UNION EUROPEENNE

SANCO

19. 06. 2006

Bruxelles, le
D(2006) 411181 HLB

Subject : **General session of the OIE May 2006**

Dear Director General,

Please find attached annex A indicating the position of the Community including written comments on the report of the Terrestrial Animal Health Standards Commission raised at the General Session in May 2006 in Paris which I understand will be taken on board during the next meeting of the Terrestrial Code Commission.

In addition our comments on a number of Chapters of the diagnostic manual proposals are enclosed at annex B for the next meeting of the Biological Standards Commission including comments on the list of veterinary critical important antimicrobials

The Community comments for the next meeting of Aquaculture Code Commission will follow later.

I trust you will find this useful.

Thank you for your continued cooperation and I am very pleased that the OIE Annual General Session went so well.

Kind regards

Ulrich Herzog
Chief Veterinary Officer

Paola Testori-Coggi
Acting Deputy Director General

Annex: 1

Copy: All Directors/Chief Veterinary Officers of the Community and Bulgaria, Croatia, FYROM, Iceland, Norway, Romania, Switzerland and Turkey.

Dr. B. Vallat
Directeur général OIE
12 rue de Prony
F-75017 Paris

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 1.6.2006
SANCO/10264 Rev 4 Animal Health
SEC (2006) 634 FINAL

COMMISSION STAFF WORKING DOCUMENT

Position and written comments of the Community on the OIE Terrestrial Animal Health Code and Diagnostic Manual to be submitted for adoption and consideration in the 74th General Session to be held in May 2006

ANNEX A

74th General Session International Committee
World organisation for animal health Paris, 21-26 May 2006

74 SG/12/CS1 B

Original: English
March 2006

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

Paris, 6-10 March 2006

———

The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission) met at the OIE Headquarters in Paris from 6 to 10 March 2006.

The members of the Terrestrial Code Commission and other participants in the meeting are listed in Appendix I. The agenda adopted is given in Appendix II.

The Director-General of the OIE, Dr B. Vallat, welcomed the members of the Terrestrial Code Commission and discussed with them the most important issues which they needed to address as a result of commitments made by the OIE President during the 2005 General Session. Dr Vallat noted the large number of responses from Member Countries to the proposals made at the September 2005 meeting of the Terrestrial Code Commission and he strongly encouraged Member Countries to participate in the development of the OIE's international standards by sending comments as specific proposed text changes, supported by a scientific rationale.

On compartmentalisation, he recalled the request from Member Countries for guidance on the application of compartmentalisation against specific diseases. Dr Vallat also noted the current discussions in the Sanitary and Phytosanitary Committee (SPS Committee) of the World Trade Organization (WTO) on regionalisation (zoning and compartmentalisation) and the requests from delegates there for the OIE to provide more detailed guidance. He asked the Terrestrial Code Commission to examine the concept paper on compartmentalisation which had been drafted by the Scientific Commission for Animal Diseases (hereafter referred to as the Scientific Commission) to see which parts could be included in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*).

Dr Vallat raised the problems associated with the notification of avian influenza in wild birds. He asked the Terrestrial Code Commission to discuss with Dr K. Ben Jebara ways to improve the notification of avian influenza in wild birds without unjustified trade restrictions being placed on Member Countries.

Finally, Dr Vallat noted the obligation on the OIE to present for adoption in May 2006 improved chapters on the evaluation of veterinary services (VS) to assist Member Countries' assessments of their compliance with the OIE standards, using the *Performance, Vision and Strategy* [PVS] *Instrument*. He said that the role of the OIE was also to designate international experts to facilitate the process. Several key donors (such as the World Bank) considered the OIE proposal to support the veterinary services of developing and in-transition countries on the basis of assessment, endorsed by the OIE, for their compliance with OIE standards on the quality of veterinary services.

The Terrestrial Code Commission recognised the contribution of the following Member Countries in providing comments: Argentina, Australia, Canada, Chile, the European Union (EU), Guatemala, Japan, New Zealand, Republic of Korea, South Africa, Sudan, Switzerland, Thailand and the United States of America (USA).

The Terrestrial Code Commission examined various *Terrestrial Code* texts from its September 2005 report in the light of Member Countries' comments. The outcome of the Terrestrial Code Commission's work is presented as appendices to the September 2005 report and to this report. Additions made during the September 2005 meeting are shown as double underlined text, with deleted text in strikeout, and those made at this meeting (March 2006) in a similar fashion but with a coloured background to distinguish the two groups of proposals.

The following texts are proposed for adoption. The texts are included in full in the September 2005 report of the Terrestrial Code Commission; articles modified at the March 2006 meeting are presented in appendices in Part A of this report. Both reports will be in the Delegates' folders for the 74th General Session.

Issue	**Appendix number in the September 2005 report**	**Appendix number in the March 2006 report**
General definitions (Ch. 1.1.1.)	Appendix III	Appendix III
Evaluation of Veterinary Services (Ch. 1.3.3.)	Appendix IV	Appendix IV
Guidelines for Evaluation of Veterinary Services (Ch. 1.3.4.)	Appendix V	Appendix V
Zoning and compartmentalisation (Ch. 1.3.5.)	not relevant	Appendix VII
Criteria for listing diseases (Ch. 2.1.1.)	not relevant	Appendix VIII
Foot and mouth disease (Ch. 2.2.10.)	Appendix IX	Appendix IX
Foot and mouth disease surveillance (App. 3.8.7.)	Appendix X	Appendix X (blank)
Bluetongue (Ch. 2.2.13.)	Appendix XI	Appendix XI (blank)

Bovine spongiform encephalopathy (Ch. 2.3.13.)	not relevant	Appendix XIII
Bovine spongiform encephalopathy surveillance (App. 3.8.4.)	Appendix XIV	Appendix XIV
Classical swine fever (Ch. 2.6.7.)	Appendix XV	Appendix XV
Avian influenza (Ch. 2.7.12.)	Appendix XVI	Appendix XVI
Avian influenza surveillance (App. 3.8.9.)	Appendix XVII	Appendix XVII (blank)
Avian influenza virus inactivation guidelines	not relevant	Appendix XVIII
Bovine and small ruminant semen (App. 3.2.1.)	Appendix XIX	Appendix XIX
Animal welfare–sea transport (App. 3.7.2.)	Appendix XX	Appendix XX
Animal welfare–land transport (App.3.7.3.)	Appendix XXI	Appendix XXI
Animal welfare–slaughter of animals (App. 3.7.5.)	Appendix XXII	Appendix XXII
Animal welfare–killing for disease control (App. 3.7.6.)	Appendix XXIII	Appendix XXIII
Ante- and post-mortem inspection	not relevant	Appendix XXIV
Animal identification and traceability	not relevant	Appendix XXV
Equine infectious anaemia (Ch. 2.5.4.)	Appendix XXVI	Appendix XXVI
Equine piroplasmosis (Ch. 2.5.6.)	Appendix XXVII	Appendix XXVII (blank)
Equine rhinopneumonitis (Ch. 2.5.7.)	Appendix XXVIII	Appendix XXVIII (blank)
Glanders (Ch. 2.5.8.)	Appendix XXIX	Appendix XXIX (blank)
Disposal of dead animals	no proposal	Appendix XXX

The following texts are presented in Part B of this report for Member Countries' comment:

Bovine spongiform encephalopathy risk assessment recommendations (Appendix 3.8.5.) at Appendix XXXI;

Bovine brucellosis (Chapter 2.3.1.) at Appendix XXXII;

Equine influenza (Chapter 2.5.5.) at Appendix XXXIII;

International transfer of pathogens (Chapter 1.4.5.) at Appendix XXXIV;

Guidelines for traceability at Appendix XXXV.

Further comments on the *Terrestrial Code* texts need to reach the OIE Headquarters by 25 August 2006 in order to be considered at the September 2005 meeting of the Terrestrial Code Commission.

A. TEXTS WHICH ARE SUBMITTED FOR ADOPTION

1. General definitions (Chapter 1.1.1.)

The Terrestrial Code Commission reviewed Member Countries' comments on various animal welfare definitions, and made appropriate changes. The modifications to the text in the September 2005 report are at Appendix III.

Community position:
The European Community can support this proposal but has communicated written comments on some particular issues which are incorporated in the Appendix and as certain Community amendments initially proposed in September were not taken into account and the Community would like to confirm that it maintains its comments previously communicated to the OIE on 15 February 2006. The European Community hopes that all those comments included will be considered later by the relevant OIE Working Group.

2. Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4.)

The Terrestrial Code Commission reviewed Member Countries' comments on the changes proposed in the September 2005 report.

Member Countries expressed concern at the apparent need to use the PVS *Instrument* to conduct evaluations. The Terrestrial Code Commission addressed these concerns in its revision of Articles 1.3.3.5, 1.3.4.1 and 1.3.4.2 by clarifying that the PVS *Instrument* could be used in self-evaluations, bilateral evaluations and in third party evaluation. The Terrestrial Code Commission also clarified the role of OIE experts in facilitating these evaluations.

The modifications to the text in the September 2005 report are at Appendices IV and V.

Community position:
The Community can support these proposals as it believes that these are very useful tools and will help in generating confidence between veterinary services. The Community would like to take the opportunity to point out that it is not clear

how the conclusions of the experts(s) would bind the OIE (and thereby the member countries) and would it have any official status. It would like to know if it's the intention of the OIE to incorporate the Performance, Vision and Strategy document in the code and what exactly is the status of the PVS document if it is not incorporated in the code.

3. Zoning and compartmentalisation (Chapter 1.3.5.)

The Terrestrial Code Commission reviewed Member Countries' comments and made appropriate changes to the chapter. The modifications to the text in the September 2005 report are at Appendix VII.

The Terrestrial Code Commission took note of a submission from the EU and recent discussions in the WTO SPS Committee, but was of the view that the chapter should provide general guidance to Member Countries without prescribing time limits for decision-making. The time taken by trading partners to define and recognise zones and compartments would depend in part on the epidemiology of the disease (which is addressed in the specific disease chapters in the *Terrestrial Code*) and on national administrative arrangements. The Terrestrial Code Commission did not believe that such administrative arrangements were part of the scope of the *Terrestrial Code*.

In response to a question from South Africa, the Terrestrial Code Commission was of the view that, other than for the diseases for which OIE official recognition of freedom may be given, the acceptance of a claim for freedom of a country, zone or compartment from a particular disease was a matter for bilateral negotiation.

The Terrestrial Code Commission was also of the view that, rather than an enterprise developing new management layers, the process of compartmentalisation should adopt as much as possible existing management procedures associated with biosecurity, but enhancing these as necessary to address the epidemiology of the disease of concern. The Terrestrial Code Commission noted that a paper was being developed at the OIE Headquarters on practical biosecurity guidelines for avian influenza, some of which may be incorporated into the *Terrestrial Code* as soon as possible.

The Terrestrial Code Commission indicated that it would examine the concept paper on compartmentalisation (Appendix III-B of the Scientific Commission report of January 2006) with a view to incorporating relevant parts in a revised chapter on zoning and compartmentalisation.

Community position:

The Community supports this proposal but has some comments incorporated in the Appendix which it would like reviewed during the next meeting of the Code Commission for possible inclusion in the Chapter. However it would like to point out that there appears there are differences of opinion in interpreting a zone. Some member countries appear to believe that one can only have a free zone however this is not true as one can have an infected zone and the rest of the country free; trade can take place from the rest

of the country. It all depends on if one is eradicating a disease or if there has been a disease incursion. The Community would strongly suggest that this is better clarified in the text. Furthermore problems are continually being raised in Geneva concerning the implementation of this Chapter and the Community requests that the OIE liaise with the WTO SPS to ensure that any administrative guidelines on regionalisation produced there are compatible with the OIE Code Chapter and do not encroach on the technical responsibilities of the OIE. It is very important for trade that member countries regionalise without unnecessary delay. If the procedures take longer than the time scales in the OIE code for regaining the status of the country then nothing is gained. In this context the Community would ask the OIE to consider expanding official OIE recognition to other diseases, as was done for BSE, and to take into account particular disease problems in wildlife.

4. Criteria for listing diseases (Chapter 2.1.1.)

The Terrestrial Code Commission met with Dr K. Ben Jebara, Head of the Animal Health Information Department.

Dr Ben Jebara summarised the work of an *ad hoc* Group on diseases/pathogenic agent notification (chaired by Prof. A. Shimshony) which had considered Member Countries' submissions on the criteria and the list of diseases, and had made appropriate modifications to them. The report of the *ad hoc* Group is at Appendix XXXVI (Part C of this report).

Dr Ben Jebara also proposed some changes to the decision tree in Articles 2.1.1.1. and 2.1.1.2 in relation to emerging diseases.

The recommendation of the *ad hoc* Group regarding the reference to avian influenza in the list of diseases was modified to address the importance of Member Countries notifying findings in wild birds.

These changes were endorsed by the Terrestrial Code Commission and the modifications to the text in the September 2005 report are at Appendix VIII.

Community position:
The Community supports this proposal but points out one spelling mistake in the Chapter where Wildebeest is incorrectly spelt.

In addition the Community also appreciates that highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry will be included in the OIE disease list and that all members will need to report these outbreaks starting from the end of the General Session.

5. Foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7)

The Terrestrial Code Commission received from the Scientific Commission its conclusions on Member Countries' comments received during 2005, and modified Article 2.2.10.9, accordingly. The modifications to the text in the September 2005 report are at Appendix IX.

Regarding a comment from Canada which applied to text in several places in the chapter and the appendix, the Terrestrial Code Commission recalled that the term 'virus circulation' rather than 'infection' had been adopted because 'infection' was extremely difficult, if not impossible, to detect if vaccination is practised.

Considering the nature of the comments from Member Countries, the Terrestrial Code Commission decided to forward all comments to the Scientific Commission for further examination, and will await recommendations from the Scientific Commission before further modifying the text.

As the Terrestrial Code Commission had accepted the recommendation from the Scientific Commission to delete the references to compartmentalisation, the appendix on surveillance is presented for adoption unchanged (Appendix X of the September 2005 report).

Community position:
The Community can support these proposals but would like the minor inconsistencies incorporated in the Appendix taken on board. In addition it would like to point out that it is still very concerned about the requirements in Article 2.2.10.20 as it believes the risk of importing bone in meat from an area which is free of FMD with vaccination may be too high. The recent outbreaks tend to highlight this problem as there have been some confirmed outbreaks and in addition some suspicions with clinical signs but no virus isolation in certain vaccinated areas. The Community fully supports the guidelines for surveillance as it believes the use of compartmentalisation for FMD is too high a risk to accept at this time and points out that this is in line with the advice from the Scientific Commission.

