment with a moderate BSE risk

The cattle population of a country or zone/compartment may be considered as presenting a moderate BSE risk if:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;

2) the BSE incidence rate has been measured using a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4., and is:

a) if based only on Article 3.8.4.2., greater than or equal to, one indigenous *case* per million and less than or equal to, one hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone/compartment calculated over the past 12 months; or

b) if based on Articles 3.8.4.2., 3.8.4.3. and 3.8.4.4., greater than, or equal to, two indigenous *cases* per million and less than, or equal to, two hundred indigenous *cases* per million within the cattle population over 24 months of age in the country or zone/compartment calculated over the past 12 months; or

c) less than two indigenous *cases* per million per year, but for less than the four consecutive 12-month periods required in paragraph 2) b) of Article 2.3.13.5 *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*;

~~3) the affected cattle as well as:~~

~~a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~

~~b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~

~~c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.~~

3) all BSE *cases*, as well as:

a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Countries and zones/compartments where the BSE incidence rate has been less than one indigenous *case* per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones/compartments with a moderate BSE risk.

Appendix VIII (contd)

Article 2.3.13.7.

Country or zone/compartment with a high BSE risk

The cattle population of a country or zone/compartment may be considered as presenting a high BSE risk if it cannot demonstrate that it meets the requirements of another category.

Article 2.3.13.8.

When importing from a BSE free country or zone/compartment, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in point 1) of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country or zone/compartment complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

Article 2.3.13.9.

When importing from a BSE provisionally free country or zone/compartment, *Veterinary Administrations* should require:

for cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;

2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females.

Article 2.3.13.10.

When importing from a country or zone/compartment with a minimal BSE risk, *Veterinary Administrations* should require:

for cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not exposed cattle as described in point 2) b) iii) of Article 2.3.13.5.;

   b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.11.

When importing from a country or zone/compartment with a moderate BSE risk, *Veterinary Administrations* should require:

for cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not exposed cattle as described in point 3) of Article 2.3.13.6.;

   b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.12.

When importing from a country or zone/compartment with a high BSE risk, *Veterinary Administrations* should require:

for cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

~~3) all affected cattle as well as:~~

   ~~a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~

   ~~b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or~~

   ~~c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,~~

   ~~if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;~~

3) all BSE *cases*, as well as:

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a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

4) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

   b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.13.

When importing from a BSE provisionally free country or zone/compartment, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;

2) ante-mortem ~~inspection is~~ and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* ~~destined for export~~ originate.

Article 2.3.13.14.

When importing from a country or zone/compartment with a minimal BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) ante-mortem ~~inspection is~~ and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* ~~destined for export~~ originate;

3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* destined for export do not contain the tissues listed in point 3) of Article 2.3.13.18., nor mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 2.3.13.15.

When importing from a country or zone/compartment with a moderate BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

3) ~~ante-mortem inspection is carried out on all bovines;~~ ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate;

4) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;

5) the *fresh meat* and *meat products* destined for export do not contain the tissues listed in point 1) and point 2) of Article 2.3.13.18. nor mechanically separated meat from skull and vertebral column from cattle over ~~6~~ 12 months of age, all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 2.3.13.16.

When importing from a country or zone/compartment with a high BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

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

1) the country or zone/compartment complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

2) the meat destined for export does not contain the tissues listed in point 1) of Article 2.3.13.18., all of which have been completely removed in a manner to avoid contamination with these tissues;

3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have been completely removed in a manner to avoid contamination with these tissues;

4) the *meat products* destined for export are derived from deboned meat and do not contain the tissues listed in point 1) and point 2) of Article 2.3.13.18. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been completely removed in a manner to avoid contamination with these tissues;

5) a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;

6) ante-mortem inspection is carried out on all bovines;

Appendix VIII (contd)

7) the cattle from which the *meat* or *meat products* destined for export originate:

   a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

   b) are not the progeny of BSE suspect or confirmed females; and either:

      i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced; or

      ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;

   c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;

8) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

~~9) all affected cattle as well as:~~

   ~~a) if these are females, all their progeny born within 2 years prior to and after clinical onset of the disease, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, and~~

   ~~b) all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed, or~~

   ~~c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle, if alive in the country or zone, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.~~

9) all BSE *cases*, as well as:

   a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

   b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

   c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

Article 2.3.13.17.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from countries with a minimal, moderate or high BSE risk should not be traded between countries.

Article 2.3.13.18.

1) From cattle of any age originating from a country or zone/compartment with a moderate or a high BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum ~~intestine~~, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle originating from a country or zone/compartment with a moderate or a high BSE risk, that were at the time of slaughter over 12 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

3) From cattle, originating from a country or zone/compartment with a minimal BSE risk, that were at the time of slaughter over 30 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.19.

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones or from hides and skins from the head and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the ~~bones~~ *commodities* came from:

1) a BSE free or provisionally free country or zone/compartment, or from a country or zone/compartment with a minimal BSE risk; or

Appendix VIII (contd)

2) a country or zone/compartment with a moderate BSE risk; and

   a) skulls and vertebrae (excluding tail vertebrae, and from hides and skins from the head) have been excluded;

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

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

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

      or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.20.

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE free or provisionally free country or zone/compartment, or

2) a country or zone/compartment with a minimal BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.18., or

3) a country or zone/compartment with a moderate BSE risk, and it originates from cattle which have been subjected to ~~an~~ ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.18.

Article 2.3.13.21.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) they originate from a BSE free or provisionally free country or zone/compartment, or from a country or zone/compartment with a minimal BSE risk;

OR

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

~~Article 2.3.13.23.~~

~~Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.~~

~~Countries wishing to import bovine materials for such purposes should therefore consider the following factors:~~

~~1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;~~

~~2) the age of the donor animals;~~

~~3) the tissues required and whether or not they will be pooled samples or derived from a single animal.~~

~~Additional factors may be considered in assessing the risk from BSE, including:~~

~~4) precautions to avoid contamination during collection of tissues;~~

~~5) the process to which the material will be subjected during manufacture;~~

~~6) the amount of material to be administered;~~

~~7) the route of administration.~~

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Appendix IX

APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

Surveillance for bovine spongiform encephalopathy (BSE) has at least two goals: to determine whether BSE is present in the country, and, if present, to monitor the extent and evolution of the epizootic, thus aiding control measures and monitoring their effectiveness.

The cattle population of a country or zone not free from BSE, will comprise the following sub-populations in order of decreasing size:

1) cattle not exposed to the infective agent;

2) cattle exposed but not infected;

3) infected cattle, which may lie within one of three stages in the progress of BSE:

   a) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

   b) some will progress to a stage at which BSE is detectable by testing before clinical signs ~~of disease~~ appear;

   c) the smallest number will show clinical signs ~~of disease~~.

A surveillance programme~~s~~ on its own cannot guarantee BSE status and should be determined by, and be commensurate with, the outcome of the risk assessment referred to in Article 2.3.13.2. and should take into account the diagnostic limitations associated with the above sub-populations and the relative distributions of infected animals among them.

~~Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While~~ Surveillance should focus on the sub-population containing cattle displaying clinical signs consistent with BSE as described in Article 3.8.4.2.~~this sub-population~~ Where it is difficult to access all cattle displaying such clinical signs, investigation of other sub-populations ~~using the new diagnostic techniques~~ may provide a more accurate assessment ~~picture~~ of the BSE situation in the country or zone. A surveillance ~~strategy~~ programme may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below.

Appendix IX (contd)

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-populations identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. ~~Any shortfall in~~ In addition, ~~the first two sub-populations should be addressed by the~~ surveillance can be complemented by sampling of normal cattle over 30 months of age at slaughter according to Article 3.8.4.4. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the *Terrestrial Manual.*

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.6. on surveillance and monitoring of animal health.

Article 3.8.4.2.

Examination of cattle displaying clinical signs consistent with bovine spongiform encephalopathy

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying ~~with compatible~~ clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals.

Table 1 indicates the minimum number of animals exhibiting one or more clinical signs of BSE that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. The calculations assume a prevalence of one BSE clinically affected animal per one million adult cattle; a mortality rate not exceeding one percent per year in adult cattle; and a prevalence of central nervous system (CNS) signs not exceeding one percent within dying cattle. In countries where these assumptions do not apply, a different sampling rate needs to be used to reach the same conclusions.

As this sampling is not random, and as the mortality rate and prevalence of CNS signs within dying cattle may vary, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction. This table should only be employed as a general guideline. Sampling in excess of the number indicated, ideally extending towards all cattle over 30 months of age showing clinical signs consistent with BSE, would give greater confidence in the outcome and is to be encouraged. In those cases, where there is a shortfall in the number of samples required under this article, the difference may be made up by any combination of samples defined under Articles 3.8.4.3 and 3.8.4.4.

Table 1. ***Minimum number of annual investigations of cattle showing clinical signs consistent with BSE required for effective surveillance according to the total cattle population over 30 months of age***

Total cattle population over 30 months of age	Minimum number of samples to examine
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336
10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

[Note: Need to develop numbers for populations lower than 500,000.]

Article 3.8.4.3.

Examination of targeted cattle displaying clinical signs not necessarily indicative of bovine spongiform encephalopathy

Cattle over 30 months of age that have died or have been killed for reasons other than routine slaughter should be examined. This population will include cattle which have died on farm or in transit, cattle which are unable to rise or to walk without assistance, ~~'fallen stock'~~, and ~~stock~~ cattle sent for emergency slaughter.

Many of these cattle may have exhibited some of the clinical signs listed in Article 3.8.4.2. which were not recognised as being ~~compatible~~ consistent with BSE. Experience in countries where BSE has been identified indicates that this population is the second most appropriate population to target in order to detect BSE. Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 100 or more animals in this category in terms of its ability to detect BSE within an infected cattle population.

This multiplication factor of 100 should be applied in calculating the minimum sample size to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2.

Article 3.8.4.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter of cattle over 30 months of age is a means of monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Empirical evidence indicates that surveillance conducted on one clinical suspect from Article 3.8.4.2. is equivalent to that conducted on 5,000 to 10,000 animals in this category in terms of its ability to detect BSE within an infected cattle population.

Appendix IX (contd)

This multiplication factor of 5,000 to 10,000 should be applied in calculating the minimum sample size to substitute for any shortfall in the sample numbers specified in Article 3.8.4.2 and a multiplication factor of 50 to 100 applied regarding any shortfall in the sample numbers specified in Article 3.8.4.3.

Within each of the above sub-populations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.

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Appendix X

APPENDIX 3.6.3.

PROCEDURES FOR THE REDUCTION OF INFECTIVITY OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS ~~INACTIVATION PEOCEDURES~~

Article 3.6.3.1.

Meat-and-bone meal

~~For the inactivation of transmissible spongiform encephalopathy agents for the production of meat-and-bone meal containing ruminant proteins, the following procedure should be used:~~

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of meat-and-bone meal containing ruminant proteins:

1. The raw material should be reduced to a maximum particle size of 50 mm before heating.

2. The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

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Appendix XI

Original: English
March 2004

MEETING OF THE *AD HOC* GROUP TO REVIEW THE BLUETONGUE CHAPTER IN THE OIE *TERRESTRIAL ANIMAL HEALTH CODE*

Paris, 29 March 2004

The OIE *ad hoc* Group to review the bluetongue chapter in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) met at the OIE Headquarters on 29 March 2004. The list of participants is at Appendix A. The agreed agenda is at Appendix B.

Dr D. Wilson welcomed the two participants on behalf of Dr B. Vallat, Director General of the OIE. He recalled that, during the December 2003 meeting of the OIE Terrestrial Animal Health Standards Commission, the Director General had given a high priority to a review of the bluetongue chapter as a result of the 2003 OIE Bluetongue Conference in Sicily, for discussion at the 2004 OIE General Session. Accordingly, the outcomes of that Conference (see report at Appendix C) were used as a basis for discussion of proposed changes to the *Terrestrial Code* chapter. Some comments from Member Countries were also taken into account, including on proposals to protect animals from *Culicoides* attack. The proposed revised chapter is at Appendix D.

Regarding a surveillance appendix for bluetongue, Dr V. Caporale confirmed that the OIE *ad hoc* Group on epidemiology would take into account in its work on developing an appendix, the relevant outcomes of the Conference and the comments received from Member Countries.

Specific issues discussed and the relevant reference(s) in the report of the 2003 OIE Bluetongue Conference are as follows:

1. Infective period for bluetongue

Studies undertaken to follow viraemias in experimentally infected cattle revealed that the virus can be recovered by virus isolation techniques for as long as 45 to 50 days. In contrast, viral RNA can be detected by polymerase chain reaction (PCR) for as long as 220 days after infection. The significance of this observation is that careful consideration of the clinical signs and PCR results is critical for appropriate diagnosis.

In the case of healthy, non-vaccinated animals, animals (whether seropositive from natural infection or seronegative) may move at any time without posing a risk of virus spread provided that an adequate surveillance system has been in place in the source population for a period of 60 days immediately prior to dispatch without detecting evidence of bluetongue virus circulation.

Appendix XI (contd)

2. Global BTV distribution

It was shown that the northern distribution of BTV in Asia and Europe is similar to that in North America, and far beyond the 40° N limit that was traditionally proposed. Specifically, BT has recently occurred to approximately 45° N in Europe, and BTV infection of ruminants has been documented as far as 50° N in Asia. Much remains to be understood about these northern Eurasian BTV episystems, in terms both of their species of insect vector as well as the specific strains of BTV that occur within each. Similarly, the strains of BTV and the relative importance of different potential vector species awaits adequate characterization in variable portions of the extensive BTV episystems that occur in South America, Africa, the Middle East and Asia.

Significant changes in our understanding of BT became evident during the course of the symposium when we learned that the global distribution has changed. As recently as our previous symposium, the distribution was thought to occur between the latitudes of 40 degrees north and 35 degrees south. Since 2000, BT appears to have become established at 45 to 50 degrees north latitude. These new observations of distribution have expanded our perceptions of BT.

3. Vector competence

The vector competence of Culicoides species and populations should be measured, where possible using field viruses. Candidate species can be prioritised on the basis of epidemiological evidence, feeding preference for hosts and level of abundance. Epidemiological analysis (serosurveys, vector surveys, ecological analysis, study of outbreaks) can provide guidance for the selection of candidate species for vector competence studies, and can be used to assess the likely significance of results.

The OIE should reconsider the broad use of the term "Culicoides" to indicate midges from the genus Culicoides spp. that have been shown or are suspected to be probable vectors of BTV. In other words, be specific as to the species involved.

4. Surveillance

[As far as] the extent of a surveillance programme in countries adjacent to a country that does not have free status [is concerned], a distance of 100 km is specified but a lesser distance could be acceptable if there are relevant geographical features that interrupt the transmission of BTV.

5. Vaccination

In considering the potential movement of BTV seropositive animals from an infected to a free zone or country, the Working Group concludes that animals may move at any time without posing a risk of virus spread if they have been vaccinated with a licensed or authorized attenuated, inactivated, subunit, or genetically manipulated vaccine at least one month prior to movement provided that the vaccine used covers all serotypes which would be expected to be present at origin from adequate surveillance and that the animals are identified as vaccinates.

Animals receiving vaccines produced by culture in embryonated chicken eggs shall not be moved internationally.

6. Diagnosis

The AGID assay, while easy and cheap to perform, lacks sensitivity and manifests cross reactions with EHDV. The C-ELISA is now standard technology.

.../Appendices

Appendix XI (contd)

Appendix A

MEETING OF THE *AD HOC* GROUP TO REVIEW THE BLUETONGUE CHAPTER IN THE OIE *TERRESTRIAL ANIMAL HEALTH CODE*

Paris, 29 March 2004

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List of Participants

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Appendix XI (contd)

Appendix B

MEETING OF THE AD HOC GROUP TO REVIEW THE BLUETONGUE CHAPTER IN THE OIE *TERRESTRIAL ANIMAL HEALTH CODE*

Paris, 29 March 2004

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Agenda

1. Issues arising from the Bluetongue Conference in Sicily
2. Proposed revised *Terrestrial Animal Health Code* chapter
3. Surveillance appendix on bluetongue
4. Other issues

Appendix XI (contd)

Appendix C

THIRD INTERNATIONAL SYMPOSIUM ON BLUETONGUE: CONCLUSIONS

Introduction

Executive Committee
V. Caporale,
N.J. MacLachlan,
J.E. Pearson
A. Schudel

Introduction

The timely need for a third international symposium on bluetongue (BT) was emphatically emphasized by the unexpected and unprecedented recent occurrence of the disease throughout much of the Mediterranean Basin. Furthermore, international understanding of BT clearly has not kept pace with scientific developments since the last symposium in 1991, and it also now is nearly 10 years since the Uruguay Round of negotiations of the General Agreement on Tariffs and Trade; these negotiations lead to the introduction of the Sanitary and Phytosanitary regulations of the World Trade Organization that now guide international trade of animals and animal products.

Intense international interest in BT and BTV was reflected in the some 300 individuals who attended the symposium, and in the 45 scientific oral presentations and over 90 posters in which relevant information was presented. In conjunction with the symposium, international experts were assigned to various working groups that were charged with providing constructive, transparent and science-based recommendations pertaining to the understanding and international regulation of BT.

Critical conclusions and findings from the symposium

Global occurrence of bluetongue virus episystems: Several researchers elegantly confirmed the original concept pioneered by P. Gibbs, A. Gould and others at the second BT symposium in 1991 that distinct strains of BTV (virus topotypes) vectored by different species of Culicoides vectors occur in specific regions of the world. It was further shown that the topotypes of BTV and the vector species that occur within each episystem are relatively stable, despite extensive and ongoing trade and movement of ruminants between individual episystems. Much remains to be learned about the ecological, climatic and environmental factors that lead to expansion of BTV episystems, as recently occurred in the Mediterranean Basin for example, but it is increasingly evident that an understanding of these factors is prerequisite to defining what limits the boundaries of individual BTV episystems.

It was shown that the northern distribution of BTV in Asia and Europe is similar to that in North America, and far beyond the 40° N limit that traditionally was proposed. Specifically, BT recently has occurred to approximately 45° N in Europe, and BTV infection of ruminants has been documented as far as 50° N in Asia. Much remains to be understood about these northern Eurasian BTV episystems, in terms both of their species of insect vector as well as the specific strains of BTV that occur within each. Similarly, the strains of BTV and the relative importance of different potential vector species awaits adequate characterization in variable portions of the extensive BTV episystems that occur in South America, Africa, the Middle East and Asia.

Appendix XI (contd)

Appendix C (contd)

Although further refinement and sophistication is ongoing, existing diagnostic technology is adequate for comprehensive global surveillance and monitoring of the distribution and activity of BTV. Indeed, there has been remarkable international acceptance and adoption of virus-detection assays based on the polymerase chain reaction (PCR) since the second symposium, and the widespread use of PCR technology also has enhanced our understanding of the global ecology of BTV infection because it has facilitated sequence analysis of the strains of BTV that infect the insect vectors and ruminants that reside within each of the various BTV episystems. A potential disadvantage of the PCR technology is that it is so exquisitely sensitive that it can detect BTV nucleic acid in the tissues of previously infected ruminants in the absence of infectious virus, an issue that is relevant to the regulation of animal movement from BTV-endemic areas. Clearly, however, the available diagnostic technologies specifically and sensitively can identify BTV infection of the insect and animal hosts of the virus. Thus, the global and regional distribution of BTV can now comprehensively be determined using appropriate surveillance and monitoring. Furthermore, the collation of such data should be an issue of the highest priority to the international community given that BTV has been identified on every continent except Antarctica, and that little information currently is available from many areas of the world. An integrated, comprehensive network of surveillance, monitoring and reporting is required to establish the global limits of the distribution of BTV and of competent Culicoides vectors.

Lifecycle of bluetongue virus infection

Several studies confirmed conclusions of the first and second symposia that BTV infection of ruminants is transient, whereas infection of the Culicoides insect vector is persistent. Detailed and elegant studies by Australian workers who evaluated large numbers of naturally infected cattle have unequivocally shown that BTV infection of these animals does not persist more than a few weeks. Thus, international trade policies must increasingly reflect the reality that BTV infection of ruminants is transient and that seropositive animals are resistant to reinfection with the homologous BTV serotype and can be safely moved. Attention should now be focused on the climatic, ecological and environmental factors that determine the range of the insect vectors that persistently harbour BTV within each episystem, because detailed understanding of these factors, and not unwarranted restrictions on animal movement, is prerequisite to the ultimate control of BT.

Vaccines and vaccination

Inactivated, live-attenuated (modified live), and subunit vaccines all have been developed to protectively immunize ruminants against BTV infection. Each of these different vaccines types has perceived inherent advantages and disadvantages, including their ease of production and cost, number of immunizations required, availability, efficacy, duration of immunity, and potential adverse side-effects. However, only live-attenuated BTV vaccines currently are commercially available in the quantities that are required to confront major outbreaks of BT; thus, these vaccines will continue to be utilized until such time as viable substitutes are produced in sufficient quantity. Given the enormous scope of recent outbreaks of BT in the Mediterranean Basin and elsewhere, there is a clear need to develop and evaluate all potential vaccine strategies to both protect animals and to facilitate trade from endemically infected areas. Provocative data also was provided suggesting that strategic vaccination of all susceptible animals reduced virus circulation during the recent incursion of BTV into the European episystem, an observation that clearly warrants further study.

Summary

The third symposium showcased the remarkable progress that has been made on the understanding of BT and BTV since the first and second international symposia that were held in 1984 and 1991. Attention has now shifted from ruminants to Culicoides insects as the primary host of BTV, meaning that animals can safely be moved between and within BTV episystems using transparent, science-based criteria. Current diagnostic technology provides the tools for very accurate surveillance and monitoring within BTV episystems, and to better predict incursion of BTV into previously unaffected areas and to guide the safe movement of animals. Critical deficiencies persist in regard to our understanding of the global ecology of BTV and its episystems, however, including the lack of detailed understanding of the environmental factors that precipitated the recent expansion of the range of competent insect vectors and/or BTV in the Mediterranean Basin for example. Similarly, some global BTV episystems are yet to be defined in any detail at all, including those in South

America, portions of Africa and Asia, and at the northern margins of the virus' range in Eurasia. Lastly, viable options (choices) of vaccines that can be produced in the quantities needed to confront an extensive BT outbreak currently are limited to live-attenuated vaccines, meaning that efforts should continue to evaluate all potential strategies to minimize the economic impact of BTV when it incurs into previously unaffected regions.

Summary of the OIE Third International Symposium on Bluetongue

B. I. Osburn, School of Veterinary Medicine University of California, Davis, Ca, USA

Scientists, regulatory officials and livestock producers met at the Third International Symposium on Bluetongue (BT) to discuss current scientific advances, issues and policies as well as to identify areas needing additional research related to policy matters. The symposium addressed:

1) epidemiology and global distribution;
2) monitoring and surveillance;
3) biology of BT and its vectors;
4) diagnostics;
5) vaccines; and
6) strategies for intervention.

Epidemiology and Global Distribution

Significant changes in our understanding of BT became evident during the course of the symposium when we learned that the global distribution has changed. As recently as our previous symposium, the distribution was thought to occur between the latitudes of 40 degrees north and 35 degrees south. Since 2000, BT appears to have become established at 45 to 50 degrees north latitude. These new observations of distribution have expanded our perceptions of BT.

At the Second International Symposium on BT, the epidemiology of BT viruses (BTV) was categorized into zones: endemic, epidemic and incursion zones. The endemic zone lies in tropical climates where competent Culicoides spp. are actively spreading BTVs all year. BT disease is rarely observed in this zone. The epidemic zone is located in temperate climates where competent Culicoides spp. appear during the warm season, and some disease is observed seasonally. The incursion zones are those where BT appears every decade or so, associated with climatic changes. The competent Culicoides spp. appear for one to two years, and outbreaks disease occur as long as competent vectors are in the area.

Maps depicting the distribution of BT are historic records of BT's occurrence. Boundaries move with the vectors, which do not respect political boundaries. Instead, vector distribution is based on climatic and environmental conditions. We realized that we must now approach BT, not as a disease of countries, but one of continents.

Monitoring and surveillance

The symposium highlighted the critical role of vectors as the principal means of spreading BTVs. Not all Culicoides spp. transmit BTV. When seeking to determine potential distribution of BTVs, regulatory agencies need only consider those Culicoides spp. that are competent for transmission of BTV. In the absence of competent Culicoides spp. vectors, BTV will not survive in an area. There is no evidence that BTV persist in cattle, a clear indication that ruminants are of no importance in the movement of BTV from one geographic region to another.

Symposium participants acknowledged the importance of competent Culicoides spp. vectors in the distribution of BTV in Europe.

Appendix XI (contd)

Appendix C (contd)

Biology of Bluetongue and its Vectors

BTVs are gastrointestinal viruses of Culicoides spp. Domestic and wild ruminants are the amplifying hosts for the insect vectors of BTV. One gene controls BTV competency in Culicoides spp. The phenotypic expression of the gene is influenced by temperature, rainfall, soil pH, and other factors. The role of these vectors in overwintering of BTV in Culicoides spp. appears to be based on temperature. If the environmental temperature is not sufficient for complete viral protein assembly, incomplete virus will remain in the intestinal cells of the vector until the critical temperature for virus assembly is reached.

Identifying the Culicoides spp. vectors in Europe and Central Asia will assist in better understanding the distribution of BTV. The genotyping of viruses based on Non-structural protein 3 (NS-3) has led to the concept of "topotyping" and topotyping makes a significant difference in determining the limitations of the virus serotypes in various locations around the world. For example, BTV 2, 10, 11, 13 and 17 occur in North America.. BTV 2 is only described in Florida and adjacent states in the United States (U.S.). The vector for BTV 2 is Culicoides insignis (C. insignis), whereas the other North American serotypes are transmitted by C. sonorensis. BTV 2 has not adapted to C. sonorensis, even though this vector is in Florida.

Scientists have also made remarkable progress in characterizing the BTV structure and function since the Second International Symposium on BT. Phenomenal advances have taken place with the BTV model, which has helped define serology, virulence, cell biology, and viral assembly.

Topotyping strategies have led to important advances in our understanding of the biology of BTV. The topotyping procedures of BTVs in Australia, Southeast Asia, and South-Central Asia have led to the recognition of regionally distinct viral groupings classified as Australia A, Java A, Java C and Malaysia A. Classifying these viral isolates is important for evaluating whether new groupings will move into defined geographical areas. Experimental evidence was presented to demonstrate that BTV is a quasi-species virus.

Understanding the pathogenesis of BTV infection in ruminants helps define the pathogenic characteristics of these viruses in sheep and cattle. BTV infection is capable of causing hemorraghic lesions. BTV in sheep causes vascular damage resulting in disseminated intravascular coagulopathy with secondary effects include hemorrhage, edema and vascular thrombi leading to skeletal and cardiac muscle necrosis. Endothelial damage does not occur in cattle and therefore clinical disease is rare.

Studies undertaken to follow viremias in experimentally infected cattle revealed that the virus that can be recovered by virus isolation techniques for as long as 45 to 50 days. In contrast, viral RNA can be detected by polymerase chain reaction (PCR) for as long as 220 days after infection. The significance of this observation is that careful consideration of the clinical signs and PCR results is critical for appropriate diagnosis.

Diagnostics

Researchers have also developed improved viral diagnostics by applying molecular techniques to PCR assays for the identification of viral RNA in tissues of infected animals. The potential for application of new sophisticated technologies could greatly enhance diagnostic capabilities for virus identification and differentiation in the near future. Serological tests can be used in a variety of ways to evaluate BTV infections and epidemiology.

Vaccines

Information derived from molecular studies of viral assembly have led to the development of subunit viral proteins that can be recombined to create efficacious and safe vaccines. These newer vaccine types may ultimately replace attenuated and inactivated vaccine products which have been associated with fetal malformation and contamination of semen.

The South African attenuated virus vaccine strategies used on ruminants on Corsica and Italy were described. The sophisticated epidemiological studies will provide the relevant information as to the effectiveness of the vaccines in controlling infection, mortalities and distribution of BTV in Southern Europe. The vaccine strategies used in South Africa were described where 3 different vaccinations containing 5 serotypes of virus are administered over a 3 week period. This strategy has proven to be an effective means of controlling disease in ruminants in South Africa.

Control and Trade Issues

A review of the OIE International Standards for BT set the stage for reports of regulatory procedures in North America, South America and in the European Union. The movement of animals in North America bridges all of the epizones that BT is known to occur. Cattle movement from Mexico with similar and different serotypes of virus found in the U.S. was confined by the vector species. Cattle movement did not influence the distribution of virus beyond the vector boundaries. Similarly, the movement of cattle from the epizootic and incursion zones of the U.S. into the non-BT Northeastern U.S. and Canada has not resulted in the establishment of BTV infection in those zones. Again, C. sonorensis is not present in Northeastern U.S. or Canada thereby limiting the distribution of BTV to those areas. BTV infection was described in Argentina, Brazil and Chile. The virus was confined to the more temperate climates of these South American countries.

Monitoring and Surveillance - Group 1

Working Group Members

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Y. Goto Japan
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Committee charge:

Consider what monitoring and surveillance practices might be developed to address all of the animal, vector and virus factors associated with the potential risk of spread of BTV, and how these practices would be interfaced with the current OIE Terrestrial Animal Health Code. Also, consider innovative ways to evaluate risk pertaining to movement of animals from BTV-endemic areas, including the risk associated with the movement of immune versus non-immune animals.

Prior to consideration of a review of the requirements for surveillance and monitoring for BTV, the group was briefed (AC/AG) on a planned OIE Chapter on General Guidelines for Surveillance and Monitoring. The key features of the draft of the proposed General Surveillance and Monitoring Chapter are:

- Compared to the surveillance guidelines in the current Bluetongue Chapter, the proposed chapter on surveillance and monitoring is not prescriptive. If adopted, it would be acceptable to use a number of different sources of data and the merits of each different source could be taken into account. Data sources also could be derived on a random or non-random (structured/planned) basis.
- The analysis of data must be scientifically sound. The proposed chapter recognises the merits of merging data from different sources. Though different data sets may be complex, they may enhance each other.
- The aim of surveillance and monitoring is to generate data for use in risk-based assessments to support trade and usually aims to demonstrate freedom from infection, or the presence of an agent and define areas of low risk. The approach in the proposed chapter is intended to be output oriented, not method oriented.
- The Working Group recommends that OIE convene an ad hoc Group to review the current Bluetongue Chapter. The current BT Chapter is too prescriptive and confusing. In particular, there are a number of issues that require attention. They are listed in the order in which they appear in the Code and not in any order of priority. Those that need to be addressed are:
- The infective period - currently defined as 100 days but there is no data to support a period of longer than 60 days. Consideration could be given to risk assessments based on probabilities determined from the distribution of the duration of viraemias.

Appendix XI (contd)

Appendix C (contd)

- Reference to northern and southern limits in terms of latitude.
- In view of the changing distribution of BTV, specifying actual northern or southern latitude is not appropriate. In the absence of confirmed disease, when a country lies within the latitude of the current distribution of BTV, or is adjacent to an infected country or region, a surveillance and monitoring program should be conducted.
- Use of the term "Culicoides" on its own is misleading because most countries have one or more species of midges from this genus. The taxonomic term should be clarified to indicate midges from the genus Culicoides that have been shown or are suspected to be vectors of BTV.
- Methods of surveillance and levels of sampling needed to achieve the required degree of confidence need not be specified, rather that surveillance complies with the provisions of the proposed general chapter. Nevertheless, some examples of appropriate surveillance systems that provide guidance to the intensity and frequency of surveillance could be of benefit.
- The extent of a surveillance program in countries adjacent to a country that does not have free status. A distance of 100 km is specified but a lesser distance could be acceptable if there are relevant geographical features that interrupt the transmission of BTV.
- When a country is proven to be free, consideration should be given to less frequent surveillance if the country is not immediately adjacent to a bluetongue zone where the situation is unstable.
- The term "surveillance zone" is confusing because surveillance also occurs within the free zone. The purpose of this zone is to acknowledge a degree of uncertainty in the exact limits of BTV activity and to increase confidence in the status of the free zone. The term "buffer zone" is more appropriate though it is acknowledged that this term is defined in the Code as a zone that is used to prevent spread of a disease or agent into a free zone. Depending on geographical features, this zone may not actually prevent spread of BTV, though it does provide additional assurance for the safety of the free zone. While the width of such a zone has been suggested as 50 km, this may need to be narrower or wider, depending on local circumstances that are relevant to BTV transmission.
- It would be of benefit if the Manual of Diagnostic Tests in future specifies measures of sensitivity and specificity to assist the design of surveillance programs. In the absence of these measures in the Manual or when different tests are used, when a surveillance program is designed the performance characteristics of the test should be described.
- When surveillance is conducted, the species and age of animals needs to be considered to ensure that there is appropriate sensitivity for that surveillance. While cattle are usually more readily infected, other species may be used if they have been shown to be infected at a higher incidence.
- The presence of ecological zones for BTV in different parts of the world warrants recognition. Factors pertaining to vectors and hosts in one system may not be relevant to another.
- In consideration of the movement of live animals and germplasm between countries or zones within a country, it is suggested that a risk-based approach be adopted. Persistent infection with BTV does not occur. Further, the occurrence of virus in semen is rare and confined to the early period of viraemia. Consequently, appropriate strategies can be developed to allow the safe movement of animals (including those that are seropositive either as a result of natural infection or vaccination) and semen from animals in zones where BTV infection may occur. These movement controls should reflect the finite period of viraemia in both natural infections and after vaccination with live vaccines.

Research Needs

The following research activities would be of benefit to surveillance and monitoring activities:

- For surveillance purposes, tests that distinguish between vaccinated and naturally infected animals will be of value;
- Detailed studies of viruses, vectors and their relationships at the boundaries of continental episystems;
- Improved type-specific serology;
- Enhanced methods for antigenic and genetic analyses of viruses;

The group also endorses the recommendations for research on vectors.

Vectors - Group 2

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Committee charge;
To develop specific recommendations that address issues pertaining to assessment of:
Vector competence
Vector capacity
Vector speciation and systematics
Vector ecology and control

Vector systematics and taxonomy

A clear understanding of Culicoides systematics and taxonomy is crucial to virtually all bluetongue virus (BTV) vector studies. Most important Culicoides vectors exist as species complexes and the members of these complexes may occur together or in different regions. Since individual members may differ widely in vector capacity it is vital that they are able to be distinguished.

Recommendation 1
Better tools to identify and distinguish members of these complexes are urgently required. Tools to be developed should be both morphological and molecular, with the one informing the other.

At least one important Culicoides vector, C. imicola, appears to be spreading rapidly in Europe. The pattern of spread is not known. There is evidence that C. imicola in Europe occurs as several haplotypes.

Recommendation 2
Molecular tools to identify haplotypes and other specific traits should continue to be developed as a priority to enable vector population movement to be identified and monitored.

In many parts of the world, especially Europe, Asia and South America, the systematics and taxonomy of Culicoides are in need of revision. Identification of related species may facilitate the discovery of novel vectors and should significantly improve our ability to assess disease risk.

Recommendation 3
The systematics and taxonomy of Culicoides in Europe, Asia, South America and other parts of the world should be addressed. Phylogenetic analysis of the sequences of multiple genes should be used to identify the relationships between known and novel vector species.

Worldwide, there are few competent Culicoides taxonomists.

Recommendation 4
Consideration should be given to capacity building in the systematics and taxonomy of Culicoides.

Appendix XI (contd)

Appendix C (contd)

Vector Competence

Vector competence is under genetic and environmental control, and varies inter- and intra-specifically. In refractory species or individuals, barriers to infection may occur at several steps in the infection and transmission processes. These barriers are poorly understood, and consequently, no methods currently exist for predicting whether species or populations are competent.

Recommendation 5

Barriers to the infection and dissemination of BTV within individual Culicoides should be characterised, and molecular genetic tools developed that permit prediction of vector competence.

Vector competence is difficult to measure, as field-caught Culicoides do not survive well in captivity and rarely feed. Consequently, transmission from field-caught Culicoides to hosts can rarely be demonstrated. There is some recent preliminary evidence suggesting that vertical transmission of BTV might occur in vector Culicoides species.

Recommendation 6
Methods to improve laboratory survival and feeding of field-caught Culicoides should be investigated. Direct and indirect methods of recording transmission, or transmission potential, should be evaluated. Possible vertical transmission of BTV in vector Culicoides should be further investigated.

Relatively little is known about the competence of Culicoides vectors in many parts of the world, especially Europe, Asia and South America. Work to date indicates complex relationships between vector species and their competence for different orbiviruses and/or viral genotypes as well as intraspecific variability in vector competence.

Recommendation 7
The vector competence of Culicoides species and populations should be measured, where possible using field viruses. Candidate species can be prioritised on the basis of epidemiological evidence, feeding preference for hosts and level of abundance.

Epidemiological analysis (serosurveys, vector surveys, ecological analysis, study of outbreaks) can provide guidance for the selection of candidate species for vector competence studies, and can be used to assess the likely significance of results.

Recommendation 8
Future and historical data sets should be analysed to investigate the possible role played by different vector species in the transmission of BTV.

Vectorial capacity

Vectorial capacity provides a measure of disease risk, incorporating vector competence, abundance, biting rates, survival rates and extrinsic incubation period. Many of these remain to be determined. Methods and tools for measuring some components remain to be developed, particularly in a field context. Interactions of these variables with the environment remain to be characterised.

Recommendation 9

Standard techniques for measuring the variables of vectorial capacity should be developed and adopted, to facilitate comparison of data and data sharing. Trapping methods should be evaluated against a 'gold standard' (e.g. drop-trap over animal, and the Onderstepoort-type light trap). Biases in trapping methods should be measured.

Improved methods for reliably aging Culicoides should be developed.

Improved methods for recording host preferences should be developed.

The effects of the environment, host demography and climate on vectorial capacity should be investigated.

Measures of vectorial capacity should be correlated with other indicators of disease risk, such as host disease status.

Ecology

The ecology of the major and minor Culicoides vectors is poorly understood and their breeding sites are largely uncharacterised. Means and rates of adult dispersal, both local and long distance are unknown. The comparative value of sentinel herds or wild-caught Culicoides as an aid to the early detection of virus activity has not been fully investigated. Adult overwintering in temperate zones has been little studied, but could play a part in the persistence of BT.

Recommendation 10
Larval microhabitats and diets should be characterised as an aid to colonisation and to the identification of breeding sites. Means and rates of dispersal of adult Culicoides, both local and long distance, need to be defined. Rates and times of virus or viral RNA detection in sentinel herds and vector surveillance systems should be compared. The possibility of adult overwintering in temperate and cool zones needs to be investigated. Development of vector population-simulation models is a long-term goal.

Control

Vector control methods are often used in the event of BT disease outbreaks, but there has been little quantitative work on short and long-term efficacy. Other means of reducing virus transmission that have lower environmental impact (e.g. physical and chemical barriers, husbandry modification), have received little attention.

Recommendation 11
Specific methods for the long and short-term suppression of Culicoides populations (adults and immatures) should be evaluated and quantified, and clear recommendations given to veterinary authorities. Alternative methods of interrupting the transmission cycle, such as the use of repellents, housing, breeding site destruction or modification, should be investigated. These measures should be evaluated in the context of existing arthropod control efforts. Control success should be judged in terms of disease reduction and/or seroconversion.

Diagnostics working group - Group 3

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H. Yadin, Israel
H. Takamatsu, UK
C. Hamblin, UK
A Samuel, UK
J. Pearson, OIE

Committee charge:

To develop specific recommendations that address issues pertaining to the perceived advantages and disadvantages of existing and new virologic and serologic diagnostic procedures for detection of BTV infection of insects and animals and how these interface with the OIE Manual.

Specifically address the issue of the role of the polymerase chain reaction (PCR) assay in the regulation of animal movement.

Appendix XI (contd)

Appendix C (contd)

Existing procedures in the *Manual*:

Virus isolation

Intravenous inoculation of embryonated chicken eggs (ECE) is the most sensitive technique for isolation of BTV. However, it is a slow procedure, compounded by the need for subsequent virus identification steps. Some ECE-propagated viruses may not readily replicate in cell culture

Virus identification

Serogrouping

A number of techniques such as anti-antigen capture ELISA and immunofluoresence that take advantage of the availability of serogroup-specific monoclonal antibodies work well. The use of serogroup-reactive PCR increases the speed of identification. Precautions must be taken to prevent cross-contamination while doing PCR.

Serotyping

The neutralisation test is biologically relevant and has a number of successful formats such as plaque reduction and microtitre neutralisation. Virus cross-relatedness may make interpretation of results difficult. Maintaining serotyping reagent uniformity is difficult, particularly on a world-wide basis. Such reagents are also costly to make.

'Typing' by PCR-sequencing is a novel and welcome addition to the repertoire of typing tests. It is very rapid and highly information (see new procedures).

Serological tests

The AGID assay while easy and cheap to perform do lacks sensitivity and manifests cross reactions with EHDV. The C-ELISA is now standard technology.

New procedures

Typing instead of serotyping

PCR/sequencing provides information on 'type', genotype and topotype very rapidly. Segments coding for VP2, VP5, VP3, NS1 and NS3 are currently relevant.

Successful identification of BTV around the world depends on availability of relevant sequence data for primer development

Every effort should be made to send viruses or PCR products to all OIE reference labs or other competent laboratories to be sequenced and primer information made available (via the web) to facilitate characterization at the source laboratory

An excellent start has been made in the process of collecting relevant sequence data

http://www.iah.bbsrc.ac.uk/dsRNA_virus_proteins/
http://www.iah.bbsrc.ac.uk/dsRNA_virus_proteins/btv_sequences.htm
provides phylogenetic tree analysis of BTV isolates based on RNA2.

Real time versus nested PCR?

Real time PCR technology is faster and more expensive than traditional PCR methods but is less susceptible to contamination problems. There may be problems attempting to identify new isolates with already-existing 'real time' probes. The technology requires expensive equipment.