6. Bluetongue (Chapter 2.2.13.)

The Terrestrial Code Commission noted a comment from the USA questioning the terms 'likely to be competent' as applied to *Culicoides* spp. The Terrestrial Code Commission decided to retain the terms as it took account of the rapidly changing information on the competence of certain species of such vectors, and provided a conservative approach.

The chapter is presented for adoption unchanged (Appendix XI of the September 2005 report).

The Terrestrial Code Commission noted that an *ad hoc* Group under the Scientific Commission will be examining in the near future Member Countries' comments on the bluetongue surveillance appendix.

Community position:
The Community supports this proposal however it would still like to draw the attention of the OIE to its request in Article 2.2.13.8 concerning the Community request that it would like the OIE to reassess this 60 day period in the light of data which could become available in the future on newly developed inactivated BT vaccines and of its other comments incorporated in the Appendix.

For the Surveillance Chapter the Community supports this proposal but would like to suggest that sentinel animals must be individually identified.

7. Bovine spongiform encephalopathy (Chapter 2.3.13, and Appendices 3.8.4. and 3.8.5.)

The Terrestrial Code Commission recognised the positive contributions made by Member Countries and four regional gelatine manufacturers' organisations in their comments on the chapter on bovine spongiform encephalopathy (BSE) and on the appendix on BSE surveillance.

The Terrestrial Code Commission agreed with the revisions proposed and the justifications provided by the *ad hoc* Group on BSE. The report of the January 2006 meeting of the *ad hoc* Group is at Appendix XXXVII (Part C of this report).

However, the Terrestrial Code Commission noted with concern that once again some Member Countries' comments on the BSE text seemed to have been formulated without regard to the science-based approach promoted by the OIE. Submissions requesting the re-opening of issues that have been discussed and adopted need to be supported by relevant new scientific information.

The Terrestrial Code Commission also noted the significant work of the informal *ad hoc* Group led by the Secretary General of the Terrestrial Code Commission in aligning the guidelines on risk assessment for BSE (Appendix 3.8.5.) with the revised BSE chapter. See Part B of this report for further details.

Community position:
The Community is very pleased and wants to thank the Terrestrial Animal Health Standards Commission with the progress made related to BSE Chapter and the Appendix on surveillance.

In relation to the BSE Chapter the Community welcomes the position of OIE to keep the 30 months age limit for boneless beef as tradable product and to await the outcome of further research on this issue. The Community also welcomes the intention of the OIE to further examine the risks in countries of "negligible BSE risk" associated with animals born before the full implementation of the risk reducing measures. It is the Community's position that this should be addressed at the latest when a Resolution will be adopted to categorise countries in this risk category. The Community supports the improvement of the surveillance Appendix requiring testing all clinical suspects in addition to animals of other risk groups.

In summary the Community can support the current proposal but would like to highlight three important issues within this Chapter.

Firstly based on the experience within EU in relation to the implementation of the feed ban and the problems linked to cross contamination the Community would like the OIE to reconsider expanding the ruminant to ruminant feed ban and to a mammalian to mammalian feed ban.

Secondly on gelatine and collagen concerning Article 2.3.13.14. the Community can support the OIE proposal. Nevertheless the Community recommends that the OIE

examine in more detail the different processes used in the production of collagen and gelatine and proposes that the OIE lays down much more detailed requirements for the safe processing of these products. The Community has indicated certain process requirements in its submission to the OIE.

The last but very important topic linked to the categorisation of countries according to their BSE risk. OIE as the World Organisation for Animal Health should play a leading role in this process. In saying that, the process should be carried out in full transparency in order to allow the Member countries to evaluate the work done at OIE level in this respect. The Community welcomes the preparatory work done by the OIE in order to launch the classification procedure and is ready to share its experience with the former Geographical risk assessment process.

To conclude the Community can support the current proposal but encourages the OIE to consider the comments made in particular in relation to the feed ban, the production standards for the gelatine production and urges a prompt and transparent classification progress which needs to be achieved by the next AGS in 2007.

a) Chapter 2.3.13.

The Terrestrial Code Commission agreed with the recommendation of the *ad hoc* Group on BSE regarding Article 2.3.13.1.

Regarding gelatine, the Terrestrial Code Commission took into account comments from Canada, the recommendations of the *ad hoc* Group and information referred to in the New Zealand submission. The Terrestrial Code Commission decided to include the recommendations from the *ad hoc* Group regarding Article 2.3.13.14. Information referred to by four regional gelatine manufacturers' associations will be examined by BSE experts before the September 2006 meeting of the Terrestrial Code Commission.

In response to a comment from Canada regarding the rare reports of BSE in small ruminants, the Terrestrial Code Commission was of the view that it was unlikely that countries would have BSE in their small ruminant population without it manifesting in the indicator species, namely cattle. No change was proposed to the chapter in this regard.

Several Member Countries commented on the release assessment referred to in Article 2.3.13.2. The Terrestrial Code Commission decided to replace the current text with that developed by the experts who had been working on the revision of Appendix 3.8.5.

The EU comments on point 2 of Article 2.3.13.3. in which the EU proposed to maintain the higher intensity surveillance (Type A) in countries reporting indigenous cases were not accepted by the Terrestrial Code Commission. The opinion of the ad hoc group for BSE surveillance was that, once target points had been reached through Type A surveillance, the country could switch to Type B surveillance, regardless of the prevalence of BSE. The Terrestrial Code Commission considered that given the long incubation period of BSE, the number of cases, which reflected situation in the distant past, was not as important as the implementation of mitigation

measures. Consequently, the expenditure of resources on testing more samples was considered to be less valuable than verifying that mitigation measures were currently being strictly enforced.

The Terrestrial Code Commission noted that some concerns had been raised in relation to the need to further clarify the BSE status of countries in the process of upgrading their status from 'controlled risk' to 'negligible risk'. It was considered self-evident that, if a country had qualified for 'controlled risk' but had not yet met the criteria for a country with 'negligible risk', the country would retain its 'controlled risk' status and would not regress into the status of a country with 'undetermined risk'.

In response to Member Countries' comments on point 3 b) of Article 2.3.13.3., the Terrestrial Code Commission agreed that the date of birth of the indigenous case rather than the date of reporting of the case was preferable as the reference date. However, after considering comments from Japan and Argentina, and some quantitative data supplied by the EU, the Code Commission extended the time period from 8 years to 11 years.

Regarding point 3 b) iii) of Article 2.3.13.3, in response to comments from Member Countries requesting the scientific bases justifying the deletion of the reference to the progeny of female cases, the Terrestrial Code Commission recalled that this issue had been reviewed by the *ad hoc* Group on BSE (at its meeting in January 2006). The Terrestrial Code Commission considered the deletion to be appropriate as animals born to female cases were not necessarily exposed to the BSE agent and were not considered to present a higher risk than the general population. It noted that the increased risk associated with progeny which had been exposed to the BSE agent was appropriately addressed.

Comments from the EU on Articles 2.3.13.6., 2.3.13.9. and 2.3.13.12. concerning the risks in 'negligible risk' countries associated with animals born before the full implementation of the measures, will be sent to the *ad hoc* Group on BSE for further examination.

A request from the EU to modify Article 2.3.13.10. to exclude mechanically separated meat from all bones was not adopted because ensuring the correct sourcing was considered to be a matter of management, rather than science.

A request from the EU regarding fresh meat and meat products from cattle in Article 2.3.13.11. was not adopted as the Terrestrial Code Commission did not see any scientific justification to question the safety of those commodities from a country, *zone* or *compartment* with undetermined status, provided all recommended measures are taken.

Regarding the comment received from the EU on Article 2.3.13.13., the Code Commission noted that it had not been supported by new scientific justification. As a result, no modification was made.

Changes proposed by the *ad hoc* Group regarding Article 2.3.13.14. were incorporated.

The modifications to the text in the September 2005 report are at Appendix XIII.

b) Appendix 3.8.4.

The Terrestrial Code Commission examined comments from Member Countries on the appendix on BSE surveillance.

Regarding a comment from the EU, the Terrestrial Code Commission did not make a reference to the BSurvE model because an alternative method as the concept of equivalence underpinned all chapters of the *Terrestrial Code*. Proposals from the EU and Guatemala requesting that Table 1 be expanded to include a greater range of population sizes were not adopted. The use of alternative models, such as BSurvE, can be used to address special situations such as those postulated by the EU and Guatemala.

Taking account of a comment from Switzerland, the text in paragraph 4 c) of Article 3.8.4.1 was clarified.

Comments from the EU and Japan on paragraph 5 of Article 3.8.4.1. were considered to be covered by a paragraph in Article 3.8.4.3, which states that "all clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested".

The modifications to the text in the September 2005 report are at Appendix XIV.

8. Classical swine fever (Chapter 2.6.7.)

The Terrestrial Code Commission examined Member Countries' comments on its proposals regarding Chapter 2.6.7. on classical swine fever (CSF).

In response to comments regarding country, zone or compartment freedom, the Terrestrial Code Commission redrafted Article 2.6.7.4, taking into account the different pathways for reaching free status.

With respect to the proposal from the EU to merge Article 2.6.7.7. with Article 2.6.7.4, the Terrestrial Code Commission found merit in this proposal. However, due to insufficient time, it deferred this action to its September 2006 meeting.

Because wild pigs are not subject to biosecurity management, a disease free compartment of wild pigs was not considered to be a realistic concept, except in rare cases. Similarly, a free zone of domestic pigs containing a wild pig population of unknown CSF status was not acceptable. Accordingly, the final paragraph of Article 2.6.7.7. was deleted.

Despite a request from Chile to delete paragraph 4 in Article 2.6.7.7., the Terrestrial Code Commission retained this paragraph as it was of the view that swill feeding should not need to be prohibited in a CSF free country or zone.

Japan sought clarification for the deletion of 'regularly inspected by the *Veterinary Authority*' from Articles 2.6.7.21. to 2.6.7.24. The Terrestrial Code Commission considered that this requirement was adequately covered by the preceding requirement for the establishment to be approved by the *Veterinary Administration*.

A proposal from Canada to replace 'sign of CSF' by 'signs suggestive of CSF' was not adopted, as the Terrestrial Code Commission believed that the current wording is sufficiently clear, and such wording is used throughout the *Terrestrial Code*.

The modifications to the text in the September 2005 report are at Appendix XV.

Community position:
The Community supports the proposal on the classical swine fever Chapter 2.6.7. It welcomes especially the introduction of the concept of compartmentalisation and supports the use of marker vaccination against classical swine fever.

However the present text needs to be improved in order to become clearer and coherent e.g. some articles or provisions are redundant and can be rearranged. Inconsistencies as regards the conflicting periods of recovery of a free status and the residency of animals in a free country, zone or compartment need to be addressed. Therefore the Community has incorporated some comments in the Appendix which it would like taken on board.

9. Avian influenza (Chapter 2.7.12. and Appendices 3.8.9. and 3.6.X.)

The Terrestrial Code Commission recognised the positive contributions made by Member Countries and an industry organisation in their comments on the chapter and appendices on avian influenza (AI).

a) Chapter 2.7.12.

Point 2 of Article 2.7.12.1. was modified to clarify the intention to include all domesticated poultry, including backyard and village birds, in the definition of 'poultry'.

The Terrestrial Code Commission agreed with New Zealand on the need to refer to vaccination in Article 2.7.12.6.

The Terrestrial Code Commission took into account information provided by the EU (an EFSA opinion, http://www.efsa.eu.int/science/ahaw/ahaw_opinions/1145_en.html) that there was no evidence that natural low pathogenicity avian influenza (LPAI) infections in layers had resulted in eggs containing virus internally. However, as LPAI virus was excreted in the faeces, surface sanitation was considered necessary. As a result, it proposed the deletion of paragraph 2 in Article 2.7.12.12.

The Terrestrial Code Commission decided to forward detailed comments on vaccination from Japan and Chile to the Scientific Commission for expert opinion.

The modifications to the text in the September 2005 report are at Appendix XVI.

Community position:

The Community thanks the Code Commission for taking its comments on the AI Code Chapter into account. The Community believes this AI Code Chapter and the guidelines for surveillance on AI are good tools to enable safe trade with poultry and other birds and product derived from them in relation to AI and can support this proposal. However recent experiences have shown that there are problems in international trade in relation to the use of vaccination against AI. The Community hopes that from this General Session a clear signal in respect of the research into and use of vaccination against AI with minimal trade impact will have been sent out.

b) Appendices

No change was made to the appendix on surveillance for AI, which is proposed unchanged for adoption at Appendix XVII in the September 2005 report.

The Terrestrial Code Commission made the necessary corrections to the table in Appendix 3.6.X, updating older industry standards to values determined by recent scientific studies.

The modifications to the text in the September 2005 report are at Appendix XVIII.

Community position:

The Community can support the proposals for the adoption of the proposed Annexes XVII and XVIII but would like the comments in the Appendices taken on board.

c) Reporting avian influenza findings in wild birds

Highly pathogenic avian influenza of the H5N1 strain is spreading globally. Strategies to protect poultry from avian influenza can be strengthened by having a better understanding of the behaviour of the virus in wild birds which constitute an important vector for the international transmission of the virus. For this reason, Member Countries are strongly encouraged to investigate reports of illness in wild birds; findings of highly pathogenic avian influenza need to be reported immediately to the OIE, using the OIE's immediate notification and follow-up reports. It is in the interests of all countries that information on highly pathogenic avian influenza in wild birds be distributed as widely and as quickly as possible.

For countries wishing to demonstrate continued freedom from the disease in poultry, such reports may be accompanied by information on the surveillance conducted in poultry

Community position:

The Community strongly supports this recommendation.

d) Recognition of health status for avian influenza

There is no OIE official recognition of disease-free status for avian influenza. Any claim to free status (free from all notifiable avian influenza or free from notifiable highly pathogenic avian influenza only) for a country, zone or compartment would be based on a self-declaration by the country concerned.

Under the OIE standard for avian influenza, a country, zone or compartment which meets Articles 2.7.12.3 (free from all avian influenza) or 2.7.12.4 (free from highly pathogenic avian influenza only) of the *Terrestrial Code*, and which has found avian influenza virus only in wild birds, does not lose its status with regard to notifiable avian influenza in poultry. These standards include a requirement for surveillance in accordance with Appendix 3.8.9 to provide evidence that the poultry compartment is adequately separated from wild birds.

The Terrestrial Code Commission strongly urged that measures imposed on trade in poultry commodities be based on the OIE standards.

Community position:

The Community strongly supports this recommendation.

10. Bovine and small ruminant semen (Appendix 3.2.1)

Member Countries' proposals on paragraph 2 of Article 3.2.1.5. regarding brucellosis were accepted, pending the outcome of the current revision of the brucellosis chapter (see below).

The clarification proposed by New Zealand for caprine arthritis/encephalitis at Article 3.2.1.6. was adopted.

Border disease was not reinstated at Article 3.2.1.6 despite a suggestion from the EU.

Text for disinfection techniques was modified in Articles 3.2.1.9. and 3.2.1.10. for consistency and accuracy in line with a suggestion from New Zealand.

A proposal by the EU regarding paragraph 3 of Article 3.2.1.5. was not adopted, as an '*official veterinarian*' was one accredited for various official tasks and, in this case, could include the centre veterinarian.

The modifications to the text in the September 2005 report are at Appendix XIX.

Community position:
The Community can support this proposal and thanks the OIE for taking some

points into account but would still like the comments incorporated in the draft Chapter taken into account in the next OIE expert meeting on this subject.

11. Animal welfare (Section 3.7.)

Dr J. Pinto reported to the Terrestrial Code Commission on the OIE's work on animal welfare. The Terrestrial Code Commission examined comments from Member Countries and some industry and non-governmental organisations (NGOs) on the four *Terrestrial Code* chapters on animal welfare. The Terrestrial Code Commission acknowledged the quality and relevance of these comments.

The Terrestrial Code Commission considered that the competence of the animal handler underpinned the OIE's approach to allocating responsibilities for animal welfare, and believed that such competence should be independently evaluated and certified.

As a result of a proposal from several Member Countries, the Terrestrial Code Commission decided to seek the advice of the Animal Welfare Working Group on whether to move the section on animal behaviour in the appendix on slaughter (Appendix 3.7.5.) to the appendix dealing with general principles (Appendix 3.7.1), as an appreciation of animal behaviour was essential to all aspects of animal welfare. However, the Terrestrial Code Commission decided not to move species specific issues to the same chapter as they were still under development, and more specific details would follow.

The Terrestrial Code Commission considered that some comments received needed to be discussed by either the OIE Animal Welfare Working Group during its next meeting in July 2006, or by specific *ad hoc* groups before the Terrestrial Code Commission's next meeting in September 2006.

The modifications to the text in the September 2005 report are at Appendices XX, XXI, XXII and XXIII.

The Terrestrial Code Commission also noted the official OIE position regarding the receipt of comments from sources other than the Delegates of Member Countries; this may be found on the OIE Web page.

Community position for Appendices 3.7.2 and 3.7.3, land and sea transport:

The European Community can support these proposals but has some comments on some particular issues which have been highlighted in the Appendices. In particular to ensure the proper application of these guidelines the responsibilities of all those persons involved in the transport chain need to be very clearly explained. The European Community hopes that all of its comments will be considered by the relevant OIE Working Group.

Community position for Appendices 3.7.5 and 3.7.6, slaughter of animals and killing of animals for disease control purposes:

The European Community can support these proposals but has some comments on some particular issues which have been highlighted in the Appendices.

Furthermore in order to facilitate the application of these guidelines in practice it is important that information and training materials are prepared and disseminated. These guidelines also need to be updated over time to take account of important scientific advances in these areas. The European Community hopes that all of its comments will be considered by the relevant OIE Working Group.

12. Animal production food safety

Drs W. Droppers and F. Berlingieri advised the Terrestrial Code Commission of the progress made by the Animal Production Food Safety Working Group (APFSWG) during its January-February 2006 meeting (Appendix XXXVIII in Part C of this report). The Terrestrial Code Commission welcomed the enhanced cooperation between the Codex Alimentarius Commission (CAC) and the OIE in the standard setting process.

The Terrestrial Code Commission supported the APFSWG recommendations on improving the Guide to Good Farming Practices in cooperation with the Food and Agriculture Organization of the United Nations (FAO) (with assistance from the World Health Organization [WHO]) with the outcome being for a joint OIE/FAO publication.

The Terrestrial Code Commission agreed with the APFSWG recommendation on animal feeding and decided to ask the Director General to convene an *ad hoc* group. It amended the proposed terms of reference and suggested that this *ad hoc* group work in close collaboration with the experts working on the Guide to Good Farming Practices.

The Terrestrial Code Commission endorsed the APFSWG recommendations regarding the revision of the OIE model certificates, through the setting up of a specific *ad hoc* group, and decided to address the issue in more detail at its next meeting in September 2006. It recognised that new certification covering animal health and food safety would help to minimise administrative load.

The Terrestrial Code Commission also supported the recommendation of the APFSWG to address salmonellosis in poultry. It decided to ask the Director General to set up an *ad hoc* group to update the current OIE standards in order to complement the on-going work of the CAC on the methods for control of *Salmonella* spp. in flocks.

The Terrestrial Code Commission welcomed and addressed the comments from Member Countries and the APFSWG on the draft "Appendix x.x.x. Guidelines for the Control of Hazards of Public Health and Animal Health Importance through Ante- and Post-Mortem Meat Inspection". The modifications to the text in the September 2005 report are at Appendix XXIV.

The Terrestrial Code Commission examined the *modus operandi* of the APFSWG (Appendix XXXVIII
– Appendix F) and clarified that the APFSWG mandate addressed the on farm production of all animal products, including meat, milk and eggs.

Community position:
The Community can support this proposal but would like the written comments which have been highlighted in the Appendices taken into account at the next

meeting of the Code Commission to improve the text. However the whole document focuses on the responsibilities of the Veterinary services and the Community believes that Industry must play its part as well. Therefore the Community proposes that the following is included: "The primary responsibility for ensuring compliance with food law and in particular food safety rests with the food business. Similarly this must be applied to feed businesses. To complement and support this principle there must be adequate and effective controls organised by the veterinary services."

13. Animal identification and traceability

The Terrestrial Code Commission noted the report of the second meeting of the OIE *ad hoc* Group on Animal Identification and Traceability, which is at Appendix XXXIX (Part C of this report) for the information of Member Countries.

The Terrestrial Code Commission noted that the *ad hoc* Group had drafted guidelines for animal identification and traceability to provide an instrument for Member Countries to improve animal health, public health, and to contribute to better management of health crises at international and national levels. These guidelines, although at an early stage of development, are submitted for Member Countries' comments (Appendix XXXV in Part B of this report).

The Terrestrial Code Commission supported the recommendations of the *ad hoc* Group in revising the draft definitions and principles of animal identification and traceability. The modifications to the text in the September 2005 report are at Appendix XXV.

Community position:
The Community supports this proposal.

14. Equine diseases other than equine influenza (Chapters 2.5.4., 2.5.6., 2.5.7., 2.5.8., 2.5.10. and 2.5.14.)

The Terrestrial Code Commission examined comments on several equine diseases received from Member Countries and decided to ask the Director General of the OIE to convene *ad hoc* groups of experts on equine viral arteritis and African horse sickness.

Community position:
The Community can support this initiative as it had some serious concerns over the drafting of these Chapters and has incorporated some comments in the draft Chapters which it hopes will be taken on board.

The Terrestrial Code Commission took into account Member Countries' comments in modifying the chapter on equine infectious anaemia. The modifications to the text in the September 2005 report are at Appendix XXVI.

Community position:
The Community can support this proposal but would like the points incorporated in the draft Chapter taken on board at the next OIE meeting on this subject.

Chapters on equine piroplasmosis, equine rhinopneumonitis and glanders are presented for adoption unchanged (Appendices XXVII, XXVIII and XXIX of the September 2005 report).

Community positions:
1. The Community can support the proposal for equine prioplasmosis but would like the comments incorporated in the draft Chapter taken into account at the next OIE meeting on this subject as no Community comments were taken into account for this proposal.

2. The Community can support proposal equine rhinopneumonitis but would like to point out that the disease should be called "Equine herpes virus infection"

3. However, unfortunately, the Community cannot support this proposal for glanders. The Community comments on this draft were not taken into account and a number of important points remain to be discussed. The Community comments have been incoporated in the Appendix.

15. Disposal of dead animals

The Terrestrial Code Commission received a revised draft appendix on the disposal of dead animals from the Scientific Commission. It endorsed the experts' proposal and the proposed appendix is presented as clean text at Appendix XXX for adoption.

Community position:
The Community supports this proposal.

B. TEXTS FOR THE COMMENT OF MEMBER COUNTRIES

16. Factors to consider in conducting a BSE risk assessment (Appendix 3.8.5.)

Following a request at the September 2005 meeting of the Terrestrial Code Commission, the Secretary-General of the Terrestrial Code Commission convened an informal consultation to update the appendix on factors to consider in conducting the BSE risk assessment recommended in Chapter 2.3.13. The Terrestrial Code Commission acknowledged the contributions of Dr Victoria Bridges (USA), Dr Dagmar Heim (Switzerland), Dr Geoff Ryan (Australia), Dr Katsuaki Sugiura (Japan), Dr Agustina Carballo (Argentina), Prof. Vitor Salvador Picão Gonçalves (Brazil) and Dr Danny Matthews (United Kingdom).

The revision of Appendix 3.8.5. was necessary because of changes made in the BSE chapter. While many of the changes in the revised Appendix were structural, important issues addressed by the experts involved the time periods to be considered in risk assessments and the risks posed by small ruminants.

The time periods specified in the BSE chapter relate to the categorisation of country status. For example, the eight-year period is relevant for the implementation and enforcement of risk mitigation measures. However, in considering risks, the importation of BSE through cattle or feed may have occurred long before that period and, therefore, the agent could have been recycled within the country for some time. A country that applies for Negligible Risk status is required to demonstrate that all risks have been properly managed for at least 8 years and that it has had no BSE cases for the same period. On the other hand, the experts considered that the only way one could assess the likelihood of having introduced the BSE agent was to look back as far as necessary.

Then, the risk assessment would indicate whether the present risk was negligible or not, even if there was some likelihood that BSE had been imported some time in the past.

If BSE surveillance as described in Appendix 3.8.4. was in place, the experts considered that, with the passage of time it would indicate that either BSE had not been introduced in the distant past or that a country's cattle production system was sufficiently stable that the disease did not recycle and amplify.

The experts acknowledged that risk assessments should address relevant risk factors identified through knowledge of the epidemiology of the disease being assessed. The current scientific knowledge regarding the epidemiology of BSE indicated that transmission via feed was the primary risk factor that should be addressed, including avenues of how the domestic cattle population could be exposed to contaminated feed stuffs and risk mitigating activities of feed bans and SRM removals. These risk factors of greatest concern regarding BSE are addressed individually. As scientific knowledge of BSE progresses, additional risk factors might need to be addressed when conducting risk assessments. However, they considered that risk factors that are not known to contribute significantly to the overall risk of BSE should be thoroughly scrutinized prior to being included in the risk assessment process. The experts noted that BSE had recently been reported in two goats and two sheep. However, they considered that cattle posed the only demonstrated risk and must be regarded as the best 'indicator species' for the presence of BSE in a country. They considered that cattle, therefore, were the only species of concern when a country is conducting surveillance for BSE, until scientific knowledge changes to indicate otherwise.

The experts were not in favour of the idea that a country which had failed to demonstrate the presence of BSE in its cattle population should be required to implement a large, structured scrapie surveillance programme. If BSE was present in a sheep population, it was only because it had been introduced into that species from the cattle BSE epidemic. They believed that it was very unlikely that countries would might have BSE in their small ruminants without it manifesting in the sentinel indicator species, namely cattle.

The Terrestrial Code Commission noted that the majority view had been to confine the assessment to BSE and to regard cattle as the best 'indicator species'. The *ad hoc* Group had considered that the time periods involved in assessing BSE risk factors compared to those for determining BSE status had a significantly different basis, and had used 'any time since 1980' as the base date in determining risk factors.

Appendix 3.8.5 is presented as clean text at Appendix XXXI for the comment of Member Countries.

Community position:
The Community welcomes the work done by the Code Commission and can support Appendix 3.8.5. if the comments made there are taken on board.

17. Brucellosis (Chapter 2.3.1.)

The Terrestrial Code Commission received from the Scientific Commission a draft chapter on bovine brucellosis which was prepared using the chapter on bovine tuberculosis as a model.

The draft chapter is presented at Appendix XXXII for the comment of Member Countries.

Community position:
The Community can only support this proposal if the points which have been highlighted in the Appendix are taken on board at the next OIE meeting on this subject. In particular, the status free with vaccination and free without vaccination, do not equate one with the other. A country free without vaccination should not import a vaccinated animal. In addition the Community would like an explanation of why B. suis is included.

18. Paratuberculosis (Chapter 2.2.6.)

The Terrestrial Code Commission thanked six Member Countries for addressing the issues raised in its September 2005 report. However, because of the complex epidemiology and the absence of adequate diagnostic tools, the Terrestrial Code Commission was unable to further develop the chapter.

The Terrestrial Code Commission decided to ask the Biological Standards Commission if there had been any recent improvements in diagnostic techniques.

Community position:
The Community supports this initiative

19. Equine influenza (Chapter 2.5.5.)

The Terrestrial Code Commission noted the report of the meeting of the *ad hoc* Group on equine influenza which had developed a heavily revised chapter (Appendix XXXX in Part C of this report). The draft chapter (Appendix XXXIII) is submitted to Member Countries for comments.

Community position:
The Community supports this proposal

20. Bovine viral diarrhoea-mucosal disease

Based on the comments received from Member Countries, the Terrestrial Code Commission decided to ask experts to provide general guidance on the control and eradication of the disease. Because of the nature of the disease, the Terrestrial Code Commission does not intend to incorporate any such guidelines into the *Terrestrial Code*, but to use another approach to make the information available.

Community position:
The Community supports this initiative

21. International transfer of pathogens (Chapter 1.4.5.)

The Terrestrial Code Commission endorsed the approach taken by the Biological Standards Commission in revising the chapter. The revised chapter is at Appendix XXXIV for the comment of Member Countries.

Community position:
The Community supports this proposal

22. Revision of Chapters 1.3.1. and 1.3.2. of the *Terrestrial Code* on import risk analysis

Following a request at the September 2005 meeting of the Terrestrial Code Commission, the Secretary-General convened an informal consultation to review the current chapters of the *Terrestrial Code* on import risk analysis.

The Terrestrial Code Commission acknowledged the contributions of Drs Howard Pharo (New Zealand), Mike Nunn (Australia), Marion Wooldridge (UK), Noel Murray (Canada), Katsuaki Sugiura (Japan), Eric Breidenbach (Switzerland) and Randall Morley (Canada) in helping to determine whether there was a need to revise the current text of Chapters 1.3.1. and 1.3.2. The Terrestrial Code Commission endorsed the conclusion of the experts that there was no need to revise the current text, but that, should a revision of these chapters be proposed in the future, an expert group should examine the feasibility of aligning OIE terminology to that of the Codex.