IgM ELISA

An IgM ELISA would provide information on recent infection status and offer an opportunity to determine if the presence of IgM antibodies was correlated with the duration of viraemia.

Future trends

Possibilities include multiplexed flat and bead DNA and protein technologies and biosensing technologies

Recommendations

That the AGID test remain in the manual but not be a prescribed test for international trade

That research into novel diagnostic methods continues with tests showing promise being subject to validation by collaborating OIE laboratories and other competent national laboratories.

That the genetic characterisation continues of BTV isolates from diverse regions of the world with the aim of:

. compiling sequence data and identifying new viruses and their genetic relationships

. sharing sequence information thereby increasing the size of the data bases

. facilitating establishment of PCR technology and use of appropriate primers in the submitting country

. validating the technology by reference to the 'gold standard' neutralisation test

That, following extensive validation by collaborating laboratories, the current neutralisation-based virus serotyping system be replaced by a genetic typing system.

That an IgM ELISA or similar test be investigated to determine if they would provide a simple test that correlates with viraemia in infected animals and could be used to facilitate trade.

That use of the PCR to differentiate between wild-type and vaccine virus continue.

Vaccines & vaccinations - Group 4

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P.Roy UK
C.Patta Italy
G.Gerbier France
M.Vitale Italy
G.L. Autorino Italy
M.Papin France

Specific recommendations in regard to vaccines and vaccination strategy:

- Encourage the development and transfer of complementary and alternative vaccine materials and strategies that provide safe and efficacious inactivated or subunit BTV vaccines, and further encourages that vaccine companies adopt these products and make them available to producers.

- Vaccine strains should be fully sequenced and the data made available to the FAO/OIE Reference database as well as other databases such as the EMBL data base.

- Encourage the development and validation of technologies that will distinguish vaccinated from infected animals, both for current vaccines and the vaccines that are likely to be available in the foreseeable future

Appendix XI (contd)

Appendix C (contd)

- Encourage countries applying current or future vaccine technologies and strategies to make all data on monitoring of vaccination programs, and the surveillance of control programs, available to OIE for addressing future disease outbreaks.

- Animals receiving vaccines produced by culture in embryonated chicken eggs shall not be moved internationally.

- Update and keep current the OIE Manual on research information and data on the efficacy of both subunit and inactivated BT vaccines.

Impact of interventional strategies on virus spread, disease and regulation - Group 5

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Committee charge:

Address issues pertaining to the impact of interventional strategies on monitoring and surveillance practices and the risk of spread of BTV.

Conclusions:

Considering the potential movement of bluetongue seropositive animals from an infected to a free zone or country:

- animals may move at any time without posing a risk of virus spread if they have been vaccinated with a licensed or authorised attenuated, inactivated, sub-unit or genetically manipulated vaccine at least one month prior to movement, provided that the vaccine used covers all serotypes which would be expected from adequate surveillance to be present at origin and that the animals are identified as vaccinates in the accompanying certification;

- in the case of healthy, non-vaccinated animals, animals (whether seropositive from natural infection or seronegative) may move at any time without posing a risk of virus spread provided that an adequate surveillance system has been in place in the source population for a period of 60 days immediately prior to dispatch without detecting evidence of bluetongue virus circulation.

Pursuant to the above recommendations, the working group invites the OIE to review the relevant chapters of the *Terrestrial Animal Health Code* to bring them in line.

The working group recommends the OIE to back up safe trade in bluetongue seropositive animals by ensuring the existence of an adequate network of reference laboratories which shall inter alia ensure the archiving of viral strains and derived sequence data to provide a comprehensive database to be made available for research, surveillance and trade purposes.

The working group recommends that animals vaccinated with attenuated vaccines reduced by culture in embryonated eggs shall not be moved.

Control and Trade - Group 6

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T. Walton USA
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J. Pearson USA

Committee Charge:

To address the potential impact of issues raised by the other 5 working groups on international trade and movement of animals; specifically, to address issues pertaining to the movement of seropositive as well as potentially viremic animals.

Specific conclusions of the Working Group:

A. In considering the potential movement of BTV seropositive animals from an infected to a free zone or country, the Working Group concludes that animals may move at any time without posing a risk of virus spread if they have been vaccinated with a licensed or authorized attenuated, inactivated, subunit, or genetically manipulated vaccine at least one month prior to movement provided that the vaccine used covers all serotypes which would be expected to be present at origin from adequate surveillance and that the animals are identified as vaccinates.

B. In the case of healthy, non-vaccinated animals, animals (whether seropositive from natural infection or seronegative) may move at any time without posing a risk of virus spread provided that an adequate surveillance system has been in place in the source population for a period of 60 days immediately prior to dispatch without detecting evidence of bluetongue virus circulation.

C. The committee endorses the recommendations of Working Group 5 (Impact of Interventional Strategies on Virus Spread, Disease and Regulation) that the OIE should reevaluate the Terrestrial Animal Health Code in light of conclusions of the 3rd symposium. Further, that the OIE can further ensure the continued safe movement of ruminants that are seropositive to BTV by supporting the network of reference laboratories that will archive BTV strains and derived sequence data to ensure that a comprehensive database is available for research, surveillance and trade purposes.

D. The committee encourages the OIE to ensure that periodic surveillance for BTV occurs in zones with no previous evidence of virus activity; and, that any new evidence of virus activity in these zones be immediately reported to OIE.

E. The committee considers that the agar gel immunodiffusion (AGID) test assay lacks the requisite sensitivity and specificity (because of potential cross reactions with other viruses, particularly EHDV). The C-ELISA is now considered the standard and appropriate technology for serological diagnosis of previous exposure to animals to BTV.

F. The committee endorses the use of polymerase chain reaction (PCR)-based technologies for detection of BTV nucleic acid in animals and insects. The "real time" PCR technology is faster than traditional PCR methods, and is less susceptible to the problems of contamination that compromise nested PCR assays in particular. However, further validation is required as there may be problems in the identification of new strains of BTV with existing "real time" probes.

Appendix XI (contd)

Appendix C (contd)

G. The Working Group recommends that OIE convene an ad hoc Working Group to address the current Bluetongue Chapter and the guidelines for bluetongue surveillance and monitoring, as it is agreed that the current Chapter is both prescriptive and confusing.

H. Issues to be addressed, as detailed by the working group (Working Group 1):

- Infective period based on current scientific information and technologies, i.e., vector capabilities and competence, cell culture and PCR information, etc.
- The recent information on the distribution of BTV makes the current BTV limits based on latitudes obsolete. Consider that BTV distribution is based on continental ecological zones or episystems with associated defined parameters. Adjacent zones should have surveillance and monitoring practices for BTV presence. Evidence of BTV in the adjacent zone should be immediately reported to OIE.
- Reconsider the broad use of the term "Culicoides" to indicate midges from the genus Culicoides spp. that have been shown or are suspected to be probable vectors of BTV. In other words, be specific as to the species involved.
- Consider broad guidelines addressing the intensity and frequency of surveillance, which will compliment the provisions of the general chapter.
- The extent of a surveillance program in countries (zones) adjacent to a country (zone) that does not have free status. (Leave as stands)
- When a surveillance program is designed, the predictive value of the tests used in the program should be described as part of the study.
- When surveillance is conducted, the species and age of animals needs to be considered to ensure that there is appropriate sensitivity for that surveillance.
- The presence of ecological zones for BTV in different parts of the world warrants recognition. Factors pertaining to vectors and hosts in one system may not be relevant to another.
- Tests that distinguish between vaccinated and naturally infected animals will be of value to surveillance programs.

I. Specific recommendations in regard to vaccines and vaccination strategy:

- Encourage the development and transfer of complementary and alternative vaccine materials and strategies providing safe and efficacious inactivated or sub unit vaccines and further encourages that vaccine companies adopted these products and make them available to producers.
- Vaccine strains should be fully sequenced and the data are made available to a reference database(s).
- Encourage the development of technologies, which will distinguish vaccinated from infected animals.
- Encourage countries applying current or future vaccine technologies and strategies to make all data on monitoring and surveillance of control programs available to OIE for addressing future disease outbreaks.
- Animals receiving vaccines produced by culture in embryonated chicken eggs shall not be moved internationally.
- Update and keep current the OIE Manual on research information and data on the efficacy of both subunit and inactivated bluetongue vaccines.

Appendix XI (contd)

Appendix D

CHAPTER 2.1.9.

BLUETONGUE

Article 2.1.9.1.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be ~~100~~ 60 days.

The global BTV distribution ~~historically has been shown to be~~ is currently between latitudes of approximately 50~~40~~°N and 35°S but is known to be expanding in the northern hemisphere.

In the absence of clinical disease in a country or zone within this part of the world, its BTV status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) designed in accordance with the epidemiology of the disease, i.e. focusing on climatic and geographical factors, the biology and likely competence of *Culicoides* and/or serology of susceptible animals. The programme may need to be adapted to target parts of the country or zone at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Chapter 1.3.6. ~~Random and targeted serological surveillance should provide at least a 95% level of confidence of detecting an annual seroconversion incidence of 2% in cattle (or other ruminant species if sufficient cattle are not available).~~

All countries or zones ~~located outside this part of the world but~~ adjacent to a country or zone not having free status should be subjected to similar surveillance. The surveillance ~~programme~~ should be carried out over a distance of at least 100 kilometres from the border with that country or zone, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV.

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

Article 2.1.9.2.

BTV free country or zone

1) A country or a zone may be considered free from BTV when bluetongue is notifiable in the whole country and either:

   a) the country or zone lies wholly north of 50~~40~~°N or south of 35°S, and is not adjacent to a country or zone not having a free status; or

   b) a surveillance and monitoring programme as described in Chapter 1.3.6 ~~Article 2.1.9.1.~~ has demonstrated no evidence of BTV in the country or zone during the past 2 years~~, nor have any ruminants been vaccinated against bluetongue in the country or zone during the past 12 months;~~ or

   c) a surveillance and monitoring programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or zone.

~~For maintenance of the free status, the provisions of the last paragraph of Article 2.1.9.1. may need to be complied with on a continuous basis according to the geographical location of the country or zone.~~

Appendix XI (contd)

Appendix D (contd)

2) A BTV free country or zone in which surveillance and monitoring has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or zones.

3) A BTV free country or zone in which surveillance and monitoring has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or zones, provided:

   a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, and that the animals are identified in the accompanying certification as having been vaccinated; or

   b) the animals are not vaccinated, and a surveillance and monitoring programme as described in Chapter 1.3.6 has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

4) A BTV free country or zone adjacent to an infected country or zone should include a ~~*surveillance*~~ zone in which surveillance is conducted as described in Chapter 1.3.6 ~~Article 2.1.9.1~~. Animals within this ~~the *surveillance*~~ zone must be subjected to continuing surveillance. The boundaries of ~~the *surveillance*~~ this zone must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission ~~infection~~.

Article 2.1.9.3.

BTV seasonally free zone

A BTV seasonally free zone is a part of an infected country or zone for which for part of a year, surveillance and monitoring demonstrate no evidence either of BTV transmission or of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 2.1.9.7., 2.1.9.10. and 2.1.9.14., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the surveillance and monitoring programme), or of the cessation of activity of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 2.1.9.7., 2.1.9.10. and 2.1.9.14., the seasonally free period is taken to conclude either:

1) at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or

2) immediately if current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent BTV vectors.

A BTV seasonally free zone in which surveillance and monitoring has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or zones.

Article 2.1.9.4.

BTV infected country or zone

A BTV infected country or zone is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 2.1.9.5.

Veterinary Administrations of countries shall consider whether there is a risk with regard to BTV infection in accepting importation or transit through their territory, from other countries, of the following *commodities*:

1) ruminants and other BTV susceptible herbivores;

2) semen of these species;

3) embryos/ova of these species;

4) *pathological material* and biological products (from these species) (see Chapter 1.4.6. and Section 1.5.).

Other *commodities* should be considered as not having the potential to spread BTV when they are the subject of *international trade*.

Article 2.1.9.6.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

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

1) were kept in a BTV free country or zone since birth or for at least 60~~100~~ days prior to shipment; or

2) were kept in a BTV free country or zone for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, ~~such as the BT competition ELISA or the BT AGID test~~, and remained in the BTV free country or zone until shipment; or

3) were kept in a BTV free country or zone for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* ~~a BTV isolation test or polymerase chain reaction test on a blood sample~~, and remained in the BTV free country or zone until shipment; or

4) were kept in a BTV free country or zone for at least 7 days, and were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, were identified as having been vaccinated and remained in the BTV free country or zone until shipment;

AND

5)~~4)~~ if the animals were exported from a free zone, either:

a) did not transit through an infected zone during transportation to the *place of shipment*; or

b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected zone; or

c) had been vaccinated in accordance with point 4) above.

Appendix XI (contd)

Appendix D (contd)

Article 2.1.9.7.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

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

1) were kept during the seasonally free period in a BTV seasonally free zone for at least 60~~100~~ days prior to shipment; or

2) were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 28 days prior to shipment, and were subjected during the residence period in the zone to a serological test to detect antibody to the BTV group, according to the *Terrestrial Manual* ~~such as the BT competition ELISA or the BT AGID test~~, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 days after the commencement of the residence period; or

3) were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 14 days prior to shipment, and were subjected during the residence period in the zone to an agent identification test according to the *Terrestrial Manual* ~~to a BTV isolation test or polymerase chain reaction test,~~ with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after the commencement of the residence period; or

4) were kept during the seasonally free period in a BTV seasonally free zone, and were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, were identified as having been vaccinated and remained in the BTV free country or zone until shipment;

AND

5)~~4)~~ if the animals were exported from a free zone, either:

a) did not transit through an infected zone during transportation to the *place of shipment*, or

b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected zone, or

c) were vaccinated in accordance with point 4) above.

Article 2.1.9.8.

When importing from BTV infected countries or zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

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

1) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60~~100~~ days prior to shipment; or

2) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 28 days prior to shipment, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 days after introduction into the *quarantine station*; or

3) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 14 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual* ~~a BTV isolation test or polymerase chain reaction test~~, with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after introduction into the *quarantine station*; or

4) were vaccinated in accordance with the *Terrestrial Manual* at least 30 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, and were identified in the accompanying certification as having been vaccinated;

5) are not vaccinated, a surveillance and monitoring programme as described in Chapter 1.3.6. has been in place in the source population for a period of 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected;

and

6) were protected from attack from Culicoides likely to be competent BTV vectors during transportation to the *place of shipment*; or

7) were vaccinated 30 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6.

Article 2.1.9.9.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

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

1) the donor animals:

   a) were kept in a BTV free country or zone for at least 60~~100~~ days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test,~~ between 28 and 60 days after the last collection for this consignment, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* ~~a virus isolation test or polymerase chain reaction (PCR) test~~ on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2.

Appendix XI (contd)

Appendix D (contd)

Article 2.1.9.10.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

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

1) the donor animals:

   a) were kept during the BTV seasonally free period in a seasonally free zone for at least 60~~100~~ days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group ~~such as the BT competition ELISA or the BT AGID test~~, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* ~~a virus isolation test or polymerase chain reaction (PCR) test~~ on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.11.

When importing from BTV infected countries or zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

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

1) the donor animals:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60~~100~~ days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group ~~such as the BT competition ELISA or the BT AGID test~~, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* ~~a virus isolation test or polymerase chain reaction (PCR) test~~ on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.12.

Regardless of the bluetongue status of the *exporting country*, *Veterinary Administrations* of *importing countries* should require:

for *in vivo* derived bovine embryos/oocytes

the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.1.9.13.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores

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

1) the donor females:

   a) were kept in a BTV free country or zone for at least the 60~~100~~ days prior to, and at the time of, collection of the embryos; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, between 28 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* ~~a BTV isolation test or polymerase chain reaction test~~ on a blood sample taken on the day of collection, with negative results;

2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.1.9.14.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1) the donor females:

   a) were kept during the seasonally free period in a seasonally free zone for at least 60~~100~~ days before commencement of, and during, collection of the embryos/oocytes; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, between 28 and 60 days after collection, with negative results; or

Appendix XI (contd)

Appendix D (contd)

c) were subjected to an agent identification test according to the *Terrestrial Manual* ~~a BTV isolation test or polymerase chain reaction test~~ on a blood sample taken on the day of collection, with negative results;

2) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.1.9.15.

When importing from BTV infected countries or zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1) the donor females:

a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60~~100~~ days before commencement of, and during, collection of the embryos/oocytes; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, between 28 and 60 days after collection, with negative results; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* ~~a BTV isolation test or polymerase chain reaction test~~ on a blood sample taken on the day of collection, with negative results;

2) the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

~~Article 2.1.9.16.~~

Protecting animals from Culicoides attack

When transporting animals through BTV infected countries or zones, *Veterinary Administrations* should require strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during transport, taking into account the local ecology of the vector.

Strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during transport through an infected country or zone should take into account the local ecology of the vector.

Potential risk management strategies include:

1) treating animals with chemical repellents prior to and during transportation;

2) loading, transporting and unloading animals at times of low vector activity i.e. bright sunshine, low temperature;

3) ensuring vehicles do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

4) darkening the interior of the vehicle, for example by covering the roof and/or sides of vehicles with shadecloth;

5) monitoring for vectors at common stopping and offloading points to gain information on seasonal variations;

6) using historical, ongoing and/or BTV modeling information to identify low risk ports and transport routes.

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Appendix XII

CHAPTER 1.3.6

ANIMAL HEALTH SURVEILLANCE

1. Introduction and Objectives

In general, surveillance is aimed at demonstrating the absence of disease or infection, determining the occurrence or distribution of disease or infection, while also detecting as early as possible exotic or emerging diseases. The type of surveillance applied depends on the desired outputs needed to support decision-making. The following guidelines may be applied to all diseases, their agents and susceptible species as listed in the *Terrestrial Code*, and are designed to assist with the development of surveillance methodologies. Except where a specific surveillance method for a certain disease or infection is already described in the *Terrestrial Code*, the guidelines in this chapter may be used to further refine the general approaches described for a specific disease or infection. Where detailed disease/infection-specific information is not available, suitable approaches should be based on the guidelines in this chapter.

Animal health surveillance is an essential component necessary to detect diseases, to support claims for freedom from disease or infection, to provide data to support the risk analysis process, and to substantiate the rationale for sanitary measures. Surveillance data underpin the quality of disease status reports and should satisfy information requirements for accurate risk analysis both for international trade as well as for internal decision-making.

Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:

- that the particular Member Country complies with the provisions of Chapter 1.3.3 of the *Terrestrial Code* on the quality and evaluation of the *Veterinary Services*;

- that surveillance data where possible, be complemented by other sources of information e.g. scientific publications, research data, documented field observations and other non-survey data.

- that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1.3 of the *Terrestrial Code*.

The objectives of this chapter are to:

- Provide guidance to the type of outputs that a surveillance system should generate
- Provide guidelines to assess the quality of disease surveillance systems

2. Definitions

The following definitions apply for the purposes of this chapter.

Bias

A tendency of an estimate to deviate in one direction from a true value (as by reason of nonrandom sampling)

Case Definition

A case definition is a set of criteria used to classify an animal or epidemiological unit as a case or non-case.

Confidence

In the context of demonstrating freedom from infection, confidence is the probability that the type of surveillance applied would detect the presence of infection if the population were infected. The confidence depends on among others the design prevalence, or the assumed level of infection in an infected population. Confidence therefore refers to our confidence in the ability of the surveillance applied to detect disease, and is equivalent to the sensitivity of the surveillance system.

Early detection system

A system for the timely detection and identification of an incursion or emergence of disease/infection in a country or compartment. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

- representative coverage of target animal populations by field services;
- ability to undertake effective disease investigation and reporting;
- access to laboratories capable of diagnosing and differentiating relevant diseases;
- a training programme for veterinarians, animal health professionals and others involved in handling animals for detecting and reporting unusual animal health incidents;
- the legal obligation of private veterinarians in relation to the *Veterinary Administration*;
- a national chain of command.

Epidemiological Unit

A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or flock, however an epidemiological unit may also refer to groups such as the animals belonging to residents of a village, or animals sharing a communal dipping tank system.

Outbreak definition

An outbreak definition is a set of criteria used to classify the occurrence of one or more cases in a group of animals or units as an outbreak

Probability sampling

A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample

The group of elements (*sampling units*) drawn from a population, on which *tests* are performed to provide surveillance information.

Sampling Units

The *unit* that is sampled, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals (e.g. an *epidemiological unit*). Together, they comprise the sampling frame.

Sensitivity

The proportion of truly positive units that are correctly identified as positive by a test.

Specificity

The proportion of truly negative units that are correctly identified as negative by a test.

Study population

The population from which surveillance data is derived. This may be the same as the target population or a subset of it.

Surveillance

The systematic ongoing collection, collation, and analysis of data and the timely dissemination of information to those who need to know so that action can be taken.

Surveillance System

A method of surveillance that may involve one or more component activities that generates information on the animal health status of populations.

Survey

An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

Target population

The population about which conclusions are to be drawn from a study.

Test

A procedure used to classify a unit as either positive or negative with respect to an infection or disease.