Community position:
The Community supports this conclusion

C. REPORTS OF WORKING GROUPS AND *AD HOC* GROUPS

The following reports are for the information of Member Countries:

– ***Ad hoc* Group on Disease/Pathogenic Agent Notification** (Appendix XXXVI)

– ***Ad hoc* Group on Bovine Spongiform Encephalopathy** (Appendix XXXVII)

– **Animal Production Food Safety Working Group** (Appendix XXXVIII)

– ***Ad hoc* Group on Animal Identification and Traceability** (Appendix XXXIX)

– ***Ad hoc* Group on Equine Influenza** (Appendix XXXX).

.../Appendices

Appendix I

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6-10 March 2006

_____

List of Participants

MEMBERS

Dr A. Thiermann
President
US Mission to the OECD
19, rue de Franqueville
75016 Paris
FRANCE
Tel: 33-(0)1 44 15 18 69
E-mail: a.thiermann@oie.int

Dr W.-A. Valder
Vice President
National Expert, SANCO
European Commission
Rue Froisart 101/ 3-76
Brussels
BELGIUM
Tel: (32-2)-2958916
E-mail: wolf-arno.valder@cec.eu.int

Prof S.C. MacDiarmid
Secretary General
Principal International Adviser,
Risk Analysis,
International Coordination
Biosecurity New Zealand
P.O. Box 2526
Wellington
NEW ZEALAND
Tel: (64-4) 819 0420
E-mail: stuart.macdiarmid@maf.govt.nz

Dr S.K. Hargreaves
Principal Director of Livestock
and Veterinary Services
Ministry of Agriculture
PO Box CY66 Causeway
Harare
ZIMBABWE
Tel: (263-4) 791 355/722 358
E-mail: skhargreaves@zol.co.zw

Prof A.N. Panin
Director
The All-Russian State Centre for Quality
and Standardisation of Veterinary
Drugs and Feedstuff (VGNKI)
5, Zvenigorodskoye shosse
123022 Moscow
RUSSIA
Tel/fax: (7-095) 253 14 91
E-mail: vgnki-vet@mtu-net.ru

Prof A.M. Hassan
Undersecretary
Ministry of Animal Resources
PO Box 293
Khartoum
SUDAN
Tel: (249)183 465218 / 464 984 / 476 958
Fax: (249) 183 475996
E-mail: pacesud@yahoo.com
ahmedhassan32@hotmail.com

OIE HEADQUARTERS

Dr B. Vallat
Director General
12, rue de Prony
75017 Paris
FRANCE
Tel: 33 (0)1 44 15 18 88
Fax: 33 (0)1 42 67 09 87
E-mail: oie@oie.int

Dr D. Wilson
Deputy Director General
Tel: 33 (0)1 44.15.18.80
E-mail: d.wilson@oie.int

Dr T. Ishibashi
Chargée de mission
International Trade Department
Tel: 33 (0)1 44.15.18.92
E-mail: t.ishibashi@oie.int

Dr K. Ben Jebara
Head
Animal Health Information Department
Tel: 33 (0)1 44 15 18 52
E-mail: k.benjebara@oie.int

Dr W. Droppers
Chargé de mission
Tel: 33 (0)1 44 15 18 90
E-mail: w.droppers@oie.int

Dr F. Berlingieri
Deputy Head
International Trade Department
Tel: 33 (0)1 44 15 18 90
E-mail: f.berlingieri@oie.int

Dr J.Pinto
Deputy Head
International Trade Department
Tel: 33 (0)1 44 15 18 72
E-mail: j.pinto@oie.int

Appendix II

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6-10 March 2006

_____

Agenda

Item 1 General definitions (Chapter 1.1.1.)

Item 2 Evaluation of Veterinary Services (Chapters 1.3.3., 1.3.4. and PVS)

Item 3 Zoning and compartmentalisation (Chapter 1.3.5.)

Item 4 Criteria for listing diseases (Chapter 2.1.1.)

Item 5 Foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7.)

Item 6 Bluetongue (Chapter 2.2.13. and proposed surveillance appendix)

Item 7 Bovine spongiform encephalopathy (Chapter 2.3.13., and Appendices 3.8.4. and 3.8.5.)

Item 8 Classical swine fever (Chapter 2.6.7.)

Item 9 Avian influenza (Chapter 2.7.12., Appendix 3.8.9. and proposed virus inactivation appendix)

Item 10 Semen (Appendix 3.2.1.)

Item 11 Animal welfare (Section 3.7)

Item 12 Animal production food safety (including ante- and post-mortem inspection)

Item 13 Animal identification and traceability

Item 14 Paratuberculosis (Chapter 2.2.6.)

Item 15 Equine diseases (Section 2.5)

Item 16 Bovine viral diarrhoea-mucosal disease

Item 17 International transfer of pathogens (Chapter 1.4.5.)

Item 18 Future work programme of the OIE Terrestrial Animal Health Standards Commission and the OIE Scientific Commission for Animal Diseases

Item 19 Other issues_____

Appendix III

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Community position:

The European Community can support this proposal but has some comments on some particular issues (see below). The European Community hopes that all those comments included below will be later considered by the relevant OIE Working Group.

Animal handler

A person with a knowledge of the behaviour and needs of animals which, with appropriate experience and a professional and positive response to an animal's needs, results in effective management and good welfare. Their competence should be demonstrated through independent assessment and certification from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

Community written comments:

The last sentence should be re-considered: "Their competence should be demonstrated through independent assessment and certification from the *Competent Authority* or from an independent body accredited by the *Competent Authority*."

It could be replaced by the sentence "Competence may be gained through formal training and/or practical experience".

Justification

The current wording would imply that all animal handlers involved in the transport of any animals in any OIE member country would need to have "a current certificate from the *Competent Authority* or from an independent body accredited by ~~a~~ the *Competent Authority*". **This would have profound implications. A more appropriate wording is used in Article 3.7.6.1 of the guidelines for the killing of animals for disease control purposes where this requirement for the certification of all personnel has been deleted "All personnel involved in the humane killing of animals should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience. ~~This competence should be demonstrated through a current certificate from an independent body accredited by a Competent Authority."~~**

It is important to have a consistent approach between the various OIE guidelines. Furthermore the terminology used across the OIE guidelines varies so it is unclear

as to who would be required to be assessed and certified. In some sections the term "personnel" is used instead of "animal handler".

Container

A non-self-propelled receptacle or other rigid structure for holding animals during a *journey* by one or several means of transport.

Death

Irreversible loss of brain activity demonstrable by the loss of brain stem reflexes.

Journey

An animal transport journey commences when the first animal is loaded onto a *vehicle/vessel* or into a *container* and ends when the last animal is unloaded, and includes any stationary resting / holding periods ~~of less than 48 hours~~. The same animals do not commence a new journey until after a suitable period ~~of over 48 hours~~ for rest and recuperation, with adequate feed and water.

Killing

Any procedure which causes the death of an animal.

Lairage

Pens, yards and other holding areas used for accommodating animals in order to give them necessary attention (including water, feed, rest) before they are moved on or used for specific purposes including slaughter.

Loading/Unloading

Loading: the procedure of moving animals onto a *vehicle/vessel* or into a *container* for transport purposes; **unloading:** the procedure of moving animals off a *vehicle/vessel* or out of a *container.*

Post-journey period

The period between *unloading* and either recovery from the effects of the *journey* or slaughter (if this occurs before recovery).

Pre-journey period

The period during which animals are identified, and often assembled for the purpose of loading them.

Resting point

A place where the *journey* is interrupted to rest, feed or water the animals; the animals may remain in the *vehicle/vessel* or *container*, or be unloaded.

Restraint

The application to an animal of any procedure designed to restrict its movements.

Slaughter

Any procedure which causes the death of an animal by bleeding.

Community written comment:
The Community wonders whether the wording is correct as slaughter should refer to animals the meat of which is intended to be used for consumption and some animals may be dead prior to bleeding e.g. if they are shot first. The following alternative definition of slaughter is suggested:
Slaughter **"Any procedure which causes the death of an animal intended for human consumption."**
Justification: Animals may be killed without bleeding and since there are a number of methods where death intervenes before bleeding (e.g. gas killing, two-cycle electrical procedures, free-bullet) the definition of slaughter should be replaced by the afore-mentioned text.

Space allowance

The measure of the floor area and height ~~on a *vehicle/vessel* or *container*~~ allocated per individual or body weight of animals ~~transported~~.

Stocking density

The number or body weight of animals per unit area on a *vehicle/vessel* or *container*.

Community written comments:
In the next bullet point the words "would allow" should be replaced by "may allow".
Justification
There are cases where an animal may not recover full consciousness having been stunned by certain methods (e.g. penetrating captive bolt").

Stunning

Any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the animal to recover consciousness.

Transport

The procedures associated with the carrying of animals for commercial purposes from one location to another by any means ~~land (road and rail), sea or air~~.

Transporter

The person licensed by the *Competent Authority* to transport animals.

Travel

The movement of a *vehicle/vessel* or *container* carrying animals from one location to another.

Vehicle/vessel

Any means of conveyance including train, truck, aircraft or ship that is used for carrying animal(s).

Slaughterhouse/abattoir

Premises, including facilities for moving or lairaging animals, used for the slaughter of *animals* to produce animal products ~~for human consumption or animal feeding~~, and approved by the *Veterinary Services* or other *Competent Authority*.

Quarantine station

A facility under the control of the *Veterinary Authority* where ~~a group of~~ animals are ~~is~~ maintained in isolation with no direct or indirect contact with other animals, to prevent the transmission of specified pathogen(s)~~disease(s)~~, ~~in order to~~ while the animals are undergoing observation for a specified length of time and, if appropriate, testing and treatment

Community written comments:
The Community proposes the following wording: "A facility under control of the Veterinary Authority where an animal or a group of animals….".

In addition "…to prevent the transmission of specified disease(s)…" : it would be more relevant to refer to "specific pathogenic agents" (according to the Code, a disease is only clinical and/or pathological manifestation of infection).

- - - - - - - - - - - - - - -

— text deleted

Appendix IV

CHAPTER 1.3.3.

1. EVALUATION OF VETERINARY SERVICES

Community position:
The Community can support this proposal as it believes that this is a very useful tool and will help in generating confidence between veterinary services. The Community would like to point out that it is not clear how the conclusions of the experts involved in the assessment of veterinary services would bind the OIE and thereby its members i.e. what would be the status of this assessment. In addition it would like to know if it's the intention of the OIE to incorporate the Performance, Vision and Strategy document in the code and what exactly is its status if its not incorporated in the Code.

Article 1.3.3.1.

The quality of the *Veterinary Services* depends on a set of factors, which include fundamental principles of an ethical, organisational and technical nature. The *Veterinary Services* shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Veterinary Services* of a Member Country is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Member Countries.

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health measures, or issuing some *international veterinary certificates* is exercised by an organisation other than the *Veterinary Services*, or by an authority or agency on behalf of the *Veterinary Services*. In all cases, the *Veterinary Services* retain ultimate responsibility for the application of these principles.

These fundamental principles are presented in Article 1.3.3.2. ~~The remaining~~ Other factors affecting ~~of~~ quality are described in Part 1. (notification, principles of certification, etc.). ~~and the document entitled Guidelines for the evaluation of Veterinary Services included in Chapter 1.3.4.~~

The quality of *Veterinary Services* can be measured through an evaluation, whose general principles are described in Article 1.3.3.3. and in Article 1.3.3.4.

Guidelines for the evaluation of *Veterinary Services* are described in Chapter 1.3.4.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

Article 1.3.3.2.

Fundamental principles of quality

The *Veterinary Services* shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The personnel of *Veterinary Services* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

Care should be taken to ensure that *Veterinary Services*' personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

The *Veterinary Services* should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

The *Veterinary Services* should guarantee that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified and corrected.

5. Objectivity

The *Veterinary Services* should at all times act in an objective, transparent and non-discriminatory manner.

6. General organisation

The *Veterinary Services* must be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health measures, and of international veterinary certification activities. Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, they should define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of animal movements, animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

The *Veterinary Services* should have at their disposal effective systems for animal disease surveillance and for *notification* of disease problems wherever they occur, in accordance with the provisions of this *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They should at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international veterinary certificates*.

Each position within the *Veterinary Services* which has an impact on their quality should be described. These job descriptions should include the requirements for education, training, technical knowledge and experience.

7. Quality policy

The *Veterinary Services* should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to

their areas of activity and appropriate for the type, range and volume of work that they have to perform. The guidelines for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member Country choose to adopt a quality system.

8. Procedures and standards

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

a) programming and management of activities, including international veterinary certification activities;

b) prevention, control and notification of disease *outbreaks*;

c) risk analysis, epidemiological surveillance and zoning;

d) inspection and sampling techniques;

e) diagnostic tests for animal diseases;

f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;

g) border controls and import regulations;

h) *disinfection* and *disinfestation*;

i) treatments intended to destroy, if appropriate, pathogens in animal products.

Inasmuch as the OIE has adopted standards on these matters, the *Veterinary Services* should comply with these standards when applying animal health measures and when issuing *international veterinary certificates*.

9. Information, complaints and appeals

The *Veterinary Administration* should undertake to reply to legitimate requests from *Veterinary Administrations* of other Member Countries or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

10. Documentation

The *Veterinary Services should* have at their disposal a reliable and up to date documentation system suited to their activities.

11. Self-evaluation

The *Veterinary Services* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

~~A Member Country can request the Director General of the OIE to arrange for an expert or experts to assist in the process.~~

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

12. Communication

Veterinary Services should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

13. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 1.3.3.3.

For the purposes of this *Terrestrial Code*, every Member Country should recognise the right of another Member Country to undertake, or request it to undertake, an evaluation of its *Veterinary Services* where the initiating Member Country is an actual or a prospective importer or exporter of *commodities* and where the evaluation is to be a component of a risk analysis process which is to be used to determine or review sanitary measures which apply to such trade.

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE Guidelines for the evaluation of *Veterinary Services* presented in Chapter 1.3.4. of this *Terrestrial Code*.

A Member Country has the right to expect that the evaluation of its *Veterinary Services* will be conducted in an objective manner. A Member Country undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 1.3.3.4.

A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* should give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Veterinary Services* by another Member Country, and following bilateral agreement of the evaluation process and criteria, a Member Country should expeditiously provide the other country with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 1.3.3.1. and in Article 1.3.3.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 1.3.3.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.3.

Article 1.3.3.5.

1.1. ~~*Voluntary*~~ *Evaluation facilitated by OIE experts under the auspices of the OIE*

The OIE ~~maintains~~ has established ~~a~~ procedures for the evaluation of the *Veterinary Services* of a Member Country, ~~on a voluntary basis~~ upon request by the Member Country.

The OIE International Committee endorses a list of approved experts to facilitate the evaluation process.