Test system

A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Units

Individually identifiable elements. This is a generic concept used to describe, for example, the members of a population, or the elements selected when sampling. In these contexts, examples of units include individual animals, pens, farms, holdings, villages, districts etc.

3. General Principles of Surveillance

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 1.3.3).

3.1. Types of surveillance

Surveillance may be based on many different data sources and can be classified in a number of ways, including:

- the means by which data are collected (active versus passive surveillance);
- the disease focus (pathogen-specific versus general surveillance); and
- the way in which units for observation are selected (structured surveys versus non-random data sources).

In this chapter, surveillance activities are classified as being based either on:

- structured population-based surveys, such as:
  - systematic sampling at slaughter;
  - random surveys; or
- structured non-random surveillance activities, such as:
  - disease reporting or notifications;
  - control programmes/health schemes;
  - targeted testing/screening;
  - ante- and post-mortem inspections;
  - laboratory investigation records;
  - biological specimen banks
  - sentinel units
  - field observations;
  - farm production records;

In addition, surveillance data should be supported by related information, such as:

- data on the epidemiology of the infection, including environmental, host population distribution, and climatic information;
- data on animal movements and trading patterns for animals and animal products;
- history of imports of potentially infected material; and
- biosecurity measures in place.

The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

3.2. Critical elements

3.2.1. Populations

Surveillance should be carried out in such a way as to take into account all animal species susceptible to the infection in a country, *zone/region* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. In the latter case, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of the *Terrestrial Code*,

TO PROPOSE FOR INSERTION IN CHAPTER 1.1.1

- **Carriers** – animals that harbour the agent and may spread it directly or indirectly while not demonstrating clinical signs of the disease. Depending on the disease, an animal may serve as a carrier animal for shorter or longer periods of time. The length of time that an infection can be spread by inapparent carriers is important in designing a surveillance scheme.

- **Reservoirs –** some pathogens require either a living organism or inanimate environment for multiplication. Recognition of the location and role of a reservoir in the persistence of an infectious agent should be considered.

- **Vectors -** a pathogen can be vector borne. Where this is the case, the biology and ecology (including seasonal effects) of vector populations should be considered.

- **Immune status –** age of an animal, previous exposure to a specific pathogens, and use of vaccination are factors that need to be considered in determining appropriate diagnostic tests or clinical measures for evidence of infection.

- **Genetic resistance –** some animals may not be susceptible to specific disease agents because of genetic resistance. If this is true for an infectious agent under surveillance, a method for identifying those animals that are susceptible or resistant may need to be factored into the design for surveillance.

- **Age, sex, and other host criteria –** some pathogens can only affect animals that possess certain host related criteria. These type of criteria should be accounted for in the definition of the target population, surveillance design and interpretation of the results

3.2.2. Epidemiological Unit

The relevant epidemiological unit for the surveillance system should be defined and documented to ensure that it is representative of the population. Therefore it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

3.2.3. Clustering

Infection in a country or zone/region or compartment usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected animals within a herd, a cluster of pens in a building, or a cluster of farms in a compartment). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and infection.

3.2.4. Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each pathogen under surveillance, using, where they exist, the standards in the *Terrestrial Code*.

3.2.5. Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be documented and supported by references to the OIE Standards, to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

3.2.6. Testing

Surveillance involves the detection of disease or infection by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance and should be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Where values for sensitivity and/or specificity for a particular test are specified in the Terrestrial Manual, these values may be used without justification.

Samples from a number of animals or units may be pooled together and subjected to a single test. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

3.2.7. Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

3.2.8. Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

3.2.9. Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes e.g. during disease control interventions, inspections for movement control or during disease eradication schemes, the consistency of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- The distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;
- The ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- Maintenance of disaggregated data rather than the compilation of summary data;
- Minimisation of transcription during data processing and communication.

3.3. General Principles for surveys

In addition to the general principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

3.3.1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following manners:

Non-probability based sampling methods, such as

- Convenience
- Expert choice
- Quota

Probability based sampling methods, such as

- Simple random selection
- Cluster sampling
- Stratified sampling

3.3.2. Systematic selection

Periodic or repeated surveys conducted in order to document disease freedom must be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

3.3.3. Survey design

The population of epidemiological units should first be clearly defined whereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the infection and the resources available

3.3.4. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of infection. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an infection in a population of unknown disease status targeted sampling methods that optimise the detection of infection can be used. In such cases, care should be taken regarding the inferences made from the results.

3.3.5. Sampling methods

When selecting epidemiological units from within a population, a formal probability sampling method (e.g. simple random sampling) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

3.3.6. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. infection) or to estimate a parameter (e.g. the prevalence of infection). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

3.4. General Principles for structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys. There is a wide variety of non-random data sources that can be used

3.4.1. Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from infection. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes).

3.4.2. Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a good specificity.

3.4.3. Control programmes / health schemes

Animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

3.4.4. Targeted testing / screening

This may involve testing targeted to selected sections of the population (sub populations), in which disease is more likely to be found. Examples include testing Culled and dead animals, swill fed animals.

3.4.5. Ante- and post-mortem inspections

Inspections of animals at abattoirs may provide valuable surveillance data. The sensitivity and specificity of such inspections for the detection of disease will be influenced by:

- The level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;
- The involvement of the Competent Authorities in the supervision of ante- and post-mortem inspection;
- The quality of construction of the abattoir, speed of the slaughter chain, lighting quality etc; and
- Staff morale.

Abattoir inspections are likely to provide good coverage only for particular age groups and geographical areas. Statistical biases are likely to be more frequent for infected animals originating from larger, better managed farms rather than for animals originating from smallholder or backyard production farms, as well as for healthy rather than diseased animals.

Both for traceback in the event of detection of disease, and for analysis of spatial and herd-level coverage, if possible there should be an effective identification system that relates each animal in the abattoir to its property of origin.

3.4.6. Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

3.4.7. Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from infection, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

3.4.8. Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/immune status in a specified geographical location to detect the occurrence of disease (usually serologically). They are particularly useful for surveillance of diseases with a strong spatial component, such as vector-borne diseases. Sentinel units provide the opportunity to target surveillance depending on the likelihood of infection (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from infection, or provide data on prevalence and incidence as well as the distribution of disease.

3.4.9. Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

3.4.10. Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

3.4.11. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3.4.12. Analytical methodologies

Different methodologies may be used for the analysis of non-random surveillance data.

Analytical methodologies based on the use of step-wise probability estimates to describe the surveillance system may determine the probability of each step either by:

- the analysis of available data, using a scientifically valid methodology; or where no data are available,

- the use of estimates based on expert opinion, gathered and combined using a formal, documented and scientifically valid methodology.

3.4.13. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country or compartment at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources may be able to achieve the same level of confidence in just one year.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account.

SURVEILLANCE TO DEMONSTRATE FREEDOM FROM INFECTION

4. International recognition of freedom from infection

4.1. Introduction

This section provides general principles for declaring a country or zone/region or compartment free from disease/infection in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this section are based on the principles described in sections 1 to 3 of this chapter and the following premises:

1) in the absence of disease and vaccination, the animal population would become susceptible over a period of time;

2) the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals;

3) competent and effective *Veterinary Services* will be able to investigate, detect, diagnose and report disease, if present;

4) the absence of disease/infection over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by the *Veterinary Services* of an OIE Member Country.

4.2. Additional requirements to declare a country or compartment free from infection without pathogen specific surveillance

4.2.1. Historically free

Unless otherwise specified in the relevant disease chapter, a country or zone/region may be recognised free from infection without formally applying a pathogen-specific surveillance programme when:

a) there has never been occurrence of disease; or

b) eradication has been achieved or the disease/infection has ceased to occur for at least 25 years,

provided that for at least the past 10 years;

c) it has been a notifiable disease;

d) an *early detection* system has been in place;

e) measures to prevent disease/infection introduction have been in place; no vaccination against the disease has been carried out unless otherwise provided in the *Terrestrial Code*.

f) Infection is not known to be established in wildlife within the country or zone/region intended to be declared free. (A country or zone cannot apply for historical freedom if there is any evidence of infection in wildlife. However specific surveillance in wildlife is not necessary).

4.2.2. Last occurrence within the previous 25 years

Countries or zones/regions that have achieved eradication (or in which the disease/infection has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements for surveillance in the *Terrestrial Code*, countries should follow the general guidelines for surveillance to demonstrate animal health status outlined in this chapter provided that for at least the past 10 years:

a) it has been a notifiable disease;

b) an early detection system has been in place;

c) measures to prevent disease/infection introduction have been in place;

d) no vaccination against the disease has been carried out unless otherwise provided in the *Terrestrial Code*;

e) infection is not known to be established in wildlife within the country or zone/region intended to be declared free. (A country or zone cannot apply for historical freedom if there is any evidence of infection in wildlife. However specific surveillance in wildlife is not necessary).

4.3. Guidelines for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country or zone/region that has been recognised free from infection following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

1) it is a notifiable disease;
2) an *early detection* system is in place;
3) measures to prevent disease/infection introduction are in place;
4) vaccination against the disease is not applied;
5) infection is known not to be established in wildlife.(Specific surveillance in wildlife has demonstrated the absence of infection).

4.4. International recognition of disease/infection free status

For diseases for which procedures exist whereby the OIE can officially recognise the existence of a disease free country or zone/region, a Member Country wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country or zone/region concerned. Such documentation should be presented according to guidelines prescribed by the OIE for the appropriate animal diseases.

4.5. Demonstration of freedom from infection

A surveillance system to demonstrate freedom from infection should meet the following requirements in addition to the general requirements for surveillance outlined in section 3.2.2 of this chapter.

Freedom from infection implies the absence of the pathogenic agent in the country or zone/region or compartment. Scientific methods cannot provide absolute certainty of the absence of infection. Demonstrating freedom from infection involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that infection with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from infection (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that infection, if present, is present in less than a specified proportion of the population

However, finding evidence of infection at any level in the target population automatically invalidates any freedom from infection claim.

Evidence from non-random data sources as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys

5. Surveillance for distribution and occurrence of infection

5.1. General principles

Surveillance for distribution and occurrence of infection or of other relevant health related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and an aid to decision making. It has, however, relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to surveillance to demonstrate freedom from infection, surveillance used to assess progress in control or eradication of selected diseases and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

- Prevalence or incidence of infection,
- Morbidity and mortality rates,
- Frequency of disease/infection risk factors and their quantification when the risk factors are expressed by continuous [real numbers] or discrete [integers] variables,
- Frequency distribution of herd sizes or the sizes of other epidemiological units,
- Frequency distribution of antibody titres
- Proportion of immunised animals after a vaccination campaign,

- Frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and/or to the adoption of control measures,
- Farm production records, etc.

All of the listed data may also have relevance for the risk analysis.

Appendix XIII

Original: English
April 2004

REPORT OF THE THIRD MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Paris, 1-2 April 2004

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The OIE Working Group on Animal Production Food Safety held its third meeting at the OIE Headquarters in Paris from 1 to 2 April 2004.

The members of the OIE Working Group and other participants are listed in Appendix A; apologies were received from Dr A. Randell. As Dr J. Schlundt (World Health Organization [WHO]) was unavailable, Dr P. Ben Embarek participated in his place. The Agenda adopted is given in Appendix B. The report of the previous meeting was adopted unchanged.

Introduction

Dr Bernard Vallat, Director General of the OIE, welcomed the members of the Working Group and the other participants to the OIE Headquarters. The Director General noted that one of the major responsibilities of the Working Group was coordination of the OIE's work on food safety with that of the Codex Alimentarius. He indicated that he was aware of the challenges facing both organisations in this joint work, partly due to their different cultures and procedures in adopting standards. Working efficiently with the WHO was also critical. As a result, the OIE had decided to enlarge the Working Group and, in this regard, it had invited to the meeting experts from Codex Alimentarius and the Food Safety Department of the WHO; their membership of the Working Group will be presented for formal endorsement by the OIE International Committee in May 2004. Furthermore, to assist the output of the Working Group, the OIE had increased the Headquarters resources working on food safety.

The Director General pointed to traceability and antibiotic resistance as two areas where coordination was important to achieve the necessary progress to enable Member Countries to set up national regulations. The presence of guidelines would minimise differences among the regulations of Member Countries. He also noted the two draft papers developed by members of the Working Group and considered as a useful exercise the proposed revision of the bovine tuberculosis chapter of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*).

Cooperation with Codex and WHO

Dr S. Slorach indicated that his intention was to continue the current high level of Codex cooperation with the OIE to ensure appropriate input into the standards of each organisation.

Both Dr Slorach and Dr Vallat agreed that the two organisations needed to ensure that their work together was transparent to their members, and that the members were encouraged to circulate information as broadly as possible within their countries. Dr Vallat indicated that the OIE was fully open to a formal agreement with Codex; he noted that revised agreements with the parent organisations were in the process of being adopted the following month. He also indicated the importance of the decisions to be taken by the Codex Committee on General Principles on guidelines for cooperation with other intergovernmental organisations. The Working Group recognised that a different approach was warranted in the case of the OIE, in comparison to other international organizations, in order to emphasize the unique relationship between Codex and the OIE in the standard setting process under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

Dr Slorach and the Chair reported on the most recent Codex meetings – Codex Committee on Meat Hygiene, Codex Committee on Food Import and Export Inspection and Certification Systems, and the Executive Committee of Codex. They noted agenda items listed for upcoming Codex meetings relevant to the work of the Working Group, including principles of risk analysis, antibiotic resistance, traceability, and guidelines for cooperation with other intergovernmental organisations. The outcomes of Codex Committees on Meat Hygiene, on Milk and Milk Products and the Codex task force on Animal Feeding have both included OIE input. There was general agreement that the greater level of OIE input into Codex standards had resulted from better tracking of Codex activities by the OIE.

Dr Ben Embarek informed the Working Group that the WHO was developing a database of national food safety authorities (for which comment from the OIE and Codex had been sought) and of the upcoming Global Forum for Food Safety Regulators (October 2004).

Revision of the *Terrestrial Code* chapters on bovine tuberculosis and bovine spongiform encephalopathy

The Chair updated the Working Group on the history of the revision of the tuberculosis chapter. He noted that a risk-based approach to the food safety aspects had been introduced, that there had been an attempt to differentiate animal health and public health objectives, and the concept of 'competent authority' had been introduced into the certification articles to address situations where responsibility for public health was not within Veterinary Administrations of the exporting country. There was discussion on the importance of a risk-based approach to standards development, but agreement that the measures recommended must be practicable and be able to be applied in Member Countries as a basis for international trade.

The President of the Code Commission explained that comments from Member Countries on the revised tuberculosis chapter would be reviewed just prior to the OIE General Session and, if comments were minor and positive, the revised chapter may be put for adoption. If not, it would be returned to the Code Commission for further work. He advised that the Code Commission was, for all disease chapters, trying to identify the risks (both animal and public health) presented by a commodity and to compose specific measures to address those risks. Where the risks are common to animal and public health, a reference would be made to the fact that the particular measure serves both animal and public health objectives.

The Working Group recommended that the OIE adopt a broader view of 'competent authority' in the *Terrestrial Code* to incorporate veterinary administrations and other authorities with the relevant responsibilities. There was also a need to cross reference Codex texts on certification. This would assist an integrated approach to animal health and public health risks. The Working Group noted that these comments on 'competent authorities' were also relevant to the BSE Chapter of the *Terrestrial Code*.

Coordination of OIE and Codex standards development

The Working Group noted the proposal from the Joint FAO/OIE/WHO Workshop on Non-human Antimicrobial Resistance (held in Oslo in March 2004) to establish an OIE/Codex Task Force to develop risk management options in this area. The matter will be discussed at the next session of the Codex Alimentarius Commission to be held at the end of June 2004.

The Working Group recommended that the OIE and Codex collaborate closely while separately developing guidelines on traceability dealing with animals (OIE) and animal products (Codex).

The Working Group recommended that the OIE Aquatic Animal Health Standards Commission be mindful of food safety issues in developing or revising its standards.

In view of the value of cross-referencing the standards of the two organisations, the Working Group recommended that, in their future work, the OIE and Codex continue to introduce visible linkages between standards, especially those addressing horizontal issues.

The Working Group considered that it may be useful for Codex and OIE regional officials to be involved in the work of the other organisation, to improve understanding and encourage a greater level of understanding both at national and regional level.

Paper on 'Role and functionality of veterinary services in food safety through the food chain'

The Chair noted that the paper had been written primarily to provide Veterinary Services with a bridge between the work of OIE and Codex where there was a need to meet both animal and public health objectives and was to serve as a background paper for the Director General of the OIE. The Working Group discussed several issues in the development of subordinate papers, including the inclusion of risk analysis in standards development and the inclusion of references to other disciplines.

The Chair indicated that he would take into account comments from Member Countries in finalising the document, and send it to the Director General of the OIE to serve as a guide for OIE work on food safety.

Development of principles on traceability/traceback as a precursor to guidelines/standards

The Working Group noted that 'animal identification' was an agenda item at the OIE General Session and that a draft resolution identified traceability as an OIE priority. It also noted that a draft paper was due to be discussed at the Codex Committee on General Principles. The Working Group acknowledged the importance of the issue and encouraged both organisations to coordinate closely to ensure consistency in developing systems to facilitate traceback to farms, animals and animal feed for public and/or animal health reasons. At least, there should be agreement on the principles and basic definitions.

The Working Group noted that there may be problems of cost and feasibility (regardless of need) associated with the implementation of traceability systems in developing countries and considered that it would be useful to involve Regional Commissions to help achieve the widest possible application.

Adopting a risk based approach would determine the need and extent of trace back systems required in specific Member Countries. Countries should be able to implement trace back systems according to their own situation.

Good farming practices

Dr Isabelle Chmitelin submitted the paper and indicated that this paper was designed as guidelines and adopted a farm-level animal production approach to address public health risks at the farm, at this stage generically, with the opportunity to add specific references later to address particular issues or situations in specific regions or countries. The paper was directed at veterinary administrations and other competent authorities to promote and implement good farming practices (as appropriate) within their countries as a component of the overall animal health system and, as such, would cover all farm activities but would refer to relevant documents from other organisations.

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The Working Group acknowledged that the 'guidelines' described what might be ideal in specific farming situations but might not necessarily be seen as applying to all situations in all Member Countries where risks might be different and animal husbandry practices varied.

The Working Group discussed whether the paper should be published as a joint FAO/WHO/OIE publication or as an OIE document with FAO and WHO input. It was decided that the OIE would continue with the development of this paper, but would invite WHO, FAO and the Codex to contribute. The Group felt that this approach presented fewer difficulties and that other organizations would later be encouraged to cross-reference this document, as the Codex Committee on Meat Hygiene had done with other OIE documents.

The Working Group agreed that a revised version of the paper would be reviewed by the Bureau of the Code Commission in July, before circulation to Member Countries for comment. Letters would be sent to WHO and FAO seeking input. The paper is at Appendix C.

Framework document on 'Control of hazards of public health and animal health importance through ante- and post-mortem meat inspection'

The Chair presented the paper and explained that the paper addressed one of the priorities identified by the Working Group arising from the paper on the role and functionality of veterinary services in food safety. The paper was intended as a framework covering this important area where Veterinary Services serve both animal and public health needs, and would need further development.

The Working Group discussed various aspects of the paper (including whether it could serve as a stand alone document with some modification) and agreed that the Chair would revise the paper for confirmation by Working Group members before review by the Bureau of the Code Commission in July. The Working Group recommended that the OIE then progress the development of specific guidelines, through an *ad hoc* Group. The paper is at Appendix D.

Work programme for 2004

The Working Group discussed issues identified at the previous meeting and which still needed to be addressed at some stage in the work programme. The following priorities for 2004 were agreed:

1) Horizontal issues

   a) Traceability

   b Testing, inspection and certification – the Working Group recommended that the OIE work with Codex (especially CCFICS) and other relevant international organisations (such as the IDF) to review international standards with a view to maximising harmonisation

2) OIE texts

   a) *Terrestrial* Code chapter on bovine tuberculosis – underway

   b) *Terrestrial Code* chapter on bovine brucellosis – the Working Group recommended that the OIE commence scientific review, pending International Committee approval of the approach adopted for bovine tuberculosis

   c) Salmonellosis – take into account Codex and WHO work

3) OIE input into Codex texts

   a) Upcoming Codex meetings on animal feeding, veterinary drugs and milk and milk products

b) Improvement of the current level of OIE input into Codex texts and development of a method for the most effective utilisation of Codex expertise in the work of OIE *ad hoc* Groups

4) Antimicrobial resistance

5) Development of other documents

a) good farming practices

b) framework document on 'Control of hazards of public health and animal health importance through ante- and post-mortem meat inspection'.

Resolutions and recommendations for the 72nd General Session (2004)

These would be developed from the presentation of the Chair to the OIE International Committee.

Next meeting

The Working Group agreed that its next meeting should be held at a time to enable review of Member Countries' comments on the outcomes of the current meeting and prior to the Code Commission's January 2005 meeting.

.../Appendices

Appendix XIII (contd)

Appendix A

THIRD MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Paris, 1-2 April 2004

List of participants

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Appendix B

THIRD MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Paris, 1-2 April 2004

Agenda

1) Update from the Director General of the OIE and the Chair of the CAC

2) Report of the previous Working Group meeting

3) Reports from recent relevant CAC meetings

4) Revised chapters on bovine tuberculosis and BSE proposed by the Terrestrial Animal Health Standards Commission

5) Discussion

   a) Coordination of OIE and Codex standards development

   b) 'Role and functionality of Veterinary Services in food safety through the food chain'

   c) Development of principles on traceability/traceback as a precursor to guidelines/standards

   d) Development of guidelines on 'good farming practices' as a joint publication of OIE/FAO/WHO

   e) Framework document on 'ante- and post-mortem activities in the production of meat to reduce hazards of public and animal health significance'

6) Work programme for 2004

7) Resolutions and recommendations for the 72nd General Session (2004)

8) Other issues.

Appendix C

GUIDE TO GOOD FARMING PRACTICES FOR ANIMAL PRODUCTION FOOD SAFETY

INTRODUCTION

These guidelines are intended to help competent authorities and stakeholders, especially farmers, to fully assume their responsibilities at the first stage of the food chain to optimise the food safety control of products of animal origin offered to consumers.

The recommendations in these guidelines complement the responsibilities of the competent authorities at the farm level, and in particular of the Veterinary Services.

Food safety is now universally recognised as a public health priority. It requires a global approach, from production to consumption, which is so aptly conveyed by the expressions "from the stable to the table" and "from the field to the plate".

As far as animal products and products of animal origin are concerned, this inevitably means controlling the health status of the animals from which these food products are derived. These status must of course be assessed with regard to any infectious (bacteria and viruses) or parasitic agents, and especially zoonotic agents, that they could be carrying at the primary production stage. The possibility of the animals having ingested and possibly accumulated chemical (drug residues, pesticides, heavy metals, etc.) or physical contaminants (radioactive elements, foreign bodies, etc.) during their lifetime must also be addressed.

Any such biological, chemical and physical agents present in the body of the live animal may then contaminate animal products (milk, meat, fish, eggs, etc.) at levels considered unacceptable in terms of public health. Controlling the safety of food of animal origin at the primary production stage therefore involves all the measures to be implemented at the farm or production unit level necessary to ensure that these contaminants do not end up in animal products, or, if they do, that their levels do not exceed the maximum permissible levels, notably the maximum residue limits (MRL) and microbiological criteria set by the Codex Alimentarius Commission.

The tools for controlling food safety, namely the codes of hygienic practice and the HACCP system (Hazard Analysis and Critical Control Point), have proved their effectiveness at the secondary production and distribution stages. It is clearly appropriate to try to apply them wherever possible at the primary production stage of animal products, in other words at the farm or production unit level, whenever an appreciable improvement in the level of the control of food safety may result.

SCOPE

The present document addresses all those hazards whose control at farm level can have a beneficial or even decisive effect on the food safety of products of animal origin (including: milk and milk products, meat and meat products, eggs and egg products, honey and apiculture products).

It does not address the processing of products at the farm level which comes within the scope of specific standards in the Codex Alimentarius.

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It does not address animal welfare aspects of farm production.

The hazards identified at the farm level are as follows:

1. BIOLOGICAL HAZARDS:

The biological agents of the most common and/or dangerous diseases that can be transmitted to humans via foodstuffs of animal origin are: *Salmonella*, *Campylobacter*, verotoxinogenic *Escherichia coli* (VTEC), including *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Toxoplasma*, *Leptospira*, *Coxiella Burnetii* (Q fever), *Brucella*, *Mycobacterium* (tuberculosis), *Yersinia enterocolitica*, prions (BSE agent, etc.), and parasites such as *Taenia solium, Taenia saginata* and *Trichinella spiralis*.

While these pathogens arouse the greatest concern among consumers and governments in terms of food safety, the diseases they cause are also the most difficult to prevent at the farm level as they can also be transmitted by warm-blooded animals, such as birds, crawling or flying insects and even by water or the soil.

2. CHEMICAL AND PHYSICAL HAZARDS:

These hazards chiefly consist of drug residues (notably antibiotics), growth promoters (some unauthorised hormones, substances having a thyrostatic action and anabolic substances), residues of chemical products used on the farm (pesticides, disinfectants, etc.), environmental contaminants (dioxins, PCBs, PAHs, heavy metals, radioactive isotopes, etc.) as well as foreign bodies (needles, fragments of glass, pieces of plastic or metal, etc.).

In the majority of cases, the action needed at the farm level to reduce or eliminate the risk presented by these chemical and physical contaminants is, in comparison to that needed to control biological risks, easier to implement.

The remainder of this document considers the various hazards that need to be taken into account at the primary production level and in each case recommends actions to reduce the risks that their occurrence poses for public health.

Eight areas of primary production in which these preventive actions can usefully be implemented are dealt with in turn:

I – Buildings and other facilities: surroundings and environmental control

II – Health conditions for introduction of animals into the farm

III – Animal feeding

IV – Animal watering

V – Veterinary drugs

VI – Farm management

VII - Preparation of animals for slaughter

VIII - Common measures

SECTION I – BUILDINGS AND OTHER FARM FACILITIES: SURROUNDINGS AND ENVIRONMENTAL CONTROL

Hazards: These consist of pathogenic biological agents (*e.g. leptospirosis, salmonellosis, trichinosis, legionellosis*, etc.), chemical agents (e.g. dioxins, pesticides, hydrocarbons, etc.) or physical agents (e.g. radioisotopes) which can be a direct (air-borne or feed-borne) or indirect (notably via water and feedstuffs) source of contamination for animals.

1) coming from farm's immediate surroundings

GGFP recommendations:

- Avoid conducting farming activities close to industrial activities likely to be a source of pollution (e.g. domestic waste incineration plant releasing dioxins, surface processing plant releasing solvents or heavy metals, etc.) or in an environment susceptible to air-borne pollution (e.g. near a road with heavy motor traffic – emissions of lead and hydrocarbons), soil pollution (former industrial site or site where dumping of toxic substances has taken place) or the proliferation of pests (e.g. open municipal rubbish tip),

- Site farm buildings or other facilities (e.g. in the case of extensive husbandry) so that they are independent of private buildings (residential accommodation), sufficiently far away from areas where waste materials are stored, and so that access by visitors can be effectively controlled (direction signs or "access prohibited" signs where necessary).

- Site farm buildings or other facilities away from buildings used for purposes on neighbouring farms which could increase the risk of disease transfer.

- If necessary, seek the advice of the relevant competent authorities (e.g. Veterinary Services, Environmental Services, etc.).

2) coming from failure to control the environment in livestock buildings

GGFP recommendations:

Design farm buildings and other livestock facilities:

- adequate in size and correctly ventilated,

- with a rational arrangement of the premises (separation of clean and soiled areas, absence of any intersection of production chains, separation of working areas and storage areas from animal production areas),

- allowing animals to be dealt with in single groups (poultry, pigs) and newly arrived (quarantine) or sick animals (observation pen) to be satisfactorily isolated,

- allowing easy, complete and effective cleaning and disinfection,

- correctly isolated from pests and from wild or stray animals, and from other domestic animals as appropriate,

- allowing easy, rational and effective evacuation of excreta,

- suitably equipped for the collection of farm effluents and wastewater,

- keeping the immediate surroundings clear and free from stagnant water and anywhere that could harbour pests, and arranged so as to allow easy disinfection of areas used by professional visitors (veterinarian, animal or feed deliverers, milk or egg collectors, carcass disposal agents, etc.),

- so as to make access difficult for unauthorised persons or vehicles (barriers, fences, signs),

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- taking into account the risk of natural disasters (flooding, landslides, heat waves, prolonged freezing conditions, earthquake, etc.),
- using inert construction and surface materials that cannot be a potential source of contamination (e.g. prohibit the use of lead paint),
- if necessary, seek the advice of a veterinarian, para-veterinarian or an official with the relevant competent authority.

SECTION II – HEALTH CONDITIONS FOR INTRODUCTION OF ANIMALS INTO THE FARM

Hazards: These consist of biological agents (pathogenic bacteria, viruses, parasites,…) of herds/flocks arising from animals introduced without all the necessary health guarantees.

GGFP recommendations:

- Introduce into the farm only animals from farms at which the present GGFP has been implemented,
- Introduce only animals of known health status (for example regarding tuberculosis, brucellosis, leptospirosis, vibriosis, salmonelloses and cryptosporidiosis), in accordance with the provisions adopted by the competent authority (Veterinary Services),
- Ensure that all the animals introduced are correctly identified (tagged or marked) and that their identification does indeed correspond to the accompanying health documents,
- Obtain from the seller full details of the route taken by the animals being introduced, from the hatchery, apiary, herd or flock of origin to their destination,
- Control the sanitary conditions under which the introduced animals are transported: ensure that the deliverer has a suitable vehicle and implements an effective cleaning and disinfection programme for the vehicle, so as to reduce the risk of transmitting pathogens between production units or farms,
- Obtain a declaration from the seller regarding any chemical residues that might be present due to the introduced animal's having recently been treated,
- Refuse any introduction of animals presenting suspicious clinical signs on delivery, and if necessary inform the competent authority (Veterinary Services) if a contagious disease is suspected,
- Record full details of the purchased animals: description, identification, sex, age, health status, date of introduction, name and address of the seller and of the attending veterinarian, etc.,
- Isolate the newly introduced animal(s) for a suitable surveillance and acclimatisation period,
- Arrange for a veterinarian or para-veterinarian to perform any necessary biological tests when the animals are introduced and isolated, and do not bring these animals into contact with other animals on the farm until the results of these tests are known and have proved satisfactory.

SECTION III – ANIMAL FEEDING

Hazards: These consist of biological agents (bacteria, viruses, prions, parasites, antibiotics, promoters, phytotoxins or mould toxins), chemical agents (farm chemicals (pesticides), dioxins, heavy metals, environmental contaminants,…) or physical agents (foreign bodies,…) which could be present in animal feed, and consequently in animal products (milk, meat, fish, egg products, etc…). Risks may also result from an overdosage of certain components, notably medication, in animal feed.

GGFP recommendations:

The use of veterinary drugs as supplements in animal feeding should be done in accordance with section V.

Grassland and pasture

- Carry out a risk assessment when livestock are put out to pasture outside the farm: in particular, ensure that the land where the animals are put out to pasture is not exposed to potential sources of chronic contamination (e.g. main road with heavy traffic, domestic waste incineration plant), is not polluted with chemical residues (e.g. pesticides, dioxins, heavy metals) at an unacceptable level and is not known to harbour animal pathogens (bacteria: e.g. anthrax spores; parasites: e.g. flukes),

- Ensure that the fields surrounding the pasture are not sprayed with substances that have not been shown to be safe, and that the animals cannot have access to potentially contaminating material on the perimeter of the pasture (e.g. unauthorised dumping, stocks of herbicides, posts coated with aluminium paint),

- Carefully follow the manufacturer's instructions shown on the label before spreading any chemical product on fields, pastures or in grain silos,

- Respect the recommended waiting times before animals are put out to pasture after the pasture or neighbouring pieces of land have been treated with agricultural chemicals,

- Comply with recommendations of the use of animal by-products for agricultural reclamation/spreading,

- Prevent livestock entering pastures containing toxic plants,

- When purchasing pasture or other land, require certification for the land in question regarding previous use of agricultural inputs or any chemical pollution (resulting for example from dumping of industrial waste). Where necessary, have a soil study carried out to detect the presence of any toxic chemicals.

Use of commercial feed

- Require that all the animal feed purchased is free of chemical residues and complies with regulatory requirements (obtain, if this is not stated on the label, a certificate guaranteeing that it complies with the regulations),

- Check that the feed delivered is correctly labelled (manufacturer's name, composition, manufacturing date, use-by date, instructions for use and precautionary measures to be followed, batch number, etc.) and that the packaging is intact and without any defect that might have affected the contents,

- Control the quality of the feed delivered in terms of appearance (visual examination) and keep a written record of this control,

- Refuse, treat appropriately or destroy any feed presenting traces of contamination by mould,

- Ensure that feed for ruminants is free from any trace of animal by-products prohibited by the regulations and eliminate any risk of accidental cross-contamination,

- Keep samples of purchased feed for any subsequent analytical testing should a problem of residues be identified at the farm production level,

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- Store feed in a clean area, protected from humidity and pests (insects and rodents),
- If storage conditions are not optimal, prefer more frequent deliveries of smaller quantities,
- Keep an up-to-date register of feed delivered and used (batch numbers, date used and destination),
- Seek advice if there is the slightest doubt as to the quality of the feed given to animals,
- When a problem exists, immediately inform the supplier and, if necessary, the competent authorities.

Manufacture of animal feed on the farm

- Control the quality of the raw materials delivered in terms of their appearance (visual examination, to rule out any risk of macroscopic contamination) and keep a record of this control,
- Ensure that all the raw materials of plant origin used as ingredients for animal feed have been grown, stored and treated using validated procedures,
- Keep an up-to-date register of the raw materials delivered and used (batch numbers, dates used, batch numbers of the feed in which they were used),
- Store the raw materials in a clean area, protected from humidity and pests (insects and rodents),
- Eliminate raw materials presenting traces of contamination with mould,
- Ensure that the water used is potable,
- Comply with the recommendations regarding storage (in a safe place) and the use of additives and feed supplements (always follow the recommendations on the label regarding dosage and withdrawal periods),
- Ensure uniform mixing of the different components,
- Eliminate any risk of cross-contamination, at all stages (production, storage and distribution),
- Have clearly defined written procedures for the manufacture of feed, fixing precisely the formulation, production stages, and in particular making provision for mixers to be purged between the production of two types of feed with different ingredients,
- Regularly control and calibrate weighing machines,
- Plan corrective actions to be implemented in the event of a formulation error and actions to deal with substandard batches that might constitute a hazard,
- Keep, and file for as long as necessary, up-to-date manufacturing records specifying the dosage and batch number(s) of each of the raw materials used,
- Keep samples of manufactured feed for subsequent analytical testing should a problem of residues be identified at the farm production level,
- Set a use-by date for each batch of manufactured feed, taking into account the use-by dates of each of the ingredients and the packaging and storage conditions,

- Correctly label the sacks or hoppers containing the manufactured feed (date of manufacture, feed type, batch number, use-by date),
- Store the manufactured feed in a clean place, protected from humidity and pests (insects and rodents),
- In the case of bulk feed, do not mix two batches of feed in the same container (separate hoppers),
- Have the composition of the manufactured feed controlled at least once a year (correct dosages of the various ingredients, presence of any contaminants),
- Keep an up-to-date register of feed delivered and used (batch numbers and dates of use),
- Seek advice if there is the slightest doubt as to the quality of the manufactured feed,
- When a problem occurs that could affect the safety of animal products, inform the competent authorities immediately.

General recommendations on animal feeding:

- Avoid overfilling the animals' feeding troughs (fill them twice rather than once, adapt the quantity of feed to the specific requirements of the animals),
- Remove any unused feed from the troughs before refilling,
- Clean the troughs and automatic feeders regularly,
- Ensure animals are fed with feed suitable for the species.

SECTION IV – ANIMAL WATERING

Hazards: These are basically of two types: microbiological and chemical.

Microbiological hazards

These consist of:

- pathogenic bacteria which include toxic strains of *Escherichia coli* (e.g. *E. coli* O157:H7), Salmonella spp., *Vibrio cholerae* and *Shigella* spp,
- viruses which include small round structured viruses (SRSV or Norwalk virus) and the hepatitis A virus,
- parasites which include pathogenic protozoa such as *Cryptosporidium parvum, Giardia lamblia* and Cyclospora *cayetanesis,* and eggs and larvae of nematoda, cestoda and trematoda.

Microbiological hazards are most frequently caused by human waste and animal excreta, which may contaminate the water supply used for livestock.

Chemical hazards

These consist of farm chemicals (e.g. pesticides, nitrates/nitrites), industrial contaminants (e.g. dioxins, PAHs, heavy metals), or the water supply network itself (e.g. lead piping).

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These chemical agents may eventually be found in animal products (milk, meat, egg products, aquaculture products, apiculture products, etc.) as a result of the animals' drinking this water.

GGFP recommendations:

- The use of veterinary drugs as supplements in animal watering should be done in accordance with section V,
- Prevent, by means of barriers or fences, domestic or wild animals approaching safe water reserves or watering points and polluting them,
- Prevent, by means of barriers or fences, livestock approaching polluted water reserves or watering points and contaminating themselves,
- Protect water reserves from contamination by undesirable substances, and specifically:
  - ✓ Use chemicals and organic substances with great care (comply with doses and minimum distance requirements), notably near water collection points, streams and ditches,
  - ✓ Always follow the manufacturer's instructions (see label) for the use of any chemical product for spraying or fumigating (how to apply, dosage and waiting time),
  - ✓ Avoid using pesticides and herbicides anywhere where there is a possibility of contaminating the water table or nearby water collection points,
  - ✓ Avoid cleaning spraying equipment or chemical product containers in places where any remaining substances and the flushing water can re-enter the water supply network,
  - ✓ Avoid spreading slurry, manure or dairy effluents where there is any possibility of their contaminating the water table or nearby water collection points,
  - ✓ Avoid human and animal effluent being a source of contamination.
- Monitor compliance of, maintain and regularly clean water distribution systems. Use closed-circuit systems whenever possible, so as to reduce access by other animals,
- Have the bacteriological and physico-chemical quality of water regularly tested, where appropriate (e.g. bore-hole), and ask to receive the results of analyses conducted on water in the local water supply network,
- Seek advice and test the water resources if there is the slightest doubt about the safety of water used for animals.

SECTION V – VETERINARY DRUGS

Hazards: These consist of inappropriate use of both veterinary drugs, which may induce presence of residues in food products, and antibiotics, which may induce creation of multi-resistant bacterial strains, which can pose a major threat to public health.

GGFP recommendations:

- Any therapeutic treatment should only be undertaken when the diagnosis is precise and certain, and should be based on the dual principle of maximum efficacy and minimum risk,

- Use only drugs that are authorised for the treatment of the particular species, and use antimicrobials only on veterinary prescription and as prescribed,
- Use drugs in accordance with the species, uses and doses indicated on the label, and in accordance with the instructions on the label or on the advice of a veterinarian well acquainted with the animals and the production site,
- Use only drugs that are known to be effective for the intended use and in strict compliance with the recommendations on the label or the veterinarian's prescription,
- Do not use veterinary drugs beyond their expiry date,
- Use weighing machines, animal measuring tape or other suitable measuring instrument to evaluate the weight of the animals and adjust the dose to be administered (avoid any overdosage),
- Wherever possible, isolate sick animals from healthy animals, so as to avoid the transfer of resistant bacteria, and treat animals individually,
- Strictly observe the recommended withdrawal periods so as to guarantee that residue levels in food of animal origin do not present any risk to the consumer, on the understanding that any drug likely to result in residues must be prescribed by a veterinarian,
- Use the appropriate techniques and equipment to administer drugs, and avoid any accidental contamination of the product by thoroughly cleaning equipment, such as buckets. Change the syringe for each new drug and, if appropriate, the needle for each animal.
- In the event of the injection needle breaking in the animal's muscle tissue, place an indelible mark on the injection site, note the identification number of the animal and record the problem in a written document which will accompany the animal to the abattoir,
- Keep a written record of all treatments dispensed to the animals, and keep all the laboratory reports, including bacteriological tests and sensitivity tests,
- Keep up-to-date records of the use made of veterinary drugs on the farm, including the following information:
  - ✓ name of the product or active substance, and the batch number,
  - ✓ supplier's name,
  - ✓ dates of administration and date of end of treatment,
  - ✓ identification of the animal (or group of animals) to which the drug was administered,
  - ✓ diagnosis or clinical signs treated,
  - ✓ quantity of the drug administered and the administration route (if transcutaneous, state the injection site),
  - ✓ withdrawal periods (dates from which milk, meat or any other animal product can be offered for human consumption),
  - ✓ results of laboratory tests,
  - ✓ effectiveness of the therapy.

  and place them at the disposal of the competent authority (Veterinary Services),

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- Develop rational stock management procedures for drugs, in particular vaccines and medicated premixes (keep an up-to-date record of stock movements),

- Ensure that the conditions under which antimicrobials and other veterinary drugs are stored on the farm comply with the label and insert instructions (in particular provide a safe place (cabinet in a locked room), where they can be stored in the dark and at the recommended temperature),

- Safely dispose of all veterinary drugs past their expiry date, instruments and empty containers in an environmentally friendly manner.

SECTION VI – FARM MANAGEMENT

Hazards: These consist of pathogenic biological agents which can be introduced and proliferate on farm for lack of respect of basic rules in farm management. These can also consist of chemical contaminants. Both biological agents and chemical contaminants can induce subsequent contamination of animals and their products.

GGFP recommendations:

Training, conduct and health status of staff

- Provide suitable training for staff required to handle farm chemical inputs, manufacture feed on the farm, clean and disinfect premises and equipment and treat animals, which will give them a good knowledge of hazards present on the farm and methods of managing risks so as to guarantee the safety of food products of animal origin,

- Train staff in basic biosecurity principles and practices to minimize the likelihood of introducing or spreading pathogens,

- Insist on staff wearing suitable working attire (clothing and boots), kept clean or changed as often as necessary, and respecting sanitary measures (e.g. changing clothes, washing hands or showering) before they enter controlled areas,

- Ensure that staff are regularly monitored to detect any healthy carriers of bacterial or parasitic agents that could be transmitted to animals.