Under ~~this~~ these procedures, ~~on the receipt of a request from a Member Country,~~ the Director General ~~of the OIE~~ recommends an expert(s) from ~~a~~ that list.~~ of evaluators approved by the OIE International Committee.~~

The expert(s) facilitate(s) the evaluation ~~evaluates~~ of the *Veterinary Services* of the Member Country ~~against~~ based on the provisions in Chapter 1.3.4 of the *Terrestrial Code*, using the *Performance, Vision and Strategy* [PVS] *Instrument* ~~as a guide, and produces a report~~.

The expert(s) produce(s) a report in consultation with the *Veterinary Services* of the Member Country.

The ~~final~~ report is submitted to the Director General and, with the consent of the Member Country, published by the OIE.

Community written comments:
This reworded new article and the explicit reference to PVS would imply that PVS is included in the Code. The Community questions the OIE on the future of PVS; an insertion in the Code would at least require some re-wording for standardisation and consistency (glossary, definitions etc…)
The Community would like to take the opportunity to raise the broad question of Code/import requirements versus management guidelines for OIE member countries and it is not clear how the conclusions of the experts involved in the assessment of veterinary services would bind the OIE and thereby it members i.e. what would be the status of this assessment In addition it would like to know if it's the intention of the OIE to incorporate the Performance, Vision and Strategy document in the code and if not what is its status.

- - - - - - - - - - - - - - -
— text deleted

Appendix V

CHAPTER 1.3.4.

1.2. GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Community position:
The Community can support this proposal.

Article 1.3.4.1.

2. GENERAL CONSIDERATIONS

1. Evaluation of *Veterinary Services* is an important element in the risk analysis process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade* in *animals*, animal-derived products, animal genetic material and animal feedstuffs.

   Any evaluation should be carried out with due regard for Chapter 1.3.3. of this *Terrestrial Code*.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these guidelines which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of risk analysis in *international trade*. ~~These guidelines (in conjunction with the *Performance, Vision, Strategy* [PVS] *Instrument*) will be used by OIE experts when conducting an evaluation on the request of a Member Country.~~ The guidelines are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation ~~or self-assessment~~ – and for periodic re-evaluation. These guidelines should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member Country. In applying these guidelines for the evaluation, the *Performance, Vision and Strategy* [PVS] *Instrument* should be used.

   In carrying out a risk analysis prior to deciding the sanitary/zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of risk analysis in *international trade* in *animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.

4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include resource adequacy, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and performance history, including disease reporting.

5. Competence and integrity are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner

countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.

7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

8. An *exporting* country is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.

9. As the *Veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 1.3.4.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:

   - organisation, structure and authority of the *Veterinary Services*;
   - human resources;
   - material (including financial) resources;
   - functional capabilities and legislative support;
   - animal health and veterinary public health controls;
   - formal quality systems including quality policy;
   - performance assessment and audit programmes;
   - participation in OIE activities and compliance with OIE Member Countries' obligations.

2. To complement the evaluation of *Veterinary Services*, ~~it is necessary to also consider~~ the organisational structure and functioning of the *Veterinary statutory body* should also be considered.

3. Article 1.3.4.14. outlines appropriate information requirements for:

   - self-evaluation by national *Veterinary Services* which perceive a need to prepare information for national or international purposes;

   - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;

   - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;

   - evaluation by third parties such as OIE experts or regional organisations.

~~4. The PVS Instrument should be used as a guide in conducting evaluations and self-evaluations.~~

Article 1.3.4.3.

Evaluation criteria for the organisational structure of the Veterinary Services

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.

2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.

3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological surveillance, disease control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.

4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.

5. The *Veterinary Administration* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and regionalisation are being applied. The responsibilities of the national *Veterinary Administration* and all *Veterinary Authorities* in that country should be made clear in the process of evaluation of *Veterinary Services*.

6. A *Veterinary Authority* is defined in Chapter 1.1.1. of this *Terrestrial Code*. As some countries have some official *Veterinary Authority* roles vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the national *Veterinary Services* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.

7. Similarly, where the national *Veterinary Services* have arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the quality of organisational and functional standards which apply to *Veterinary Services* should also apply to the services of these other providers.

Article 1.3.4.4.

3. EVALUATION CRITERIA FOR QUALITY SYSTEMS

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.

2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 1.3.4.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core must include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

2. In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that disease monitoring is being conducted by a sufficient number of qualified, experienced field veterinarians who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.

3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private veterinarians would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of notifiable diseases) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.

4. These data should be assessed in close conjunction with the other information described in this Chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country.

If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 1.3.4.6.

Evaluation criteria for material resources

1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 1.3.4.14. Information is required on conditions of service for veterinary staff (including salaries and incentives) and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

2. Administrative

a) Accommodation

The *Veterinary Services* should be accommodated in premises suitable for efficient performance of their functions. The component parts of the *Veterinary Services* should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes.

Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems (e.g. e-mail and Internet services) are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the national *Veterinary Services*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Services* in trading-partner countries.

c) Transport systems

The availability of sufficient reliable transport facilities is essential for the performance of many functions of *Veterinary Services*. This applies particularly to the field services components of animal health activities (e.g. emergency response visits). Otherwise, the *Veterinary Services* cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of *animals* and animal product inspection in outlying production or processing establishments.

3. Technical

Details available on laboratories should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the laboratory. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

a) Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products (e.g. vaccines) when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* must approve and designate these laboratories for such purposes and have them audited regularly.

c) Research

The scope of animal disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

Article 1.3.4.7.

3.1.1. Functional capabilities and legislative support

1. Animal health and veterinary public health

The *Veterinary Services* should be able to demonstrate that they have the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises/areas, testing, treatment, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, wildlife as it relates to the transmission of *diseases* to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal diseases in border areas and for establishing linkages to recognise and regulate transboundary activities. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export/import inspection

National Veterinary *Services* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoosanitary matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Services* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authorities* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

The national *Veterinary Services* should be able to demonstrate that they have adequate capabilities and legislative support for zoosanitary control of imports and transit of *animals*, animal products and other materials which may introduce animal diseases. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoosanitary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny and/or withdraw official certification. Penalty provisions applying to *malpractice* on the part of certifying officials should be included.

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Section 1.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the *animals* or animal product being certified and be independent from the commercial parties.

Article 1.3.4.8.

Animal health controls

1. Animal health status

An updated assessment of the present animal disease status of a country is an important and necessary procedure. For this undertaking, studies of the OIE publications such as *World Animal Health*, the *Bulletin* and *Disease Information* must be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal diseases. In the case of an OIE Member Country, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

An *exporting country* should be able to provide further, detailed elaboration of any elements of its animal disease status as reported to the OIE. This additional information will have particular importance in the case of animal diseases which are foreign to or strictly controlled in the *importing country* or region. The ability of the *Veterinary Services* to substantiate elements of their animal disease status reports with surveillance data, results of monitoring programmes and details of disease history is highly relevant to the evaluation. In the case of evaluation of the *Veterinary Services* of an *exporting country* for *international trade* purposes, an *importing country* should be able to demonstrate the reasonableness of its request and expectations in this process.

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological surveillance, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific diseases or disease complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological surveillance and animal disease emergency responses, quarantine arrangements for infected and exposed animals or herds, compensation provisions for animal owners affected by disease control measures, training programmes, physical and other barriers between the free country or *zone* and those infected, incidence and prevalence data, resource commitments, interim results and programme review reports.

3. National animal disease reporting systems

The presence of a functional animal disease reporting system which covers all agricultural regions of the country and all veterinary administrative control areas should be demonstrated.

An acceptable variation would be the application of this principle to specific *zones* of the country. In this case also, the animal disease reporting system should cover each of these *zones*. Other factors should come to bear on this situation, e.g. the ability to satisfy trading partners that sound animal health controls exist to prevent the introduction of disease or export products from regions of lesser veterinary control.

Article 1.3.4.9.

Veterinary public health controls

1. Food hygiene

The national *Veterinary Services* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products. If the national *Veterinary Services* do not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state/provincial, and municipal) which are involved. In such a case, the evaluation should consider whether the national *Veterinary Services* can provide guarantees of responsibility for an effective control of the sanitary status of animal products throughout the slaughter, processing, transport and storage periods.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities *include* the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based surveillance and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide.

Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

4. Veterinary medicines

It should be acknowledged that primary control over veterinary medicinal products may not rest with the *Veterinary Authorities* in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Services* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, importation, export, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against animal disease introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in establishments producing products of animal origin, in particular meat or dairy products, and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national disease surveillance scheme.

Veterinary Services which direct a significant element of their animal health programmes specifically towards minimising microbial and chemical contamination of animal-derived products in the human food chain should receive favourable recognition in the evaluation. There should be evident linkage between these programmes and the official control of veterinary medicines and relevant agricultural chemicals.

Article 1.3.4.10.

Performance assessment and audit programmes

1. Strategic plans

The objectives and priorities of the *Veterinary Services* can be well evaluated if there is a published official strategic plan which is regularly updated. Understanding of functional activities is enhanced if an operational plan is maintained within the context of the strategic plan. The strategic and operational plans, if these exist, should be included in the evaluation.

Veterinary Services which use strategic and operational plans may be better able to demonstrate effective management than countries without such plans.

2. Performance assessment

If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

4. Veterinary Services administration

a) Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

b) Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c) Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d) In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health organisations. Such a programme should be used in assessing the effectiveness of the Services.

e) Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f) Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g) Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 1.3.4.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a

Member Country to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary/zoosanitary status for evaluation purposes.

Article 1.3.4.12.

Evaluation of the veterinary statutory body

1. Scope

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

- objectives and functions;
- legislative basis, ~~including~~ autonomy and functional capacity;
- ~~human resources, including~~ the composition and representation of the body's membership;
- ~~institutional arrangements,~~ accountability and transparency of decision-making;
- sources and management of funding;
- ~~functional capabilities, including the ability to enforce its decisions (for example regarding registration requirements, standards of conduct, and disciplinary procedures);~~
- administration of ~~education~~ training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

The *veterinary statutory body* should define its policy and objectives, including detailed descriptions of its powers and functions such as:

- to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;
- to determine the minimum standards of ~~training~~ education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;
- to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of ~~training~~ education (initial and continuing) for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

The *veterinary statutory body* should be able to demonstrate autonomy from undue political and commercial interests.

Where applicable, regional agreements for the recognition of degrees, diplomas and certificates for *veterinarians* and *veterinary para-professionals* should be demonstrated.

4. Evaluation of membership representation

Detailed descriptions should be available in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:

- veterinarians designated by the *Veterinary Administration*, such as the Chief Veterinary Officer;
- veterinarians elected by members registered by the *veterinary statutory body*;
- veterinarians designated or nominated by the veterinary association(s);
- representative(s) of veterinary para-professions;
- representative(s) of veterinary academia;
- representative(s) of other stakeholders from the private sector;
- election procedures and duration of appointment;
- qualification requirements for members.

5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing/registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for *veterinarians* and *veterinary para-professionals*

Descriptive summary of continuing professional development, training and education programmes should be provided, including descriptions of content, duration and participants; documented details of quality manuals and standards relating to Good Veterinary Practice should be provided.

Article 1.3.4.13.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.

2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a risk analysis process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from disease or pest

threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.

3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 1.3.4.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this Chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study must be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country must be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 1.3.4.14.

This Article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

   a) National Veterinary Services

      Organisational chart including numbers, positions and numbers of vacancies.

   b) Sub-national Veterinary Services

      Organisational charts including numbers, positions and number of vacancies.

   c) Other providers of Veterinary Services

      Description of any linkage with other providers of *Veterinary Services*.

2. National information on human resources

   a) Veterinarians

      i) Total numbers of *veterinarians* registered/licensed by the *Veterinary statutory body* of the country:

      ii) Numbers of:

         - full time government *veterinarians*: national and sub-national;

         - part time government *veterinarians*: national and sub-national;

         - private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions; *[Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians.]*

         - other *veterinarians*.

      iii) Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area *[Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable.]*:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv) Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity *[Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.]*:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

v) Numbers of *veterinarians* relative to certain national indices:

- per total human population;
- per farm livestock population, by geographical area;
- per livestock farming unit, by geographical area.

vi) Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- international recognition of veterinary degree.

vii) Veterinary professional associations.

b) Graduate personnel (non-veterinary)

Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within national *Veterinary Services* and available to national *Veterinary Services*.

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

- Categories and numbers involved with farm livestock on a majority time basis:
  - by geographical area;

- proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.

- Education/training details.

ii) Veterinary public health:

- Categories and numbers involved in food inspection on a majority time basis:

  - meat inspection: export meat establishments with an export function and domestic meat establishments (no export function);

  - dairy inspection;

  - other foods.

- Numbers in import/export inspection.

- Education/training details.

d) Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).

e) Descriptive summary of the functions of the various categories of staff mentioned above

f) Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations

g) Additional information and/or comments.

3. Financial management information

a) Total budgetary allocations to the *Veterinary Services* for the current and past two fiscal years:
   i) for the national *Veterinary Services*;
   ii) for each of any sub-national veterinary authorities;
   iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

i) government budget;

ii) sub-national authorities;

iii) taxes and fines;

iv) grants;

v) private services.

c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.

d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*

e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation

Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

b) Communications

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

c) Transport

i) Itemised numbers of types of functional transport available on a full-time basis for the*Veterinary Services*. In addition provide details of transport means available part-time.

ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.

ii) Numbers of veterinary diagnostic laboratories operating in the country:

- government operated laboratories;

- private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.

iii) Descriptive summary of accreditation procedures and standards for private laboratories.

iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.

v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).

vi) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.

vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.

viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.

ix) Details of procedures for storage and retrieval of information on specimen submission and results.

x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).

xi) Strategic and operational plans for the official veterinary laboratory service (if available).

b) Research laboratories (laboratories engaged primarily in research)

i) Numbers of veterinary research laboratories operating in the country:

- government operated laboratories;

- private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

ii) Summary of human and financial resources allocated by government to veterinary research.

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research laboratories.

6. Functional capabilities and legislative support

a) Animal health and veterinary public health

i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:

- animal and veterinary public health controls at national frontiers;

- control of endemic animal diseases, including zoonoses;

- emergency powers for control of exotic disease outbreaks, including zoonoses;

- inspection and registration of facilities;

- veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;

- veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;

- registration and use of veterinary pharmaceutical products including vaccines.

ii) Assessment of ability of *Veterinary Services* to enforce legislation.

b) Export/import inspection

i) Assessment of the adequacy and implementation of relevant national legislation concerning:

- veterinary public health controls of the production, processing, storage and transportation of meat for export;

- veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;

- animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;

- animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;

- animal health controls of importation of veterinary biological products including vaccines;

- administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);

- documentation and compliance.

ii) Assessment of ability of *Veterinary Services* to enforce legislation.

7. Animal health and veterinary public health controls

a) Animal health

i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.

ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.

iii) Description and relevant data of current official control programmes including:

- epidemiological surveillance or monitoring programmes;

- officially approved industry administered control or eradication programmes for specific diseases.

iv) Description and relevant details of animal disease emergency preparedness and response plans.

v) Recent history of animal disease status:

- animal diseases eradicated nationally or from defined sub-national *zones* in the last ten years;

- animal diseases of which the prevalence has been controlled to a low level in the last ten years;

- animal diseases introduced to the country or to previously free sub national regions in the last ten years;

- emerging diseases in the last ten years;

- animal diseases of which the prevalence has increased in the last ten years.

b) Veterinary public health

i) Food hygiene

- Annual national slaughter statistics for the past three years according to official data by species of animals (bovine, ovine, porcine, caprine, poultry, farmed game, wild game, equine, other).

- Estimate of total annual slaughterings which occur but are not recorded under official statistics.

- Proportion of total national slaughter which occurs in registered export establishments, by category of animal.

- Proportion of total national slaughter which occurs under veterinary control, by category of animal.

- Numbers of commercial fresh meat establishments in the country which are registered for export by national *Veterinary Services*:

  - slaughterhouses (indicate species of *animals*);

  - cutting/packing plants (indicate meat type);

  - meat processing establishments (indicate meat type);

  - cold stores.

- Numbers of commercial fresh meat establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.

- Numbers of commercial fresh meat establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff *associated* with these premises).

- Description of the veterinary public health programme related to production and processing of animal products for human consumption (including fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.

- Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the national Veterinary Services do not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.

ii) Zoonoses

- Descriptive summary of the numbers and functions of staff of the *Veterinary Services* involved primarily with monitoring and control of zoonotic diseases.

- Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the national *Veterinary Services* do not have these responsibilities.

iii) Chemical residue testing programmes

- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.

- Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.

- Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv) Veterinary medicines

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.

- Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a) Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of *any* components thereof.

b) Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c) Audit

Details of independent (and internal) audit reports which have been undertaken of the *Veterinary Services* of components thereof.

9. Performance assessment and audit programmes

a) Strategic plans and review

i) Descriptive summary and copies of strategic and operational plans of the *Veterinary Services* organisation.

ii) Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans - copies of recent review reports.

b) Compliance

Descriptive summary of any compliance unit which monitors the work of the *Veterinary Services* (or elements thereof).

c) Annual reports of the national Veterinary Services

Copies of official annual reports of the national (sub-national) *Veterinary Services*.

d) Other reports

i) Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.

ii) Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

e) Training

i) Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.

ii) Summary descriptions of training courses and duration.

iii) Details of staff numbers (and their function) who participated in these training courses in the last three years.

f) Publications

Bibliographical list of scientific publications by staff members of *Veterinary Services* in the past three years.

g) Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary organisations with which the *Veterinary Services* have consultation or advisory mechanisms in place.

10. Membership of the OIE

State if country is a member of the OIE and period of membership.

11. Other assessment criteria

- - - - - - - - - - - - - - -

— text deleted

Appendix VI

Performance, Vision and Strategy (PVS) *for*

VETERINARY SERVICES (VS)[1]

Community position:
The Community supports this draft but please the comments in Chapter 1.3.3. at Appendix IV.

Introduction

In this era of globalization, the development and growth in many countries depends on the performance of their agricultural economies, and this, in turn, directly relates to the quality of their national veterinary services (VS). VS play also a major role in Veterinary public health including food-borne diseases and regional and international market access for animals and their products. To be effective, VS should operate based on scientific principles and be technically independent and immune from political pressures of its users'. However, efforts to strengthen official services, requires the active participation and investment on the part of both the public and the private sectors. To assist in this effort, the World Organization for Animal Health (OIE) and the Inter-American Institute for Cooperation on Agriculture (IICA) have joined forces to develop the Performance, Vision and Strategy (PVS) instrument. The PVS instrument can assist VS to establish their current level of performance, form a shared vision with the private sector, establish priorities and facilitate strategic planning in order to take full advantage of the new opportunities and obligations of globalization.

The OIE promotes animal health and public health including food-borne diseases safety in the international trade of animals and their related products by issuing harmonized sanitary guidelines on international certification and disease control methods and working to improve the resources and legal framework of the VS. Likewise, IICA helps to strengthen VS so they can be more efficient and competitive nationally and internationally and can contribute to the improved health of their consumers. Both organizations share a mutual interest to help countries comply with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO) and the standards, guidelines and recommendations of the OIE.

The traditional mission of VS has been to protect domestic agriculture and, over time, most of its resources were channeled toward the control of diseases[2] that threatened primary production. The focus of the services provided were from the national borders inward and the credibility of these services, in the eyes of its users and other countries, depended in large measure on the effectiveness of its domestic programs, and its response to emergencies arising from the entry of foreign diseases.

In light of the growing international requirements and opportunities facing countries, it behoves VS to adopt a broader mandate and vision, and provide new services that complement the portfolio of existing services. This will entail stronger alliances and closer cooperation with its users, other countries and their national veterinary service counter parts.

The WTO/SPS agreement reaffirms the right of the member countries to protect plant, animal and human life or health, but the agreement also requires that countries base their SPS measures on scientific principles and the OIE standards - the fundamental basis of operation

[1] Veterinary services means the Veterinary Administration, all the Veterinary Authorities, and all persons authorized, registered or licensed by the veterinary statutory body of a country. They will be called "VS" in all the document

[2] Clinical and/or pathological manifestation of an infection

to ensure that international trade is free of discrimination and scientifically unjustified restrictions.

Experience has shown that those countries, whose VS are more developed and credible in the eyes of its users, trading partners and other countries, contain four fundamental components: 1) the **technical capability** to address current and new issues based on scientific principles; 2) the **human and financial capital** to attract resources and retain professionals with technical and leadership skills; 3) the **interaction with the private sector** in order to stay on course and carry out relevant joint programs and services; and 4) the ability to **access markets** through the compliance with existing standards and the implementation of new disciplines such as harmonization of standards, equivalence and regionalization. These four components provide the basic structure of the PVS instrument.

Applying the PVS Instrument

To establish the current level of performance, form a shared vision, establish priorities and facilitate strategic planning, a series of five to eight critical competencies have been developed for each of the four fundamental components. For each critical competency, qualitative levels of advancement are described. To help visualize the potential or cumulative level of advancement within each critical competency, a pie chart is shown next to the written explanation for each level. A higher level of advancement assumes that the VS is complying with the preceding (and non zero) levels.

In addition to the qualitative levels, additional space has been provided after each critical competency to expand upon or clarify responses, if so desired. The following hypothetical example illustrates the level of advancement determined along with an explanation for the critical competency harmonization, one of the [twenty-eight] critical competencies in the PVS instrument.

3. Harmonization

The capability and authority of the VS to be active in harmonization and ensure that the national regulatory norms covered under its mandate are in conformity with relevant international standards, guidelines and recommendations.

Levels of advancement:

0. The VS has no process to be aware of international standards. National regulatory norms do not take account of international standards, guidelines and recommendations.
1. The VS is aware of relevant standards but has no process to identify gaps, inconsistencies, or non-conformities in national regulatory norms as compared to international standards, guidelines and recommendations.
2. The VS monitors the establishment of new international standards, guidelines and recommendations and periodically reviews national regulatory norms with the aim of harmonizing them as appropriate with international standards, guidelines and recommendations.
3. Same as previous level plus the VS is active in reviewing and commenting on draft standards, guidelines and recommendations.
4. Same as previous level plus the VS actively and regularly participates at the international level in the formulation of international standards, guidelines and recommendations.*

* A country could be active in international standard setting without actively pursuing national changes. The importance of this element is to promote national change.

Using the results

The PVS instrument is designated for easy understanding and is flexible in its application and use. More than a diagnostic tool, it is a process oriented towards the future which can be used in passive or active mode, depending on the level of interest and commitment by the users and the official service in improving their national services over time.

If it is used in the passive mode, the PVS instrument raises awareness, improves understanding and guides the different sectors participating in the process regarding the basic components and critical competencies the VS must contain in order to function adequately. In this mode the instrument can also be used to develop a shared vision, foster dialogue and adopt a common language for discussion.

The active mode is where the maximum potential is generated and the best results can be obtained, assuming the commitment is present on the part of both the public and private sector. In this mode, performance is assessed, differences are explored and priorities are established. Leadership on the part of the public sector is a critical element for success. This active mode is where actions happen, investments are evaluated and made and commitment is carried out. Continuity of the PVS process is assured when a true partnership between the official and the private sector exists.

As a very important additional reference, Chapter 1.3.3 on the Evaluation of Veterinary Services, in the Terrestrial Animal Health Code of the OIE and Chapter 1.4.3 on the Evaluation of Competent Authorities, in the Aquatic Animal Health Code, expand upon and further clarifies some of the levels of advancement described in some of the critical competencies of the PVS instrument. The instrument can be used to facilitate the dialogue with different users in the public and private sectors that share a common interest in improving the vision and performance of the public services. For example, the interested parties can jointly participate in establishing the current level of performance, identifying priorities and adopting actions that strengthen the national services. In addition, the director of the national VS can use the instrument to monitor progress in each one of the four components.

For the VS, the results of the PVS instrument can help to: 1) indicate the overall performance of each one of the four components; 2) rate the relative performance within each one of the critical competencies; 3) compare the performance of the VS with that of other veterinary services in the region or globally, in order to explore areas for cooperation or negotiation[3]; 4) identify the differences in the responses of the different users in order to arrive at common points of view; 5) foster common understanding in order to achieve greater levels of advancement; 6) help determine the benefits and costs of investing in VS and obtaining assistance from financial and technical cooperation agencies, 7) provide a basis for establishing a routine monitoring and follow up mechanism on the overall level of performance of the VS over time; and 8) help identify and present objectives and specific needs when applying for financial support (loans and/or grants). 9) Prepare a process of verification of compliance with OIE standards on quality and evaluation of VS by an external independent body under the auspices of the OIE.

FUNDAMENTAL COMPONENTS

I. TECHNICAL CAPABILITY

[3] OIE standards allow importing countries to make audits in exporting countries and in particular check the compliance of exporting countries with OIE standards on quality and evaluation of VS

II. HUMAN AND FINANCIAL CAPITAL

III. INTERACTION WITH THE PRIVATE SECTOR

IV. ACCESS TO MARKETS

I. TECHNICAL CAPABILITY

The capability of the VS to establish and apply sanitary measures and science-based procedures.

Critical competencies:

1. Diagnostic capability
2. Early detection and emergency response capability
3. Quarantine
4. Epidemiological surveillance
5. Quality systems
6. Risk analysis
7. Technical innovation

1. Diagnostic capability

The capability and authority of the VS to identify and record those biological, physical and chemical agents including those relevant for public health that can adversely affect animals and their related products.

Levels of advancement:

0. For existing diseases, the VS can carry out the clinical diagnosis, but not the laboratory[4] confirmation.

1. For zoonoses[5] and other diseases with a major economic or public health impact, the VS can collect samples in the country and immediately ship them to the laboratory for confirmation.

2. For zoonoses, and other diseases not present in the country, but known to exist in the region or could enter via trade, the VS has procedures in place to collect samples and immediately ship them to the laboratory for confirmation.

3. In the case of new and emerging diseases in the region or world, the VS has access to a network of national or international reference laboratories and can collect and ship samples to the most qualified laboratory for confirmation.

4. The VS actively promotes the accreditation of its laboratories and audits[6] the quality of its clinical diagnostic, collection and shipment of samples procedures.

2. Early detection and emergency response capability

[4] Means a properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results. The Veterinary Administration approves and monitors such laboratories with regard to the diagnostic tests required for international trade.

[5] Zoonoses (Zoonotic diseases): Any disease or infection which is naturally transmissible from animals to humans.

[6] Audits: A systematic and functionally independent examination, the objective of which is to determine if an activity or process and subsequent results meet the prescribed objectives.

The capability and authority of the VS to rapidly respond to unexpected disease outbreak[7] or other situations that put at immediate risk the sanitary status[8] of the animal populations covered under its mandate.

Levels of advancement:

0. The VS has no field network nor system to determine whether or not a sanitary emergency exists and it does not have the authority to declare such an emergency and take action.

1. The VS has a field network and a system to determine whether or not a sanitary emergency exists but lacks the necessary legal and financial support[9] to take action in response to sanitary emergencies.

2. The VS has a system to make timely decisions on whether or not a sanitary emergency exists. The VS has the legal framework and funding sources to take action in response[10] to sanitary emergencies through an efficient national chain of command.

3. Same as previous level plus the VS has contingency plans or general action plans for diseases of concern that enable it to coordinate actions with other relevant organizations or institutions and the private sector (including veterinary practitioner), in response to sanitary emergencies through an efficient national chain of command.

3. Quarantine

The capability and authority of the VS to prevent the entrance and spread of unwanted diseases in the country.

Levels of advancement:

0. The VS does not compile information on the sanitary status in its own country or maintain any type of quarantine procedures with its neighbouring countries or trading partners.

1. The VS has up-to-date information on exporting countries which it incorporates into its quarantine procedures for the commercial trade of primarily farm_animals and their related products that come into the country and may threaten its sanitary status.

2. The VS has up-to-date information on exporting countries which it incorporates into quarantine procedures for animals and their related products, even if of no significant trade or commercial value (e.g. companion animals) but enter into the country through established trade channels.

[7] Outbreak means an occurrence of one of the diseases listed by the OIE in an establishment, breeding establishment or premises, including all buildings and all adjoining premises, where animals are present. Where it cannot be defined in this way, the outbreak shall be considered as occurring in the part of the territory in which, taking local conditions into account, it cannot be guaranteed that both susceptible and non-susceptible animals have had no direct contact with affected or suspected cases in that area.

[8] The status of a country or compartment within the country with respect to a particular disease, in accordance to the criteria set forward in the Terrestrial Animal Health Code of the OIE.

[9] The phrase, legal and financial support, refers to the VS already having in place the legal framework and financial resources in order to take immediate actions.

[10] Appropriate response to sanitary emergency includes an appropriate early detection system

3. The VS can or has implemented specialized quarantine programs[11] in the country of origin for specific animals and their related products.

4. The VS carries out quality assurance audits of its own quarantine procedures and, if necessary, those of its trading partners, in compliance with OIE standards on quality and evaluation of VS.

4. Epidemiological surveillance[12]

The capability and authority of the VS to determine, monitor and verify the sanitary status of the animal populations covered under its mandate.
Levels of advancement:
0. The VS has no program in place for surveillance or monitoring.

1. The VS conducts a surveillance program based on existing information or suspected cases, where samples are collected and sent to the laboratories.