Maintenance, cleaning and disinfection of equipment, premises and immediate surroundings

- Develop and implement the appropriate procedures to maintain, clean and disinfect farm equipment, premises and immediate surroundings, respecting the manufacturer's instructions regarding the use of detergents and disinfectants (preparation of surfaces, dilution, contact period),

- Ensure that the procedures in place are effective (visual self-inspections with, if necessary, recourse to bacteriological analysis) and take any corrective measures that may be required,

- Use clean instruments so as to avoid spreading diseases.

Measures to control pests and stray animals and prevent unauthorised access

- Develop and implement a global plan to control pests (rodents, insects, spiders) within the farm, using licensed products in the appropriate manner,

- Ensure the effectiveness of this control plan (visual self-inspections) and take any corrective measures that may be required,

- Prevent domestic animals (cats and dogs) from roaming in and around livestock buildings,
- Put in place all the appropriate prevention and control measures, respecting the regulations currently in force in terms of protection of biodiversity, so as to minimise contact between livestock and wild animals,
- Ensure that no unauthorised person can enter the livestock buildings.

Stock management (feed, drugs)

- Ensure that there is a satisfactory turnover of stock, applying the FIFO (first in, first out) method, and disposing of any product that has passed its expiry date,
- Ensure that all containers (sacks or cans) are hermetically sealed,
- Ensure that storage conditions are appropriate and in particular that the recommended temperatures are respected.

Management of waste materials, effluents and expired products

- Ensure that the waste materials generated by the farm (excreta, feed remains, etc.) are regularly removed, in such a way that neither their transport to the storage site nor the conditions under which they are stored can be either a source of environmental contamination for the farm and its immediate surroundings or conducive to the proliferation of pests (rodents, insects),
- Ensure that products that have passed their expiry date (farm chemical inputs, veterinary drugs) and their packaging are disposed, of and effluents (wastewater, washing water) treated, in such a way that they cannot be a source of environmental pollution, and, indirectly, of contamination for the animals.

Storage of chemical products

- Store chemical products and equipment that may contain them safely out of reach of the animals.

Production monitoring of animals

- Ensure that the animals or groups of animals present on the farm are permanently identified and keep the farm records up-to-date,
- Minimise mixing of animals of different species,
- Conduct daily surveillance of the animals to detect any anomaly or suspicious symptom,
- Set up a system for monitoring the production performance of the animals and identify indicators that will allow the early detection of any anomaly.

Health monitoring of animals and disease prevention programmes

- Develop, in conjunction with the veterinarian in charge of the animals, an animal health and welfare plan including disease prevention measures to be implemented (e.g. mastitis programme, vaccination and deworming programmes, etc.),
- Implement this health plan, following the guidelines issued by the competent authority for animal disease control (Veterinary Services), with the advice of a veterinarian or para-veterinarian,

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- Treat animals regularly against gastrointestinal parasites,
- Seek professional advice in the event of unusual clinical signs suggestive of a disease in the herd/flock or if there is an unexpected drop in the yield or quality of animal products.
- Establish written standardised operational procedures for the detection and management of animal diseases, and for the use of veterinary products,
- Inform the veterinarian responsible for monitoring the health of the animals of any problems of disease recurrence or relapses,
- Take advantage of all the information obtained at the abattoir during ante-mortem inspections of animals and post-mortem inspection of meat and offal by official veterinarians, relating to specific pathologies for which corrective measures can be taken at the farm level (parasitism, muscular degeneration, melanosis, presence of foreign bodies [e.g. cactus spines], etc.),
- Determine whether fallen stock and dead animals need to be tested as part of an official surveillance programme.

Animal movements

- Ensure that any isolated or seasonal movement of animals outside the farm (transhumance, grazing on mountain pasture, etc.) does not expose them to an excessive risk of chemical or microbiological contamination, whether by air-borne route, digestive route or direct or indirect contact with wild animals.

Isolation of sick animals and their products

- Separate sick or potentially sick animals from healthy animals, so as to avoid the transfer of pathogenic agents and resistant bacteria,
- Comply with hygiene regulations relating to contacts between persons (veterinarians, livestock producers, owners, children) and animals undergoing treatment,
- Ensure that products from sick animals cannot be used for human consumption or for animal feed.

Storage and disposal of dead animals

- Isolate the dead animals prior to their collection or destruction, and store them in a suitable place (easy access and disinfection) so as to avoid any contact with livestock or their environment,
- Ensure that the dead animals that have died on the farm are rapidly disposed of and ensure that their removal by a carcass disposal firm cannot be a source of pathogens for the farm.

SECTION VII – PREPARATION OF ANIMALS FOR SLAUGHTER

Hazards: These consist of numerous potentially dangerous agents for humans which are present in the digestive tube, excreta, and on the hides and skins of cattle and sheep or the plumage of birds in good health. These agents include *E. coli*, *Salmonella* and *Campylobacter*, which can cause food poisoning in humans.

Stress caused by grouping animals together, loading them and transporting them to the abattoir can promote the passage of these pathogenic bacteria from the intestine into muscle tissue.

Moreover, the greater the amount of faecal soiling of hides, skins and feathers, the higher the risk of any pathogenic bacteria they may contain contaminating meat during the dressing or defeathering of carcasses at the abattoir.

GGFP recommendations:

General measures

- Ensure animals are fit for slaughter,
- Prevent animals from becoming soiled, by keeping the enclosures, gangways, and loading and unloading areas clean, avoiding overcrowding, increasing the quantity of litter and resolving any problems of effluent disposal,
- Give animals raised in livestock buildings free access to straw, hay and silage with a high dry matter content for 48 hours prior to slaughter,
- Avoid any abrupt changes in diet at the end of the production cycle,
- Give animals free access to watering points up to their departure for the abattoir, and withdraw feed from animals for the 24 hours prior to slaughter,
- Handle animals humanely and do not subject them to undue stress, given that stressed animals are more likely to release pathogenic bacteria, and especially *E. coli* O157:H7, in their excreta,
- Check the state of the animals' identification marks and bands several days before they are due to leave so as to avoid having to tag the animals immediately before they are transported to the abattoir,
- Ensure that the conditions under which the animals are transported to the abattoir are not a source of stress and are not conducive to substantial soiling of their hides, skins or plumage.

Extensively grazed livestock

Weather conditions prior to departure (e.g: heavy rainfall) and the absence of any special measures to avoid watering points becoming a quagmire, can lead to considerable soiling of ruminants (cattle, sheep, goats) and omnivores (pigs) before their departure to the abattoir. Furthermore, gathering animals together prior to their transport is an operation that causes stress, especially for animals that have ranged freely all year round in the open and are unused to the presence of humans.

It is therefore important to ensure that:

- animals at the end of the fattening phase are placed in pastures that are the least prone to the effects of inclement weather, with watering points that are sufficient in number and arranged in such as way as to avoid the animals becoming soiled with mud,
- the animals are brought together a sufficient length of time before their departure to the abattoir, in an enclosure, preferably covered, or other suitable area, so as to minimise the risk of major soiling of their hides, skins, wool or plumage.

Livestock housed on slatted flooring

The correct stocking density of feedlots and enclosures (density per square metre) throughout the fattening phase is an important consideration, as overcrowding, like under-population, prevents the satisfactory evacuation of excreta between the slats.

It is therefore important to ensure:

- that the correct stocking density is maintained for as long as possible during the fattening phase (the density depends on the size and nature of the stalls, as well as on the age of the animals),
- that the slatted flooring is kept satisfactorily clean and that the housing is correctly ventilated,
- that particular attention is given to the cleaning operations conducted just before the departure of the animals for the abattoir,
- that, wherever possible, cattle are kept on straw bedding for 1 to 20 days before slaughter.

Livestock housed on litter

The density of animals housed on litter has a significant effect on the cleanliness of the hides. The addition of extra litter will not counteract the adverse effects of over-stocking. The amount of litter required depends on factors such as the density of animals, their weight and the design of the building.

It is therefore important:

- to avoid over-stocking,
- to provide an adequate supply of clean litter as often as is necessary,
- to ensure that the premises are adequately ventilated and correctly arranged for the evacuation of effluent and cleaning water.

Health measures

- Isolate sick animal in suitable premises, treat them and wait until they have fully recovered before sending them to the abattoir,
- Check the treatment records of all the animals before they leave so as to ensure that the withdrawal periods or pre-slaughter confinement periods have indeed been respected.
- Withdraw from the batch being sent to the abattoir any animal of whose health status is in doubt or is still in the withdrawal period following the administration of medication.

SECTION VIII – COMMON MEASURES

An identification and traceability system for animals, their feed and products leaving the farm, can assist:

- to identify the true source of a problem of contamination of products of animal origin,
- and to implement measures to eliminate, or at least limit, any harmful consequences (such as by the targeted withdrawal of the products in question).

A complete and reliable system of recording procedures, actions and controls implemented on the farm can assist genuine and effective control of the risks that primary production represents for food safety. It can also assist livestock owners to prove that they have fully carried out their public health responsibilities.

GGFP recommendations:

Traceability of animals, animal feed and animal products:

- For each animal or group of animals, require and keep all commercial and health documents enabling their exact itinerary to be traced, from their farm or establishment of origin to their final destination (other farm or abattoir),
- Establish a data recording system that can be used to ascertain exactly which batches of commercial feed the farm's livestock were fed with, and what raw materials were used in feed manufactured on the farm and given to the animals. Keep samples of all the feed used,
- Establish a data recording system that can be used to ascertain the exact origin (animal batch) and destination of animal products produced by the farm,
- Keep all these documents and records and place them at the disposal of the competent authority (Veterinary Services).

Record keeping:

- Keep a record of all persons entering the farm: visitors, service staff and farm professionals (veterinarian, milk tester, inseminator, feed deliverer, carcass disposal agent, etc.),
- Keep the medical certificates of persons working in contact with animals and any document certifying their qualifications and training,
- Keep, for each animal or group of animals, all documents relating to the treatment and veterinary actions it has undergone (castration, calving, caesarean section, dehorning, debeaking, administration of medication, etc.),
- Keep all laboratory reports, including bacteriological tests and sensitivity tests (data to be placed at the disposal of the veterinarian responsible for treating the animals),
- Keep all documents proving that the bacteriological and physico-chemical quality of the water given to the animals is regularly tested,
- Keep all records of all feed manufacture procedures and manufacturing records for each batch of feed,
- Keep detailed records of any application of chemical products to fields, pastures and grain silos, as well as the dates that animals are put out to grass and on which plots of land,
- Keep all the records relating to the cleaning and disinfection procedures used in the farm (including data sheets for each detergent or disinfectant used), as well as all the records showing that these procedures have effectively been implemented (job sheets, self-inspection checks on the effectiveness of the operations),
- Keep documents relating to the pest control plan (including the data sheets for each raticide and insecticide used), as well as all the records showing that the control plan has effectively been implemented (plan showing the location of baits and insecticide diffusers, self-inspection checks on the effectiveness of the plan),
- Keep all the documents relating to self-inspections (by the livestock producer) and controls (by the authorities and other official bodies) relating to the proper management of the farm and the sanitary and hygienic quality of the animal products leaving it,

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Appendix C (contd)

- Keep all documents sent by the official inspection services, the quality control departments of food-processing firms or distributors, relating to anomalies detected at the abattoir, dairy, processing plant or during the distribution phase in products (meat, eggs, milk, fish, etc.) derived from the farm's animals,

- Ensure that all these documents are kept long enough to enable any subsequent investigations to be carried out to determine whether contamination of food products detected at the secondary production or distribution stage was due to a dysfunction at the primary production level,

- Place all these documents and records at the disposal of the competent authority (Veterinary Services) when it conducts farm visits.

ANNEX: INTERNATIONAL STANDARDS AND REFERENCES

OIE *Terrestrial Animal Health Code* (year 2003), and in particular the following sections:

- 1.1. dealing with GENERAL DEFINITIONS AND NOTIFICATION OF ANIMAL DISEASES

and, in particular, definitions of the following terms: disease, disinfection, disinfestation, establishment, infection, laboratory, official control programme, official veterinary control, Veterinary Administration, Veterinary Authority, and Veterinary Services.

- 1.3. dealing with IMPORT RISK ANALYSIS

Chapter 1.3.3. Evaluation of Veterinary Services

Chapter 1.3.4. Guidelines for the evaluation of Veterinary Services

- 3.4. dealing with HEALTH CONTROL AND HYGIENE IN ESTABLISHMENTS

APPENDIX 3.4.1. Hygiene and disease security procedures in poultry breeding flocks and hatcheries

APPENDIX 3.4.2. Hygiene and disease security procedures in apiaries

APPENDIX 3.4.3. Hygiene precautions, identification, blood sampling and vaccination

- 3.6. dealing with INACTIVATION OF PATHOGENS AND VECTORS

APPENDIX 3.6.1. General recommendations on disinfection and disinfestation

- 3.7. dealing with TRANSPORT OF ANIMALS

APPENDIX 3.7.1. Principles applicable to all forms of transport

APPENDIX 3.7.2. Principles applicable to specific forms of transport

- 3.9. dealing with ANTIMICROBIAL RESISTANCE

APPENDIX 3.9.1. Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes

APPENDIX 3.9.2. Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry

APPENDIX 3.9.3. Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine

Codes and standards of *Codex Alimentarius*, and in particular:

- *General principles of food hygiene, including the appendix on HACCP and the guidelines for implementing the system;*
- *Code of hygienic practice for meat hygiene (in the process of adoption);*
- *Codes of hygienic practice for food products of animal origin (fresh meat, milk and milk products, poultry, egg products);*
- *Individual standards for food products of animal origin*
    - *milk and milk products,*
    - *meat products,*
    - *fish and fishery products;*
- *Code of practice of good animal feeding (under review);*
- *Recommended international code of practice for control of the use of veterinary drugs;*
- *Codex general standard for contaminants and toxins in foods (under review);*
- *Codex maximum residue limits (MRL) for veterinary drugs in foods, for pesticides in foods;*
- *Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals;*
- *Code of practice for source directed measures to reduce contamination of food with chemicals;*
- *Draft Code of practice for aquaculture.*

Guide on good practices in primary production

- *Guidelines on good dairy farming practices (Task Force on Good Dairy Farming Practices) of the International Dairy Federation.*

Manual on implementing the HACCP system

- *A training manual on food hygiene and the FAO Hazard Analysis and Critical Control Point (HACCP) system (Food Quality and Safety Systems).*

Appendix D

CONTROL OF HAZARDS OF PUBLIC HEALTH AND ANIMAL HEALTH IMPORTANCE THROUGH ANTE- AND POST-MORTEM MEAT INSPECTION

Andrew McKenzie and Steve Hathaway
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Background

Food-borne disease is generally recognised as an important public health problem and an important cause of decreased economic productivity in both developed and developing countries. Similarly, transmission of hazards of animal health importance via the food chain can result in highly significant economic loss in animal populations. Inspection of slaughter animals can also provide a valuable contribution to surveillance for specified diseases of animal health importance particularly exotic disease. Consequently, control of hazards of public health and animal health importance by ante- and post-mortem meat inspection is a core responsibility for government *veterinary services*.

Recent government policy changes in many countries reflect the demand for significantly increased resources to protect public health against food-borne diseases of animal origin. Along with this, rapidly increasing trade in food at both the local and international level is resulting in increased attention to the potential for transmission of diseases of animal health importance via the food chain. In a global regulatory environment that is more and more intent on placing primary responsibility on industry for ensuring food safety and biosecurity in relation to animal health, government *veterinary services* must exercise these responsibilities in a cost-effective, transparent and interdisciplinary manner.

Scope of this paper

Increased collaboration between World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC) in respect of food standards (see below) has led to the formation by OIE of the Animal Production Food Safety Working Group (APFS WG). It is the intent of OIE that the work of the APFS WG will result in the development of recommendations on several aspects of veterinary involvement in food safety. This document on ante- and post-mortem meat inspection provides a discussion paper on which to base future development of an OIE text through the APFS WG. It is complementary to a discussion paper on "The role and functionality of *Veterinary Services* in food safety throughout the food chain" that has been circulated to OIE Member Countries and will be discussed at the OIE General Session in May 2004.

International standards

International organisations involved with public and animal health include the World Trade Organisation (WTO), Food and Agriculture Organisation (FAO), and World Health Organisation (WHO). At the sector level, the international organisations developing "standards" (standards, guidelines and related texts) are the CAC and the OIE.

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CAC

The CAC develops international food standards, guidelines and related texts (hereafter referred to collectively as "standards"). Standards concerned with food safety should be implemented within a generic framework for managing food-borne risks and should "recognise the need for flexibility consistent with the protection of consumers' health"[1]. The activities of Task Forces functioning outside of the Committee system also include risk-based approaches to food safety e.g. the goal of the *Ad Hoc* Intergovernmental Task Force on Animal Feeding is to ensure risk-based animal feeding practices at the level of primary production[2]. National competent authorities are increasingly adopting this approach.

Although the establishment of national food regulatory systems is the responsibility of governments, the CAC has a strong interest in providing guidance on sound legislative frameworks and infrastructure. Official recognition of the equivalence of alternative measures in different scenarios is a key principle of food safety risk management.

The CAC seeks wider strategic alliances with other international organisations in working towards enhancing food control on a world-wide basis. In this respect, the strategic framework of the CAC for 2003-2007 has an objective to "promote linkages between Codex and other multilateral regulatory instruments and conventions".

OIE

OIE develops international "standards" for animal health and zoonoses. These are primarily designed to prevent the introduction of infectious agents and diseases pathogenic to animals and humans into an importing country during trade.

There has been a significant increase in OIE food safety activities in recent years. Historically OIE has mainly been concerned with zoonoses that cause disease in animals but has now decided to be more active in the area of public health and consumer protection and has noted that this should include "zoonoses and diseases transmissible to humans through food, whether or not animals are affected by such diseases". OIE intends developing new standards covering all pathogens and contaminants that are dangerous for humans for inclusion into the *Terrestrial Animal Health Code* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.*

Veterinary public health issues addressed by OIE to date include: inspection regimes for products of animal origin; certification of meat; control of food-borne hazards during primary production e.g. the agent of BSE, *Salmonella* spp., *Trichinella spiralis*, cysticercosis and residues of veterinary drugs; and good veterinary practice at farm level. All these activities contribute to meat hygiene.

Where the OIE develops standards for zoonoses, the unavailability of risk assessment information for the whole food chain prevents inclusion of "appropriate level of protection" (ALOP) concepts. The Terrestrial Animal Health Code also does not generally differentiate measures intended to safeguard animal health compared to measures to safeguard human health.

[1] Report of the Twenty-third Session of the Codex Alimentarius Commission. ALINORM 99/37. FAO 1999

[2] Proposed Draft Code of Practice on Good Animal Feeding. CL 2001/36-AF. FAO 2001

Increased collaboration between OIE and CAC in respect of food borne zoonoses, particularly through the work of the OIE APFS WG, will result in standards and texts that bridge public and animal health interests across the 'production to consumption' continuum. It is the intent of OIE that collaborative work will result in increasing cross-reference to Codex in the *Terrestrial Animal Health Code*, and development of recommendations by OIE on several aspects of veterinary involvement in food safety. Similarly, it is expected that OIE will provide major contributions to the Codex codes of practice and other texts that incorporate a 'production to consumption' risk-based approach.

Codex Code of Hygienic Practice for Meat

A new Draft Code of Hygienic Practice for Meat[3] is currently being developed by the Codex Committee on Meat Hygiene (CCMH) and is at Step 6 of the Codex process. It is expected to be finalised in 2005. The Code constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the food chain. Ante-mortem inspection is described as a primary component of meat hygiene pre-slaughter, and post-mortem inspection is described as a primary component of process control in post-slaughter meat hygiene.

As the draft Code must serve as an international standard, it does not provide inspection standards for specific hazards or organoleptically detected abnormalities. The public (and animal) health risks associated with slaughter populations are very different in different geographical regions and animal husbandry systems, and ante- and post-mortem inspection should be tailored to the individual country situation and their public and animal health objectives. This remains an obligation of national competent authorities.

Other inputs to ante- and post-mortem meat inspection programmes arise from other Codex work. In particular, the Codex Committee on Food Hygiene (CCFH) develops overarching standards on food hygiene; the Codex Committee on General Principles (CCGP) develops general guidelines for risk analysis and the Codex Committee on Import and Export Inspection and Certification Systems (CCFICS) develops "horizontal" standards that guide implementation of national inspection programmes and certification.

Ante- and post-mortem inspection includes "any procedure or test conducted by a competent person…for the purpose of judgement of safety and suitability and disposition"[4]. Thus tests for compliance with the standards established by CAC for chemical residues, pesticides and contaminants may be included in these inspection activities. Similarly, the new microbiological risk assessment work of the Joint Expert Meeting on Microbiological Risk Assessment (JEMRA) will lead to specific risk management advice from CCFH on tests for microbial hazards e.g. *Salmonella* spp. in broilers, enterohaemorrhagic *Escherichia coli* in ground meats, *Listeria* spp.in manufactured meats.