2. The VS conducts active monitoring programs in animal populations on diseases of economic and zoonotic importance.

3. The VS conducts surveillance programs in populations of greatest risk covering zoonoses, and other diseases of economic importance.

4. The VS structures its surveillance programs taking into account the sanitary status of its neighboring countries and trade flows.

5. Quality systems

The authority and capacity of VS to define their veterinary public health policies, formalize their activities, in particular concerning control and certification and making sure that these are well executed.
Levels of advancement:
0. The VS has no system for the control of their activities.

1. The VS has established an administrative structure capable of ensuring the chain of command, defining the required regulations and delegation of authority.

2. The VS has defined the policies and has evaluated the resource needs.

3. The VS has implemented a a general system for registering their procedures and instructions.

---

[11] Programs that facilitate the detection of transmissible diseases and make it possible to evaluate the health of the population in question before being transported.

[12] The term, surveillance, refers to the ongoing and systematic process of collecting, analyzing, interpreting and disseminating information on the sanitary status, including early detection of exotic and emerging diseases. The term, monitoring, is more specific in its application and is directed at detecting changes in the prevalence of a pest or disease for a given population and environment.
Surveillance and monitoring procedures take into account as a minimum basis the requirements published in the appendices of the relevant chapters of the OIE *Codes* and *Manuals*.

4. The VS has a system for the evaluation of the effectiveness of their services (internal audit).

5. The VS is subjected to external audits of its Quality system.

6. Risk analysis[13]

The capability of the VS to make decisions and carry out actions based on scientific principles and evidence, including the assessment, communication and management of risk.

Levels of advancement:

0. The VS does not compile data or other kinds of information that could be used to identify potential sanitary hazards and analyze risks. Sanitary decisions are not supported by scientific evidence.

1. The VS compiles and maintains sources of information or can access the information necessary in order to assess risks. Sanitary decisions may be based on scientific evidence.

2. The VS has a system to actively seek and maintain relevant data and information for risk assessment and dedicated personnel with this responsibility. Scientific principles and evidence provide the basis for options considered by sanitary decision makers in order to manage risks.

3. Same as previous level plus the VS is consistent in conducting scientifically based risk assessments in compliance with relevant OIE standards and communicating the decisions taken to the WTO/SPS, the OIE and its relevant trading partners.

4. Same as previous level plus the VS is consistent in managing and communicating the risks in conformity with the WTO/SPS Agreement and relevant standards of the OIE.

7. Technical innovation

The capability of the VS to update its overall service, in accordance with the latest scientific advances and based on the sanitary norms and measures of the OIE, Codex Alimentarius and the WTO/SPS Agreement.

Levels of advancement:

0. The VS has only informal access to technical innovations through personal contacts or external media sources.[14]

1. The VS maintains information base on technical innovations and international norms through subscriptions to scientific journals and electronic media.

2. The VS carries out a specific program that identifies technical innovations which can improve its operation and procedures.

[13] The term, *risk*, refers to the likelihood of an adverse event and the probable magnitude of the consequences in the importing country during a specified time period. *Risk analysis* refers to the assessment, management and communication of risk, not only for imports but for domestic issues which may also arise.

[14] External media are those sources of information that may not be available or subscribed to by the VS such as scientific publications and magazines

3. The VS incorporates technical innovations into selected functions and procedures, with specific resources and the collaboration or contributions of its users.[15]

4. The VS has a dedicated budget plus the collaboration and contributions of its users, to continually implement technical innovations throughout the national service.

II. HUMAN AND FINANCIAL CAPITAL

Institutional and financial sustainability as evidenced by the level of professional talent and financial resources available.

Critical competencies:

1. Human talent
2. Training
3. Funding sources
4. Stability of policies and programs
5. Contingency funds
6. Technical independence
7. Capability to invest and grow

1. Human talent (Initial training)

The capability of the VS to efficiently carry out the professional and technical functions; measured in two ways: academic degrees[16] and qualifications of its professional staff.

A veterinary positions:

Levels of advancement:

0 In the core of the VS the majority of the veterinary positions are not occupied by personnel holding a university diploma.

1 In the core of the VS the veterinary positions are defined in terms of the area of expertise, the placement within the structure, and the level of competence and of initial training (university degree recognized by the State).

2 In the core of the VS there is a service in charge of the management of human resources and of the appropriateness of positions and diplomas according to international standards.

3 The management of veterinary human resources is subject to internal audits.

A technical and administrative positions:

Levels of advancement:

0 . In the core of the VS the majority of technical and administrative positions are not occupied by personnel with professional qualifications[17].

[15] This includes consulting with the OIE, WTO, Codex websites and books for publications and notices and regular participation in international forum

[16] Not all professional positions require a academic degree. Nonetheless, the rate of academic degrees serves as an indicator of the professional excellence within the VS.

1 . In the core of the VS the majority of technical and administrative positions are occupied by personnel with professional qualifications.

2 . In the core of the VS the technical and administrative positions are defined in terms of the area of expertise, the placement within the structure, and the level of competence and of initial training (university degree recognized by the State.

3 . In the core of the VS there is a service in charge of the management of human resources and of the appropriateness of positions and diplomas according to international standards.

4 . The management of the entire human resources is subject to internal audits.

2. Training (Continuing education)

The capability of the VS to keep its personnel up-to-date in terms of relevant information and knowledge; measured in terms of the implementation of an annual training plan
Levels of advancement:

0. The VS has no training plans. (Continuing education plan)

1. The VS has training plans but they are not updated or funded.

2. The VS has annual training plans that are updated and funded but only partially implemented[18].

3. The VS has updated and funded training plans largely implemented.

4. The VS has up to date training plans implemented for everyone.

3. Funding sources

The ability of the VS to access financial resources for its continued operation and sustainability, independent of any type of political pressure from users.
Levels of advancement:

0. Funding for the VS is neither stable nor clearly defined. The budget for the national veterinary service competes with other State institutions and depends on resources allocated irregularly from the general treasury and/or non national donors.

1. The VS is funded from a continuous specific line item prescribed within the national budget as well as resources coming from non national donors if it is the case.

2. The VS is funded from a continuous specific line item prescribed within the national budget and with user fees generated by providing specific services (e.g. quarantine and certification services).

3. In addition to the previous levels, the VS also receives additional resources from its users[19] to execute specific programs under complete transparency and ensuring full independence[20].

---

[17] OIE international standards on quality and evaluation of VS make reference to the quality of the professional judgment.

[18] Partially implemented may be only implemented for some personnel or only partially implemented for all personnel.

4. Stability of policies and programs

The capability of the VS to implement and sustain policies and programs over time; measured by the frequency of which the entire VS is reorganized and by the coordination capability between government institutions.

A. Levels of advancement (VS reorganization):

0. The VS is reorganized frequently[21] at all levels.

1. The VS is reorganized frequently at some levels.

2. The VS is reorganized only at political levels after political changes.

3. The VS, is reorganized only occasionally at political levels after political changes.

4. The VS is stable at technical and political levels.

B. Levels of advancement (coordination capability between government institutions):

0. The national regulations do not clearly define the obligations and competencies of all the official sector institutions that comprise the VS.

1. There are national regulations that define the obligations and competencies of the official sector institutions at the national and local levels.

2. There are coordinated inter and intra institutional activities in the official sector at least at the national level.

3. There are coordinated inter and intra institutional activities in the official sector at both the national and local levels.

5. Contingency funds

The capability of the VS to access extraordinary financial resources in order to respond to emergency situations or emerging issues; measured by the ease of which contingency resources can be made available.

Levels of advancement:

0. No contingency fund exists and any extraordinary resources can only be obtained through legislation or presidential decree.

1. A contingency fund with limited resources has been established, but any additional resources must be approved via presidential decree or law.

2. A contingency fund with limited resources has been established, but any additional resources must be approved by the Minister of Agriculture.

3. A contingency fund with substantial resources has been established, but additional resources must be approved by the Minister of Agriculture.

4. A contingency fund with substantial resources has been established and includes additional resources previously made available by its users[22].

---

[19] Users means farmers, livestock traders and/or industry

[20] In compliance with OIE international standards on quality regarding independency and impartiality.

[21] a stable organization maintains its core structure and functions for 5 years or more

6. Technical independence

The capability of the VS to carry out its duties with autonomy and free from political interference that may affect technical and scientific decisions; measured in two ways: political appointments[23] and technical support for decisions.

A. Levels of advancement (management positions):

0. The Director General of the entire agricultural health and food safety institution (if applicable), the Director of the VS and his/her direct reports are political appointees.

1. The Director General of the entire agricultural health and food safety institution (if applicable) and the Director of the VS are the only political appointees.

2. The selection of the Directors is not made only on political considerations.

B. Levels of advancement (technical support for decisions):

0. The technical decisions made by the VS are almost always based on political considerations.

1. The technical decisions incorporate scientific principles, but must be modified to conform to any political considerations.

2. The technical decisions are based on scientific principles but are subject to review and possible modification based on political considerations.

3. The technical decisions are based only on scientific principles and are not changed to meet any political considerations[24].

7. Capability to invest and grow

The capability of the VS to secure additional investments over time that leads to a sustained improvement in the entire service. The utilization of such resources is not subject to any type of political pressure from its users.

Levels of advancement:

0. There are no sustained actions to support the overall structure of the VS.

1. The VS elaborates and presents proposals and secures investment resources for improvements and infrastructures from cooperation or donor agencies.

2. The VS secures over time, significant investment resources for improvements and infrastructure, through extraordinary allocations from the national (general treasury) or local public resources or special line items.

3. In addition to the previous levels, the beneficiaries including farmers and/or industry provide resources to the VS for improvements and infrastructure[25].

---

[22] "Users" means there all beneficiaries of the activities of VS, such as farmers, traders, consumers and industry.

[23] The phrase, political appointments, refers to appointments made by the party in office, serving at the pleasure of politicians and subject to immediate removal

[24] In accordance with the principles of the OIE *Codes* on quality of VS

III. INTERACTION WITH THE BENEFICIARIES

The capability of the VS to collaborate with and involve the beneficiaries (including farmers and/or industry) in the implementation of programs and activities.

Critical competencies:

1. Communication
2. Consultation of beneficiaries
3. Official representation
4. Accreditation
5. Statutory body
6. Joint action programs implementation

1. Communication

The capability of the VS to inform, in a transparent, effective and timely fashion, its users of activities, programs and developments.
Levels of advancement:

0. The VS has no mechanism in place to keep users informed of activities, programs and sanitary developments.

1. The VS maintains an official communication outlet, which users can consult regarding standards, regulations and notifications.

2. The VS routinely[26] publishes the results of its activities, programs and sanitary developments.

3. The VS provides up-to-date information, accessible via the internet, on sanitary developments and its programs and activities currently underway, and actively seeks input from the private sector, including farmers.

2. Consultation of beneficiaries

The capability of the VS to maintain fluid channels of consultation with the public and private sectors[27] and users[28].

Levels of advancement:

0. The VS has no consultation mechanisms in place to facilitate the dialogue between the relevant State institutions and the users.

1. The VS maintains informal channels of consultation with the relevant State institutions and the users.

[25] in compliance with OIE standards on independence and impartiality of VS
[26] Means every six months
[27] private sector includes farmers, industry, transport and distribution
[28]“ users” means all beneficiaries of the VS activities

2. The VS establishes and promotes official dialogue with the different users on its proposed and current regulations.

3. The VS holds forums and meetings with the different users in order to establish or improve its programs and services.

4. The VS actively promotes dialogue with and solicits feedback from the different users regarding national laws and regulations and official representation at the WTO/SPS and OIE

5. The VS actively promotes dialogue with and solicits feedback from the different users regarding national laws and regulations and official representation at the WTO/SPS, OIE and Codex Alimentarius.

3. Official representation

The capability of the VS to regularly and actively participate, coordinate and provide follow up to the meetings of international organizations such as the WTO/SPS, OIE and Codex Alimentarius[29].

Levels of advancement:

0. The VS does not participate in or follow up on the meetings of the WTO/SPS, OIE and Codex Alimentarius.

1. The VS participates sporadically or passively[30] in the meetings of the WTO/SPS, OIE and Codex Alimentarius.

2. The VS takes into consideration the opinions of its users and participates regularly and actively[31] in the meetings of the WTO/SPS, OIE and Codex Alimentarius.

3. The VS, in consultation with its different users, identifies strategic topics, provides leadership and coordinates between the national delegations these topics over time as part of the agenda in the meetings of the WTO/SPS, OIE and Codex Alimentarius.

4. Accreditation / Delegation

The capability and authority of the VS to accredit and delegate[32] with third parties (e.g. private veterinarians, laboratories, etc), the execution of specific official services.

Levels of advancement:

0. The VS has neither the authority nor the capability to accredit and delegate to third parties.

[29] in compliance with international procedures and practices.

[30] *Passive participation* refers to being present at, but contributing little, to the meetings in question

[31] *Active participation* refers to preparation in advance of, and contributing during the meetings in question, including exploring common solutions and generating proposals and compromises for possible adoption.

[32] In compliance with OIE standards on quality of VS

1. The VS has authority to accredit and delegate to third parties but no specific accreditation or delegation activities.

2. The VS has accreditation and delegation programs for third parties and selected services.

3. The VS can develop and implement accreditation and delegation programs for new services.

4. The VS carries out quality assurance audits of its accreditation and delegation programs through an efficient national chain of command in order to maintain the trust of its trading partners.

5. Statutory body

The veterinary statutory body, in accordance with the OIE's definition, is an independent authority charged with the registration/licensing of veterinarians and authorization of veterinary para-professionals. Among others, it verifies the validity and the level of the veterinary diploma required to exercise the veterinary profession.

Levels of advancement:

0. There is no veterinary statutory body in the country.

1. There is a veterinary statutory body, but it does not have the power to discipline or make decisions.

2. The veterinary statutory body can only exercise its authority within the private sector.

3. The veterinary statutory body can also exercise its authority within the public sector.

4. The veterinary statutory body is subjected to auditing and evaluation procedures.

6. Joint programmes implementation

The capability of the VS and the private sector to formulate and implement joint programs on annual and/or pluri-annual bases.

Levels of advancement:

0. The VS has no joint programs.

1. The VS has established annual and/or pluri-annual joint programs but they are not updated or funded.

2. The VS has annual and/or pluri-annual joint programs that are updated and funded but only partially implemented[33].

[33] Partially implemented may be only implemented for some activities or only partially implemented for all activities.

3. The veterinary has joint programs that are updated annually and fully implemented.

IV. ACCESS TO MARKETS

The capability and authority of the VS to provide support in order to access, expand and retain regional and international markets for animals and animal products.

Critical competencies:

1. Compliance with regulations
2. Setting of regulations
3. Harmonization
4. Certification
5. Equivalency agreements
6. Traceability
7. Transparency
8. Zoning
9. Compartmentalization

1. Compliance with regulations[34]

The capability and authority of the VS to ensure that users are in compliance with laws and regulations covered under its mandate.