The Draft Code of Hygienic Practice for Meat specifically recognises the duality of objectives that slaughterhouse inspection activities deliver in terms of public and animal health.

[3] Draft Code of Hygienic Practice for Meat. ALINORM 04/27/16. FAO 2004

[4] Draft Code of Hygienic Practice for Meat. ALINORM 04/27/16. FAO 2004

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Veterinary services

Special editions of the OIE Scientific and Technical Review Series have illustrated the widely varying approaches to organisation of veterinary public health, veterinary animal health and public health services within national competent authorities[5]. Integrating all nationally-mandated food inspection systems under a single competent authority is promoted as having several advantages, including a reduction in overlap and improvement in service delivery[6]. While organisation structure can vary from country to country, it is essential that coverage, resources and scientific and technical capabilities deliver a continuously high standard of service. Further, credible public and animal health assurances are essential for access of animal products to international markets.

In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of national competent authorities who are usually Veterinary Services[7] include:

- Risk assessment
- Establishment of policies and standards
- Design and management of inspection programmes to deliver public and animal health objectives
- Assurance and certification of appropriate delivery of inspection and compliance activities
- Dissemination of information throughout the food chain
- Conformance with WTO obligations
- Negotiation of mutual recognition and equivalence agreements with trading partners.

Ante- and post-mortem meat inspection programmes

Ante- and post-mortem meat inspection programmes are primary responsibilities of national *Veterinary Services*[8]. Wherever possible, inspection procedures should be designed according to a risk-based approach and management systems should reflect international norms.

[5] Scientific and Technical Review Series: Volumes 10 (4) 1991; 11 (1) 1992; 22 (2) 2003

[6] The organisation of federal Veterinary Services in Canada: the Canadian Food Inspection Agency. Scientific and Technical Review Series: Volume 22 (2): 409-421. 2003

[7] For the purposes of this discussion paper, "Veterinary Services" refers to veterinary public and animal health activities irrespective of the organisational arrangements of competent authorities at the national level.

[8] OIE Animal Production Food Safety Working Group. “Role and functionality of veterinary services in meat hygiene throughout the food chain”. 71st General Session of the OIE. 2003

Risk assessment

In a contemporary veterinary public health and animal health environment, *Veterinary Services* should utilise risk assessment to the greatest extent possible in the development of standards. National competent authorities are facing increased demands for technical expertise to develop domestic standards on this basis, while at the same time endeavouring to meet risk analysis obligations as assumed under international trading agreements.

Risk assessment in meat hygiene

Ante- and post-mortem inspection programmes contribute to designation of meat as being "safe and suitable". However, this is generally only a *qualitative* measure of freedom from hazards to human health. Post-mortem meat inspection cannot ensure freedom from grossly-detectable abnormalities, and sampling programmes for chemical hazards have limited ability to detect randomly-occurring non-complying levels of residues and contaminants. More importantly, some transfer of microbiological contamination from the hide / fleece etc. to the carcass is inevitable in the slaughterhouse environment.

There is only limited scientific evidence linking ante- and post-mortem inspection with measurable outcomes in terms of human health. Additionally, there has been limited progress in tailoring inspection procedures to the spectrum and prevalence of the diseases/defects present in a particular class of slaughtered livestock from a specific geographical region. A risk assessment approach can be used to address these problems and facilitate the proportional allocation of meat hygiene resources according to level of risk[9].

Risk-based approaches to meat-borne risks to human health are also demonstrating that unseen microbiological contamination rather than grossly-apparent abnormalities detected at ante and post-mortem inspection, is the most important source of hazards. This has led to increasing demands for more systematic approaches to combat these hazards e.g. HACCP systems.

Risk assessment in animal health

The OIE *Terrestrial Animal Health Code* contains detailed provisions on import risk analysis. Regionalisation and monitoring of animal health in the exporting country provide important inputs to the risk assessment process. Unlike food safety, animal health risk assessment for control of endemic diseases of animal health importance in a regional environment is not commonly carried out. OIE standards for zoonoses are not based on human health risk assessments *per se*.

OIE defines risk assessment as "the evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a hazard within the territory of an importing country". For many of the standards, it is stated that there is “broad agreement concerning the likely risks”, however, these are not linked to specific decisions on an appropriate level of protection (ALOP). The recently formulated OIE risk analysis process for antimicrobial resistance introduces a risk management framework very similar to that used in food safety[10] (see below).

[9] Hathaway, S. C. (1993). Risk analysis and meat hygiene. OIE Scientific and Technical Review 12 (4): 1265-1290

[10] Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin. OIE Scientific and Technical Review 20: 811-827

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Generic framework for managing public health and animal health risks

Although public and animal health sectors have developed a different history and usage of risk analysis, many aspects are common to all sectors[11]. Application of a generic framework provides a systematic and consistent process for managing biosecurity risks while accommodating different risk assessment methodologies as appropriate. This framework generally consists of four components:

- Preliminary risk management activities
- Assessment of risk management options
- Implementation
- Monitoring and review.

Veterinary involvement in risk assessments

Whatever the biosecurity issue, there should be a strategic, organisational and operational context for veterinary aspects of risk analysis. Appropriate inputs will be required to guide the process, which should be undertaken in a transparent and consistent manner.

Veterinary involvement in risk assessments associated with development of ante- and post-mortem inspection standards is essential. In this respect, the trend toward institutional approaches that bridge the animal and public health sectors / disciplines involved is increasingly apparent at the national level and the traditional focus on regulating individual production systems is shifting to one of ensuring confidence in overall regulatory frameworks at all levels. Further, development of a more unified approach will assist general understanding of risk assessment and the optimisation of scarce technical resources in developing countries.

Establishment of policies and standards

Safety and suitability of meat

Meat hygiene is defined as "all conditions and measures necessary to ensure the safety and suitability of meat at all stages of the food chain"[12]. In the context of meat hygiene, safety is defined in terms of appropriate application of measures to protect public health, and achievement of any quantitative outcomes for hazard control that may be required. Suitability is defined in terms of meat having been produced in a hygienic manner, and meeting any non-safety quantitative standards that may be present.

Development of policies and standards for ante-and post-mortem inspection are predicated by these objectives. Technical justification, practicality and effectiveness of standards rely on veterinary public health inputs, as do establishment of competencies of inspection personnel and training requirements[13]. The national competent authority(s) must also provide an appropriate institutional environment for *Veterinary Services* to develop such policies and standards.

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[11] Hathaway S.C. Risk analysis in biosecurity for food and agriculture. Consultant Report. *In:* Report of the Expert Consultation on Biosecurity in Food and Agriculture. FAO, Rome. September 2002

[12] Draft Code of Hygienic Practice for Meat. ALINORM 04/27/16. FAO, 2004

[13] In the absence of a risk-based approach, inspection standards are prescribed according to long-standing practice: see Appendix I

Standards for ante- and post-mortem inspection of meat include disposition judgements following detection of abnormalities. Judgements must be exercised by personnel who have the appropriate competence if dispositions are to achieve the "safety and suitability" objectives described above. However, sorting and removal of all abnormal tissues from the food chain without recourse to further examination/judgement as to safety or suitability is a practical alternative in many situations. In fact, a conservative policy in regard to disposition of abnormal carcasses and/or viscera is reflected in the precautionary approach inherent in any risk assessment process[14].

Animal health surveillance and monitoring

Animal health surveillance constitutes "continuous investigation of a given population to detect the occurrence of disease for control purposes" and monitoring constitutes "on-going programmes directed at detection of changes in the prevalence of a disease in a given population"[15]. In this context, organoleptic inspection of slaughter animals can provide an important sentinel function for zoonoses and diseases solely of animal health importance. Further diagnostic tests can be applied in the case of suspect animals.

Animal health surveillance and monitoring allow *Veterinary Services* to identify and control significant endemic or exotic diseases within their territory, and substantiate reports on the animal health situation in their country. Both functions provide essential inputs to import risk analysis.

As for meat hygiene, policies and standards applied at ante- and post-mortem inspection for the purposes of animal health surveillance and monitoring should be risk-based and should be feasible and practical in the slaughterhouse environment.

An example of risk-based monitoring of zoonoses is well illustrated in the OIE standard for bovine spongiform encephalopathy (BSE)[16]. It is stated that surveillance strategies “should be determined by, and commensurate with the outcome of risk assessment” and have two primary goals: to determine whether BSE is present in a country, and once it has been detected, monitor development of the epizootic, direct control measures and monitor their effectiveness.

Control of animal health

In some situations, it may be necessary to identify and remove animals or their tissues that have the potential to infect other animals with non-zoonotic diseases via the food chain. This may be via inadvertent exposure to meat that has been passed as fit for human consumption e.g. transmission of exotic diseases by feeding of meat scraps to animals, or via meat with a designated non-human end-use e.g. uncooked petfood.

[14] Where scientific information is uncertain or incomplete, the WTO SPS Agreement provides for precautionary food safety measures to be applied. Routine rejection of tissues with abnormalities at post-mortem inspection without further recourse to detailed organoleptic inspection or tests is one manifestation of a precautionary approach

[15] OIE Terrestrial Animal Health Code

[16] OIE Terrestrial Animal Health Code. Chapter 2.3.13.1. 2002

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Other activities

Increasingly, veterinarians are developing multidisciplinary skills that extend their activities well beyond the farm and initial processing of meat. Also, veterinary activities associated with meat production systems extend beyond public and animal health. Ensuring adequate animal welfare and preventing degradation of the environment by contamination with animal wastes and animal products are two such activities.

Integration of veterinary activities

It is clear that veterinary inputs to ante- and post-mortem inspection achieve a duality of public health and animal health objectives. Irrespective of the jurisdiction of the competent authorities involved, it is obvious that *Veterinary Services* should integrate their activities to the maximum extent possible and practicable so as to prevent duplication of effort and unnecessary costs.

In addition to sharing of routine inspection activities to achieve both public health and animal health objectives, other opportunities that arise are: collection and integration of monitoring data, sharing of diagnostic facilities and methodologies, verification and enforcement of inspection requirements in an integrated manner, and pooling of technical expertise. Additionally, the primary role of industry in ensuring food safety can be better specified, allowing cost-effective structural adjustments in *Veterinary Services*.

Management of public and animal health inspection programmes

Competent Authority

In meeting veterinary public health and animal health objectives prescribed in national legislation or required by importing countries, *Veterinary Services* contribute in various ways "from the direct performance of necessary veterinary tasks to the evaluation of veterinary activities conducted by operators in the agro-industrial chain". It should be noted that "*Veterinary Services*" are no longer the sole managers of animal health protection and disease control, but rather guarantors that all parties involved in food production fulfil their respective obligations to guarantee safe food for the consumer"[17]. To this end *Veterinary Services* fulfil the role of "Competent Authority" and provide assurance both domestically and to trading partners guaranteeing safety standards have been met as well as those pertaining to suitability.

The CCMH recognises that while responsibility for meat hygiene always rests with *Veterinary Services* in the national Competent Authority, "flexibility should be allowed on how the service is delivered e.g. by the competent Authority or by an officially recognised competent body operating under the supervision and control of the Competent Authority"[18].

The OIE *Terrestrial Animal Health Code* ascribes that the quality of *Veterinary Services* can be determined through an evaluation that ensures compliance with principles on professional judgement, independence, impartiality, integrity, objectivity, general organisation, quality policy, procedures/standards, communication, and self-evaluation. Whatever the activity, *Veterinary Services* must be able to demonstrate that no conflict of interest exists between public and/or animal health objectives and economic support for the meat production and processing industry.

[17] Marabelli, R. The role of official Veterinary Services in dealing with new social challenges: animal health and protection, food safety and the environment. Scientific and Technical Review Series: Volumes 22 (2): 363-371. 2003

[18] Report of the 10th Session of the Codex Committee on Meat Hygiene. ALINORM 04/27/16. FAO, Rome

Inputs to ante- and post-mortem inspection activities may also be provided by veterinarians employed by industry e.g. industry-led quality assurance programmes at the level of primary production may involve veterinary supervision and slaughterhouse information servicing. Individual health certification of groups of slaughter animals is a common practice in a number of countries e.g. for zoonotic diseases, veterinary drug residues and vaccination regimes. Veterinary ante-mortem inspection may also be provided at the level of livestock production[19].

Quality systems

Those who benefit from inspection provided by *Veterinary Services* e.g. farmers and meat processing companies, are increasingly committing themselves to quality systems due to demand from their customers[20]. Consequently, these stakeholders are increasingly demanding inspection by competent authorities that is consistent and of high-quality.

In some countries, formal quality assurance procedures are being put in place to assure competence and reliability of *Veterinary Services* on an on-going basis[21]. Creating a quality system is a simple way of implementing the objectives contained in the quality policies that are written by veterinary managers. Tools such as quality accreditation are seen as necessary components of "modern economic management systems"[22].

Quality assurance systems can be extended in the case of ante- and post-mortem inspection to "co-regulatory" systems that integrate industry and *Veterinary Service* activities[23]. In Australia, these systems are based on HACCP principles, are nationally uniform and extend from “production to consumption”. Through a regulatory partnership arrangement, the official *Veterinary Service* is responsible for the broad design of the inspection system and its audits and sanctions, while the industry is responsible for further developing, implementing and maintaining the system. The veterinarian responsible for the specific slaughterhouse ensures that the meat safety quality assurance programme implemented by industry meets regulatory requirements on an on-going basis.

Use of non-veterinary inspection personnel

Use of private or public non-veterinary personnel to carry out ante- and post-mortem inspection activities is well established within many national programmes. However, all ante- and post-mortem inspection arrangements should satisfy the principles of independence, competence of inspectors and impartiality, and must be carried out under the overall supervision and responsibility of the official *Veterinary Services*. The Competent Authority should specify the competency requirements for all persons engaged in inspection and verify the performance of those persons[24]

[19] McKenzie, A. I. and Hathaway S. C. The role of veterinarians in the prevention and management of food-borne diseases, in particular at the level of livestock producers. 70th General Session of OIE. 2002

[20] Gary F. Accreditation of veterinary inspection systems. Scientific and Technical Review Series: Volumes 22 (2): 761-768. 2003

[21] Gerster, F., Guerson, N., Moreau, V., Mulnet, O., Provot, S. and Salabert, C. The implementation of a quality assurance procedure for the Veterinary Services of France. Scientific and Technical Review Series: Volume 22 (2): 629-659. 2003

[22] Marabelli, R. The role of official Veterinary Services in dealing with new social challenges: animal health and protection, food safety and the environment. Scientific and Technical Review Series: Volumes 22 (2): 363-371. 2003

[23] Butler R.J., Murray J.G. and Tidswell S. Quality assurance and meat inspection in Australia. Scientific and Technical Review Series: Volume 22 (2): 629-659. 2003

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Appendix XIII (contd)

Appendix D (contd)

An OIE questionnaire of Member countries identified that personnel other than veterinarians were involved in ante-mortem inspection of poultry and red meat animals in 37% and 31% of countries respectively. Personnel other than veterinarians were involved in post-mortem inspection of poultry and red meat animals in 60% and 59% of countries respectively[25].

Assurance and certification

Assurance and certification of appropriate delivery of inspection and compliance activities[26] is a vital function of *Veterinary Services*. International health certificates providing official assurances for trading of meat must engender full confidence to the country of importation.

Information networks

The SPS Agreement and the standards developed by the CAC and OIE all refer to the need for a systematic process to gather, evaluate and document scientific and other information as the basis for sanitary measures. This has long been recognised by *Veterinary Services* at the national level.

Organisation and dissemination of information throughout the food chain involves multidisciplinary inputs. Effective implementation of risk-based ante- and post-mortem inspection procedures is dependant on on-going monitoring and exchange of information. Animal identification, either as individuals or groups, is necessary in most situations and slaughtered animals should be able to be traced back to their place of origin as appropriate.

Veterinary inputs from primary production and slaughter are especially important to information networks servicing ante- and post-mortem inspection. As an example, it is likely that extrinsic cross-contamination as a result of slaughter, dressing and subsequent processing of meat is by far the most important source of hazards of public health importance. Bioloads of known food-borne pathogens that are transferred in this way are often a reflection of pre-harvest animal husbandry, the health status of the slaughter population, and pre-slaughter handling.

Conformance with WTO obligations

The World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement represents the best efforts of the global community to establish principles and guidelines governing the establishment and implementation of measures to protect public and animal health.

Veterinary Services should ensure that ante-and post-mortem inspection of slaughter is based on an overall assessment, as appropriate to the circumstances, "of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations". Further, inspection procedures utilised in import/export programmes should be comparable to those used in domestic programmes.

In implementing the provisions of the WTO SPS and TBT Agreements, *Veterinary Services* have an increasing role in developing mutual recognition and equivalence agreements with trading partners. A risk-based approach to ante- and post-mortem inspection programmes allows the performance and equivalence of different meat inspection systems to be judged in terms of in meeting animal and public health objectives, thereby mitigating technical barriers to trade.

25 McKenzie, A. I. and Hathaway S. C. The role of veterinarians in the prevention and management of food-borne diseases, in particular at the level of livestock producers. 70th General Session of OIE. 2002

26 Principles for Food Import and Export Inspection and Certification. CAC/GL 20 - 1995. FAO, Rome.

Recommendations

It is recommended that the OIE Animal Production Food Safety Working Group use this discussion paper as a basis for:

1. Agreeing on a work programme to formulate principles and guidelines on the role of *veterinary services* in design and application of systems for ante- and post-mortem inspection of slaughter animals, for establishment as an OIE guideline text.

2. Discussing the usefulness of appending examples of routine ante- and post-mortem inspection programmes for application in situations where risk assessment information is inadequate or unavailable

3. Ensuring that this work is harmonised with guideline texts being developed by other international bodies e.g. Codex Draft Code of Practice on Hygiene of Meat, FAO Manual of Meat Inspection

4. Incorporating linkages to other OIE and Codex texts that describe detailed aspects of possible veterinary inputs e.g. Principles for Food Import and Export Inspection and Certification (CAC/GL 20 - 1995).

Appendix I

Post-mortem inspection procedures

Post-mortem inspection procedures and tests should be established by the competent authority according to a science- and risk-based approach. In the absence of a risk-based system, procedures will have to be based on current scientific knowledge and practice.

Post-mortem inspection procedures based on current knowledge and practice vary considerably in different countries. The procedures that are presented in the following tables are only intended to provide general guidance in meeting public and animal health objectives, and should be adapted by the competent authority as appropriate. In particular:

1) Routine procedures may be supplemented by additional procedures to assist judgement.

2) Young animals are likely to need less intensive inspection than older animals, although some diseases are confined to young animals e.g. omphalophlebitis.

3) In the case of farmed game and farmed game birds, post-mortem inspection procedures established for similar domestic animals may act as a basis for their post-mortem inspection. These may need to be modified as necessary.

4) In the case of killed wild game and wild game birds, post-mortem inspection procedures should reflect the particular circumstances of harvesting and transport to the establishment.

5) Special post-mortem inspection procedures may need to be applied to animals that have reacted to screening tests, e.g., animals which have reacted positively to a tuberculin test should be slaughtered under special hygiene conditions and be subject to more intensive inspection procedures than non-reactor animals.

6) Special post-mortem judgements may need to be applied to animals that have reacted to screening tests, e.g., irrespective of detection of lesions suggestive of infection, the udder, genital tract and blood of animals which have reacted positively to a brucellosis test should be judged as unfit for human consumption.

Table 1: Examples of procedures for routine post-mortem inspection of the head of animals intended for human consumption

	Cattle	Pigs	Sheep/goats	Horses	Deer	Poultry
External surfaces/oral cavity	V	V	V[a]	V	V	—
Submaxillary lymph nodes	V,I[b]	V, I	—	V, P	V, I	—
Parotid lymph nodes	V, I	—	—	V, P	V, I	—
Retrophraryngeal lymph nodes	V, I	—	—	V, P	V, I	—
Tongue	V, P[c]	V	—	V, P	V, P	—
Muscles of mastication	V, P, I[d]	V, P, I	—	—	—	—
Other	—	—	—	—[e]		

V is visual inspection, P is inspection by palpation, I is inspection by incision.

[a] Notwithstanding post-mortem inspection for animal health purposes, the head may be discarded if brains and tongues are not collected for human consumption

[b] Incision of lymph nodes of the head is not necessary in calves

[c] Palpation of the tongue is not necessary in calves

[d] The muscles of mastication should be incised according to the potential for infestation with cysts of *Taenia* pp.

[e] The nasal septum should be removed and examined if glanders is present in the slaughter population

Appendix XIII (contd)

Appendix D (contd)

Table 2: Examples of procedures for routine post-mortem inspection of the carcass of animals intended for human consumption

	Cattle	Pigs	Sheep/goats	Horses	Deer	Poultry
External surfaces	V	V[a]	V	V	V	V
Prescapular lymph nodes	V	—	V	—	V	—
Thoracic cavity/pleura	V	V	V	V	V	V
Abdominal cavity/peritoneum	V	V	V	V	V	V
Superficial inguinal lymph nodes	V, P	—	V, P	V, P	V, P	—
External/internal iliac lymph nodes	V, P	—	V, P	V, P	V	—
Supramammary lymph nodes	V, P[b]	V	V	V	—	—
Pre-pectoral lymph nodes	V, P	—	V, P	V, P	V, P	—
Popliteal lymph nodes	—	—	P	—	—	—
Renal lymph nodes	V, P	V, P	—	V, P	V	—
Diaphragm	V	V[c]	V	V	V	—
Other	—[d]	—	—	—[e]	—	—

V is visual inspection, P is inspection by palpation, I is inspection by incision.

Note: The umbilicus and joints of the limbs should be viewed and palpated in very young animals.

Note: A quality assurance system should be in place to ensure that all thyroid tissue has been removed from the throat.

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[a] Castration sites should be palpated

[b] Supramammary lymph nodes should be incised in lactating animals

[c] The muscles of the diaphragm should be incised according to the potential for infestation with cysts of *Taenia* spp.

[d] The udder should be incised if it is intended for human consumption

[e] The muscles and lymph nodes beneath one of the two scapular cartilages should be examined for melanosis in all grey and white horses

Table 3: Examples of procedures for routine post-mortem inspection of the viscera of animals intended for human consumption

	Cattle	Pigs	Sheep/goats	Horses	Deer	Poultry
Lungs	V, P[a]	V, P	V, P	V, P	V, P	V
Oesophagus	V	V	V	V	V	—
Trachea	V	V	—	V	—	—
Bronchial lymph nodes	V, I[b]	V, P	V, P	V, P	V, I	—
Mediastinal lymph nodes	V, I	V, P	V, P	V, P	V, I	—
Heart	V, P, I[c]	V, P, I[c]	V, P	V, P, I	V, P	V
Pericardium	V	V	V	V	V	V
Liver	V, P	V, P	V, P	V, P	V, P	V
Portal lymph nodes	V, P	V, P	V	V, P	V, P	—
Gall bladder	V, I[d]	—	V, P	—	V, P	—
Kidneys	V	P	V	V[e]	V	V
Renal lymph nodes	V	—	—	—	V	—
Spleen	V	V	V	V	V	—
Gastrointestinal tract	V	V	V	V	V	V
Mesenteric lymph nodes	V, P	V, P	V	V, P	V, P	—
Genital organs[f]	V	V	—	V	V	V

V is visual inspection, P is inspection by palpation, I

[a] Incision of the diaphragmatic lobe can be used to examine the bronchii if lungs are intended for human consumption

[b] Incision of the bronchial and mediastinal lymph nodes is not necessary in calves

[c] The number and location of incisions in the heart muscle should be according to the potential for infestation with cysts of *Taenia* spp.

[d] An alternative to incision of the bile ducts for the deletion of distomatosis is incision through the gastric surface of the liver. Inspection for distomatosis is not necessary in calves

[e] Kidneys should be palpated if intended for human consumption; kidneys of grey or white horses should be incised

[f] Palpation and incision should be carried out as appropriate if tissues are intended for human consumption e.g. uterus of heifers.

Appendix XIV

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English
February 2004

REPORT OF THE SECOND MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

Paris, 26-27 February 2004

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The OIE Working Group on Animal Welfare held its second meeting at OIE Headquarters on 26-27 February 2004.

The members of the Working Group and other participants are listed in Appendix A. The Agenda adopted is given in Appendix B. Dr D. Bayvel chaired the meeting.

On behalf of Dr B. Vallat, Director General of the OIE, Dr D. Wilson, Head of the International Trade Department, welcomed the members of the Working Group and thanked them for agreeing to continue their work on this important mandate of the OIE. He also welcomed Dr D. Wilkins as an observer to the Working Group; Dr Wilkins explained the role of the organisation of which he is secretary, the International Coalition for Farm Animal Welfare (ICFAW). Dr Wilkins regretted that he was only able to participate in the meeting on the first day. Dr Wilson noted that Dr I.M. Reda could not be present due to illness.

1. Animal Welfare Conference

The Working Group strongly believed that the OIE's Global Animal Welfare Conference which had just concluded had achieved its aims, and that the formula of stakeholder participation had been successful. It believed that future conferences should be more narrowly focused and perhaps aligned with particular interests or needs at a regional level.

The Working Group believed that the success of the Conference was in a large part due to the planning of the Steering Committee, and the efforts of the OIE Central Office staff in the organisation and running of the Conference. From its viewpoint, the principal Conference outcomes had been:

- an enhanced understanding of the OIE's mandate, procedures, work to date and aims regarding animal welfare by a diverse group of participants, some of which had never before dealt with the OIE;
- an appreciation of the challenges of animal welfare as a global issue;
- a very strong endorsement of OIE's leadership role in animal welfare;
- the initiation of a positive dialogue.

Appendix XIV (contd)

The Working Group emphasised the need for the OIE to enhance the understanding of Delegates during the General Session of the OIE's animal welfare work. A process has been established and the first steps towards animal welfare guidelines taken, on a continuous improvement basis.

The Working Group made the following comments on the outcomes of syndicate group discussions not involving an existing ad hoc Group:

a) Animal welfare in the veterinary curriculum

- The Working Group recommended that under-graduate veterinary curricula and continuing education programmes include animal welfare and ethics.

- The Working Group recommended that the OIE consult with the World Veterinary Association (WVA) and other international veterinary and scientific associations, to ensure that suitable resource material is made available to Delegates for use in veterinary curricula within Member Countries.

b) Research

- The Working Group encouraged the animal welfare *ad hoc* Groups to identify any research topics needing to be investigated to provide scientific information regarding issues under their consideration.

- The Working Group recommended that the OIE make available to research providers the above topics to encourage funding organisations to support relevant and appropriate research.

c) Animal welfare and international trade

The Working Group recommended that the OIE and the World Trade Organization draft a document clarifying the international legal issues and treaty obligations associated with animal welfare and international trade.

d) Companion animals

- The Working Group recommended that the OIE examine in due course the applicability to companion animals of the guidelines being developed for animals in agriculture and aquaculture.

- The Working Group noted that some Conference participants had highlighted the animal / human health and animal welfare importance of effective stray dog control with particular reference to rabies.

e) Wildlife and animals in research

- The Working Group recommended that the OIE liaise closely with relevant international organisations when developing animal welfare guidelines dealing with wildlife and animals in research.

- The Working Group recommended that the OIE Working Group on Wildlife Diseases consider animal welfare aspects as well as diseases of wildlife in its future work.

f) Communications

- Noting that the Conference had encouraged greater transparency in the OIE's deliberations, the Working Group believed that the OIE may need to examine its communication and decision-making processes to ensure that consultation on animal welfare issues be as efficient as possible; the Working Group recommended that the OIE make public at an earlier stage reports of Working Group and *ad hoc* Group meetings; the Working Group also noted the importance of the OIE publicising upcoming meetings of *ad hoc* Groups to enhance stakeholder input.

- The Working Group recommended that the OIE develop a long-term communication strategy for animal welfare.

- The Working Group recommended that the OIE communicate its long-term animal welfare strategy to enhance stakeholder understanding and participation.

- The Working Group recommended that the OIE develop and advise a single contact point for its animal welfare programme.

- The Working Group recommended that Delegates communicate within their countries on upcoming OIE animal welfare issues and ensure that relevant stakeholders are included in the preparation of country comments on draft guidelines, etc.

- The Working Group recommended that stakeholders keep their Delegates informed on their activities and that all communications with the OIE should involve the relevant Delegate.

- The Working Group noted the need for improved regional awareness of new OIE standards using dialogue with local stakeholders, specialised conferences and Regional Commissions.

- The Working Group recommended that the OIE forge a strong relationship with key international scientific organisations, e.g. the International Society for Applied Ethology (ISAE), the International Society for Animal Hygiene (ISAH).

2. Reports of *ad hoc* Group meetings

The Working Group recalled that the reports of the 2003 meetings of the four animal welfare *ad hoc* Groups had been circulated to Working Group members for comment, prior to being submitted to the Code Commission. The Code Commission had endorsed the reports at its December 2003 meeting and circulated them for the comment of Member Countries. The Working Group commended the four *ad hoc* Groups on their excellent work to date.

The Working Group reiterated the importance of aquatic animal welfare being addressed as a matter of priority, through an *ad hoc* Group being assembled to address rearing, transport and slaughter issues for aquatic animals.

The Working Group then discussed each of the reports in the light of the outcomes of the Conference and made proposals for the *ad hoc* Groups to consider at their next meetings:

a) General

- The Working Group noted the need for harmonised definitions and recommended that the chairs of all the *ad hoc* Groups work towards a single list for inclusion in the *Terrestrial Code*.

- The Working Group strongly supported the principle that animal handlers be competent and that training of such operators was an important factor in animal welfare, and recommended that more specific requirements for competence be written through coordination with AATA/IATA.

- The Working Group recommended that expertise on specific issues be added to the OIE expertise database for use by *ad* hoc Groups and by Member Countries.

b) Slaughter for human consumption

The Working Group noted that the *ad hoc* Group had considered the important issue of religious slaughter and that it had recognised that the guiding principles applied equally to religious slaughter; the Working Group encouraged the *ad hoc* Group to continue to develop specific guidelines to address the issue.

c) Killing for disease control purposes

- The Working Group supported the decision of the *ad hoc* Group that procedures requiring specific commercial equipment should not be included in OIE guidelines; references to such procedures could be made.
- The Working Group noted the importance of the testing and updating of national contingency plans.

d) Land and sea transport

- The Working Group encouraged the *ad hoc* Groups to more tightly specify fitness to travel issues (including pregnancy considerations).
- The Working Group recommended that the issue of 'roll-on-roll-off' transport be further addressed, especially with regard to the duration of a journey.

3. Generic guiding principles on animal welfare

The Working Group considered again its generic guiding principles proposed for adoption at the General Session, and supported their adoption.

The Working Group considered that the Article on the scientific basis for guidelines contained some inconsistencies and redundancies, and could be strengthened; it agreed a revised text for this article which would be submitted for adoption. The Working Group considered that the ethical basis for guidelines was adequately covered in the *Terrestrial Code* and in the generic guiding principles, and that this specific text could be deleted. The revised text is at Appendix C.

4. Aquaculture animal welfare

The Working Group discussed a work programme for aquaculture animal welfare and how best it could be implemented. It considered that an *ad hoc* Group or Groups should be set up specifically to address aquaculture animal welfare, rather than for aquaculture to be added to the scope of the work of existing *ad hoc* Groups; the Working Group supported this approach.

It was decided that Professor Hastein would propose to the other members terms of reference to cover production, transport and slaughter issues for freshwater, saltwater and ornamental fish, and appropriate membership of the ad hoc Group(s).

5. Other business

The Working Group discussed its future membership needs. It noted positively the establishment of an international coalition of animal welfare organisations, ICFAW. It welcomed the participation of Dr Wilkins as an observer, due to the expertise he brought to its discussions and his demonstrated ability to communicate with a broad range of animal welfare NGOs. It recommended to the Director General that he become a full member of the Working Group.

The Working Group is also seeking direct participation of an expert drawn from animal industries with expertise in animal transport, production and slaughter, and with good communication networks with such industries. The Working Group asked the Director General to write to relevant international organisations, seeking the names of possible experts.

The Working Group asked the Director General to seek a candidate to succeed Dr Reda.

As items of interest, information and general relevance, of the working group briefly discussed the following:

- status of proposed UN Declaration on Animal Welfare

- interest shown by International Finance Corporation / Word Bank Group in animal welfare guidelines and standards
- upcoming conferences in the Netherlands (2004), UK (CIWF in 2005) and USA (WVA/AVMA in 2005)
- current scientific interest in acute phase proteins as clinical indicators of animal disease or compromised animal welfare
- FAO interest in animal welfare in relation to Good Agricultural Practice.

The OIE Publications Department confirmed its interest in publishing a review entitled 'Animal Welfare: Global Challenges, Issues and Trends'. A Working Group sub-committee was established to scope and draft a project plan in respect of the OIE's proposal.

The Working Group agreed to ask the OIE to respond formally to Joyce D'Silva, Chief Executive of Compassion in World Farming, referring to the CIWF letter writing campaign supporting the conference and clarifying the issues in respect of the reference to intensive production systems in the OIE review.

6. **Work programme**

On the basis of the above discussion, the Working Group reviewed progress against the current work programme (Appendix D) and agreed a work programme for 2004/2005 (Appendix E).

7. Next meeting

The Working Group agreed to meet again in about 12 months time to review progress, and formulate the 2005/2006 work programme.

Appendix XIV (contd)

Appendix A

SECOND MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

Paris, 26-27 February 2004

List of participants

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Appendix XIV (contd)

Appendix A (contd)

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Appendix XIV (contd)

Appendix B

SECOND MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

Paris, 26-27 February 2004

Agenda

1. Introduction
2. Review of 2003 OIE activities on animal welfare
   - Reports from OIE Ad hoc Group meetings
3. Generic guiding principles on Animal Welfare (for adoption)
4. Outcomes from the Global OIE Conference on Animal Welfare
5. Operational Plan for 2004
   - Priorities for *ad hoc* Groups
   - OIE Revue Scientifique et Technique
   - Consultation issues
6. Other Business
   - WSPA UN declaration
   - WVA conference planning 2005 USA
   - WG Membership
7. Agreed actions
8. Next meeting

Appendix C

SCIENTIFIC BASIS FOR GUIDELINES

1. Welfare is a broad term which includes the many elements that contribute to an animal's quality of life, including those referred to in the 'five freedoms' listed above.

2. The scientific assessment of animal welfare has progressed rapidly in recent years and forms the basis of these guidelines.

3. Some measures of animal welfare involve assessing the degree of impaired functioning associated with injury, disease, and malnutrition. Other measures provide information on animals' needs and affective states such as hunger, pain and fear, often by measuring the strength of animals' preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that animals show in response to various challenges.

4. Such measures can lead to criteria and indicators that help to evaluate how different methods of managing animals influence their welfare.

Appendix XIV (contd)

Appendix D

Animal Welfare Working Group 2003 work programme

	Decisions of Working Group	Implementation	Status at February 2004
Mission, guiding principles and policies	OIE process for adoption by International Committee	Working Group members to comment within 4 weeks, then OIE to include in Code Commission report	Mission and policies accepted by Member Countries in May 2003; guiding principles for adoption at May 2004 General Session
Standards and guidelines	Proposed order of work 1. Transport by land 2. Killing for disease control (as per scope) 3. Humane slaughter (as per scope) 4. Transport by sea.	 2003 2003 2004 2004	All four *ad hoc* Groups met during 2003; meeting reports have been circulated to Member Countries for comment, via Working Group and Code Commission
Expertise database	Identification of possible expertise (centres of expertise and individual experts)	Initial information from Working Group members by mid-November 2002	Database in existence, but data inadequate to date
Animal welfare conference	Initial proposals from Drs Gavinelli, Rahman and Fraser re format, participants, outcomes . to include academia, research, funding, collaboration	Proposals to OIE by mid-December 2002 Conference planned for second half 2003	OIE Global Animal Welfare Conference 23-25 February 2004
Presentation at OIE General Session	Paper by member of Working Group and questions from Member Country delegates	May 2003	Chair of Working Group presented paper on Working Group activities

Appendix XIV (contd)

Appendix D (contd)

Animal Welfare Working Group 2003 work programme (contd)

	Decisions of Working Group	Implementation	Status at February 2004
Improved animal welfare awareness in teaching	Drs Bayvel, Masiga and Fraser to draft letter from OIE for veterinary schools; coordinate with WVA activities	February 2003	Inadequate progress due to lack of resources at the OIE
Animal welfare research initiative	Drs Bayvel, Masiga and Fraser to provide input into conference programme (Dr Gavinelli) and text for OIE Web site, re research initiatives and associated funding needs	February 2003	Inadequate progress due to lack of resources at the OIE
Collaboration among academic and research institutions	Dr Fraser to provide input into conference programme (Dr Gavinelli)	February 2003	Completed
Communications plan	Working Group members to take up opportunities for publishing information articles in appropriate journals, Web pages and newsletters; Working Group members to utilise OIE Regional conferences, and other relevant conferences; OIE to develop slide show for Working Group members and other speaker use; Working Group members to provide stakeholder list for circulation of OIE information; Relationship with other international organisations involved in animal welfare activities to be communicated by OIE	Continuing Continuing mid November 2002 mid December 2002 mid December 2002	Completed Reports on OIE activities presented Slide show developed, and used by members Some progress, further work required Progress during conference; work to continue
Future activities / emerging issues	Aquaculture animal welfare Animal biotechnology	Report from Professor Tore Hastein for next meeting; Summary paper and perhaps presentation at 2003 conference	Prof Hastein gave presentation at Conference No progress as low priority

Appendix XIV (contd)

Appendix E

Animal Welfare Working Group 2004/2005 work programme

	Decisions of Working Group	**Implementation**	**Status at February 2004**
Guiding principles	To be submitted for adoption by International Committee	To revise text on 'scientific basis for guidelines' by end April (Fraser)	
Development of guidelines	Priorities identified 1. Transport by land (including by rail) 2. Transport by sea 3. Humane slaughter for human consumption 4. Killing for disease control 5. Aquaculture animal welfare 6. Transport by air	 continue, with second meeting during 2004 continue, with second meeting during 2004 continue, with second meeting during 2004 continue, with second meeting during 2004 Terms of reference to cover: - production, transport and slaughter - freshwater, saltwater and ornamental fish and appropriate membership, by May 2004 (Hastein) Liaison with IATA to continue; OIE to ensure that pre- and post-flight issues are addressed (Fraser)	
Expertise database	Identification of possible expertise (centres of expertise and individual experts)	Continuing (all)	
Presentation at OIE General Session	Chair of Working Group to present paper and respond to questions from Member Country delegates	May 2004 (Bayvel)	
Improved animal welfare awareness in veterinary curriculum and CPD	Coordinate with WVA / CVA activities	Continuing (Rahman)	

Appendix XIV (contd)

Appendix E (contd)

Animal Welfare Working Group 2004/2005 work programme (contd)

	Decisions of Working Group	Implementation	Status at February 2004
Collaboration among academic and research institutions re animal welfare research	to contact ISAE and ISAH re collaboration	continuing (Fraser) (Gavinelli)	Collaboration among academic and research institutions re animal welfare research
Communications plan	Working Group members to take up opportunities for publishing information articles in appropriate journals, Web pages and newsletters Working Group members to utilise OIE Regional conferences, and other relevant conferences OIE to develop animal welfare CD-ROM for Working Group members and Delegate use OIE and the WTO to draft a document clarifying the international legal issues associated with animal welfare and international trade To liaise with CIWF re March 2005 conference re speaker opportunity To liaise with governments and international organisations re animal welfare topics at upcoming conferences: - Netherlands conference, December 2004 - WVA conference, July 2005 Working Group members to provide stakeholder information for use by OIE	Continuing (All) Continuing (All) end 2004 (Maria Zampaglione) end April (Thiermann) (Bayvel) Continuing (All) (Gavinelli) (Bayvel) (All)	
OIE *Revue Scientifique et Technique*	Request to coordinate mid-2005 edition on animal welfare	(Bayvel, Rahman, Gavinelli)	
Membership	Member drawn from animal industries with an interest in animal transport, production and slaughter.	Director General to write to relevant international organisations	

Appendix XV

Future work programme for the Terrestrial Animal Health Standards Commission

Topic	Action	How to be managed
Traceability	The OIE requests Member Countries to submit proposals and draft texts which could form the basis of guidelines.	The Animal Production Food Safety Working Group has listed this topic as a priority.
Zoning/regionalisation and compartmentalisation	The OIE has been requested to develop guidelines to aid Member Countries in the implementation of these concepts.	The Code Commission will examine submitted proposals.
Reorganisation of *Terrestrial Code*	In view of the new single disease list and the development of new chapters in Part 1 of the *Terrestrial Code*, the Bureau of the Code Commission requested the Central Bureau to submit revised contents pages for the January 2005 meeting.	The Central Bureau will draft.
Paratuberculosis	A revised draft chapter on paratuberculosis, developed by an expert in consultation with others, was discussed with the Scientific Commission in December 2003. The Scientific Commission made no specific comments but recommended that the zoonotic potential of this disease be addressed through collaboration with the WHO.	The Code Commission will circulate the revised draft for the comment of Member Countries when it has received appropriate technical review from the Scientific Commission.
Anthrax	To develop an appendix on the inactivation of the bacillary and spore forms of *Bacillus anthracis.*	The Central Bureau will contact experts, utilising the scientific data underlying proposals made to the International Committee in 2002.
Semen and embryos	To harmonise the semen and embryo chapters.	Experts are working on the chapter on small ruminant semen to harmonise it with the chapter on bovine semen, with the ultimate intention of having a single semen chapter.
***Terrestrial Code* texts in need of revision**	To revise certain chapters and appendices, including swine vesicular disease, African swine fever, equine infectious anaemia.	
	Salmonellosis, cysticercosis, bovine brucellosis.	The Animal Production Food Safety Working Group has listed these topics as priorities.