Levels of advancement:

0. The VS has no program to ensure user compliance with laws and regulations.

1. The VS implements a compliance program consisting of inspection and verification of laws and regulations respect for selected animals, animal-products and processes, but only reports instances of non-compliance.

2. The VS implements a compliance program consisting of inspection and verification of laws and regulations respect for selected animals and animal products and processes, and, if necessary, imposes appropriate penalties in instances of non-compliance.

3. The VS implements a compliance program consisting of inspection and verification of laws and regulations respect for all animals, animal-products and processes covered under its mandate, and, if necessary, impose appropriate penalties in instances of non-compliance.

4. The VS carries out audits of its inspection and verification compliance programs through an efficient national chain of command.

2. Setting of regulations[35]

The capability and authority of the VS to propose laws and to formulate and adopt regulations for animals, animal-products and processes covered under its mandate.

[34] Regulations are sanitary measures that include all pertinent laws, decrees, regulations and technical prescriptions and procedures. Compliance is verified by VS through inspections and performance assessments

[35] Regulations are sanitary measures that include all pertinent laws, decrees, regulations and technical prescriptions and procedures. Compliance is verified by VS through inspections and performance assessments

Levels of advancement:

0. The VS does not have the authority to prepare national legislation and set regulations.

1. The VS has the technical capability to propose national legislation and formulate regulations.

2. The VS is based on national legislation and has the flexibility and legal framework necessary in order to propose legislation and set regulations s.

3. The VS is based on national legislation and proposes legislation and set regulations, applying procedures that take into consideration the opinions of its users.

3. International harmonization

The capability and authority of the VS to be active in international harmonization and ensure that the national laws and regulation covered under its mandate are in conformity with relevant international standards, guidelines and recommendations.

Levels of advancement:

0. The VS has no process to be aware of international standards. National laws and regulation do not take account of international standards, guidelines and recommendations.

1. The VS is aware of relevant standards but has no process to identify gaps, inconsistencies, or non-conformities in national laws and regulation as compared to international standards, guidelines and recommendations.

2. The VS monitors the establishment of new international standards, guidelines and recommendations and periodically reviews national laws and regulation with the aim of harmonizing them as appropriate with international standards, guidelines and recommendations.

3. Same as previous level plus the VS is active in reviewing and commenting on draft standards, guidelines and recommendations to relevant intergovernmental organizations.

4. Same as previous level plus the VS actively and regularly participates at the international level in the formulation, negotiation and adoption of international standards, guidelines and recommendations.[36]

4. Certification[37]

[36] A country could be active in international standard setting without actively pursuing national changes. The importance of this element is to promote national change.

[37] All certification procedures have to take into account the OIE standards on quality of VS and on certification.
In carrying out certification programmes, the VS must always operate free of political interference from the private sector. However some of these programmes can be executed by independent parties, which have been delegated and audited by the Veterinary Services.

The capability and authority of the VS to certify products, services and processes covered under its mandate and in accordance with the national laws and regulations and international standards, guidelines and recommendations.

Levels of advancement:

0. The VS has neither the capability nor the authority to certify animal health status, products, services or processes.

1. The VS has the authority to certify selected animals, animal products, services or processes.

2. The VS carries out certification programs for selected animals, animal products, services or processes.

3. The VS can develop and carry out certification programs for all animals, animal products, services or processes.

4. The veterinary service has certification power as necessary for all relevant animals and animal products and carries out audits of its certification programs through an efficient national chain of command in order to maintain confidence in its system.

5. Equivalency[38] and other sanitary agreements

The capability and authority of the VS to negotiate implement and maintain equivalency and other sanitary agreements with other countries on veterinary requirements under its mandate.

Levels of advancement:

0. The VS has neither the authority nor the capability to negotiate and approve equivalency and other sanitary agreements with other countries.

1. The VS has the authority to negotiate and approve equivalency and other sanitary agreements with other countries.

2. Same as previous level plus the VS evaluates and proposes equivalency and other sanitary agreements with other countries on selected animals, animal products and processes.

3. Same as previous level plus the VS actively pursues the development of equivalency and other sanitary agreements with other countries on new products and processes.

4. Same as previous level plus the VS has a program that includes the feedback of its users along with advances in international standards, guidelines and recommendations, and then pursues specific equivalency and other sanitary agreements with other countries.

[38] The term, equivalency, refers to the state wherein the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same level of protection
Guidelines on equivalency published in the OIE Codes have to be taken into account

6. Traceability

The capability and authority of the VS to track the history, location and distribution of animals and their related products covered under its mandate[39].

Levels of advancement:

0. The VS has no program to track animals and their related products.

1. The VS can document and inspect the sanitary status at specific points across the agro-food chain for selected animals and their related products.

2. The VS has procedures in place and can track and inspect selected animals and their related products across that portion of the agri-food chain covered under its mandate.

3. The VS, along with the other relevant State institutions and its users, has coordinated procedures in place that can track and inspect animals and related animal products across the entire agri-food chain.

4. The VS, in cooperation with the other relevant State institutions and its users, carries out audits of its traceability procedures.

5. The VS manage and/or inspect a national data base on relevant animals and their movements.

7. Transparency

The capability and authority of the VS to notify the WTO/SPS and the OIE of its national regulations, sanitary status and decisions on the control of relevant diseases, in accordance with the obligations, standards and procedures established by these organizations.

Levels of advancement:

0. The VS does not notify the WTO/SPS and the OIE of its national regulations and decisions on control of relevant diseases, and the OIE of its sanitary status.

1. The VS partially notifies the WTO/SPS and the OIE of its national regulations and decisions on control of relevant diseases, and the OIE of its sanitary status.

2. The VS notifies the WTO/SPS and the OIE of its national regulations and decisions on control of relevant diseases, and the OIE of its sanitary status, in full compliance with the criteria established by these organizations.

3. The VS informs users of changes in its regulations and decisions on control of relevant diseases and sanitary status, changes in the regulations and sanitary status of other countries, and raises awareness with its users of the importance of being transparent.

[39] In compliance with OIE definitions, guidelines and relevant chapters of the Code on certain diseases.

4. The VS, along with the other relevant State institutions, carries out audits of its transparency procedures[40] through an efficient national chain of command.

8. Zoning[41]

The capability and authority of the VS to establish and maintain disease free zones/ [42] or zones/ of low disease prevalence[43], in accordance to the criteria established by the WTO/SPS and the OIE.

Levels of advancement:

0. The VS cannot establish disease free zones or zones of low disease prevalence.

1. The national veterinary service can identify sub-populations to be regionalized, and establish the current sanitary status of selected animals and their related products originating from these prescribed areas.

2. The VS has implemented biosecurity control measures that enable it to establish disease free zones or zones of low disease prevalence for selected animals and their related products.

3. The VS collaborates with its users and relevant State institutions to define responsibilities execute actions and otherwise enable it to maintain disease free zones or zones of low disease prevalence for selected animals and their related products.

4. The VS demonstrates scientifically, the establishment of disease free zones/ or zones of low disease prevalence, and gains the recognition as such by other countries for selected animals and their related products.

5. The VS has a specific program that defines, establishes and demonstrates scientifically, new disease free zones or zones of low disease prevalence

9. Compartmentalization [44]

The capability and authority of the VS to establish and maintain disease free compartments[45] / or compartments / of low disease prevalence[46], in accordance to the criteria established by the WTO/SPS and the OIE.

---

[40] In compliance with OIE standards on evaluation of VS

[41] For purposes of the Terrestrial Code and the OIE, *'zoning' and 'regionalization'* have the same meaning. Implementation of these concepts has to take into account OIE standards included in the Codes

[42] The phrase, disease free zones: refers to animal sub-populations in which the absence of a given disease has been demonstrated to occur in accordance to the provisions outlined in the Terrestrial Animal Health Code of the OIE.

[43] The phrase, zones of low disease prevalence, refers to zones, which can encompass the entire territory of a country, part of a country, or subpopulations within a country, in which a given disease exists only to a limited extent, and is subject to effective surveillance, control or eradication measures

[44] Implementation of this concepts has to take into account OIE standards included in the Codes

[45] The phrase, disease free compartments, refers to animal sub-populations in which the absence of a given disease has been demonstrated to occur in accordance to the provisions outlined in the Terrestrial Animal Health Code of the OIE

[46] The phrase, compartments of low disease prevalence, refers to compartments, which can encompass subpopulation within a compartment, in which a given disease exists only to a limited extent, and is subject to effective surveillance, control or eradication measures.

Levels of advancement:

0. The VS cannot establish disease free compartments or compartments of low disease prevalence.
1. The national veterinary service can identify sub-populations to be regionalized, and establish the current sanitary status of selected animals and their related products originating from these prescribed areas.
2. The VS has implemented biosecurity control measures that enable it to establish disease free compartments or compartments of low disease prevalence for selected animals and their related products.
3. The VS collaborates with its users and relevant State institutions to define responsibilities execute actions and otherwise enable it to maintain disease free compartments or compartments of low disease prevalence for selected animals and their related products.
4. The VS demonstrates scientifically, the establishment of disease free compartments or compartments of low disease prevalence, and gains the recognition as such by other countries for selected animals and their related products.
5. The VS has a specific program that defines, establishes and demonstrates scientifically, new disease free compartments or compartments of low disease prevalence.

CHAPTER 1.3.5.

ZONING AND COMPARTMENTALISATION

Community position:
The Community supports this proposal but has some comments which it would like reviewed during the next meeting of the Code Commission for possible inclusion in the Chapter. However it would like to highlight that there are differences of opinion in interpreting a zone. Some member countries appear to believe that one can only have a free zone however this is not true as one can have an infected zone and the rest of the country free; trade can take place from the rest of the country. It all depends on if one is eradicating a disease or if there has been a disease incursion. The Community would strongly suggest that this is better clarified in the text. Furthermore problems are continually being raised in Geneva concerning the implementation of this Chapter and the Community requests that the OIE liaise with the WTO SPS to ensure that any administrative guidelines on regionalisation produced there are compatible with the OIE Code Chapter and do not encroach on the technical responsibilities of the OIE. It is very important for trade that member countries regionalise without unnecessary delay. If the procedures take longer than the time scales in the OIE code for regaining the status of the country then nothing is gained. In this context the Community would ask the OIE to consider expanding official OIE recognition to other diseases, as was done for BSE, and to take into account particular disease problems in wildlife.

Article 1.3.5.1.

Introduction

For the purposes of this *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.

Given the difficulty of establishing and maintaining a disease free status for an entire country, especially for diseases the entry of which is difficult to control through measures at national boundaries, there may be benefits to Member Countries in establishing and maintaining a *subpopulation* with a different animal health status within national boundaries. *Subpopulations* may be separated by natural or artificial geographical barriers, or in certain animal industries, by the application of appropriate management systems, including biosecurity management.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this Chapter with a view to defining *subpopulations* of different *animal health status* within its territory for the purpose of disease control and/or *international trade*. Compartmentalisation applies to a *subpopulation* when management systems related to biosecurity are applied, while zoning applies when a *subpopulation* is defined on a geographical basis.

This chapter is to assist OIE Member Countries to establish and maintain different *subpopulations* within their national ~~boundaries~~ borders using the ~~procedures~~ principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant disease chapter(s). It also outlines a process for trading partners to follow in achieving recognition of such *subpopulation*. These procedures are best implemented by trading partners through establishing parameters

and gaining agreement on the necessary measures prior to *disease outbreaks*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its animal health status will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its ~~boundaries~~ borders and within its territory.

The benefits of zoning and compartmentalisation may include a contribution to disease control or eradication within Member Countries, and to the safety of *international trade*. Zoning may encourage the more efficient use of resources within certain parts of a country to allow trade in certain *commodities* from that *zone* in accordance with this *Terrestrial Code*. Compartmentalisation may allow safe trade due to the functional separation of a *sub-population* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, compartmentalisation may be able to take advantage of ~~epidemiological linkages~~ common practices relating to biosecurity despite diverse geographical locations, to facilitate disease control.

Separate requirements will be developed for each disease for which the application of zoning or compartmentalisation is considered appropriate.

Article 1.3.5.2.

General considerations

~~Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its animal health status will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its boundaries and within its territory.~~

~~The benefits of zoning and compartmentalisation may include a contribution to disease control or eradication within Member Countries, and to the safety of *international trade*. Zoning may encourage the more efficient use of resources within certain parts of a country to allow trade in certain *commodities* from that *zone* in accordance with this *Terrestrial Code*. Compartmentalisation may allow safe trade due to the functional separation of a *sub-population* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation alone) would not achieve. Following a *disease outbreak*, compartmentalisation may be able to take advantage of epidemiological linkages despite diverse geographical locations, to facilitate disease control.~~

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the measures stipulated in the relevant Chapters in this *Terrestrial Code* and should be able to explain to the *Veterinary Services* of an *importing country* the basis for its claim of a distinct animal health status for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct health status of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the disease, environmental factors, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, commercial management and husbandry practices), and surveillance and monitoring. The *exporting country* should be able to demonstrate, through detailed documentation published through official channels, that it has implemented the measures stipulated in this *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

Community written comments:

The Community suggests that the above be reworded to clarify that the movement controls include both trade from other countries and introduction from other parts of the same country.

An *importing country* should recognise the existence of this *zone* or *compartment* when ~~the *Veterinary Administration* of the *exporting country* certifies that~~ the appropriate measures recommended in this *Terrestrial Code* are applied and the *Veterinary Administration* of the *exporting country* certifies that this is the case.

Article 1.3.5.3.

Prerequisite considerations in defining a zone or compartment

The *exporting country* should conduct an ~~practical~~ assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry, in the case of a *compartment*).

Article 1.3.5.4.

Principles for defining a zone or compartment

In conjunction with the above considerations, defining a *zone* or *compartment* should be based on the application of the following principles:

1. The extent of a *zone* and its limits should be established by the *Veterinary Administration* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.

2. The requirements regarding a compartment should be established by the *Veterinary Administration* on the basis of relevant criteria such as biosecurity management and husbandry practices, and made public through official channels.

3. Animals and herds belonging to ***subpopulations*** need to be clearly recognizable as such. The ***Veterinary Administration*** should document in detail the measures taken to ensure the identification of the ***subpopulation*** and the recognition and maintenance of its health status.

4. ~~The requirements necessary to preserve the distinct health status of a *zone* or *compartment* should be appropriate to the particular *disease* and will depend on the epidemiology of the *disease*, environmental factors, biosecurity management, animal husbandry practices, control measures~~ The procedures used to establish and maintain the distinct health status of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, commercial management and husbandry practices), and surveillance.

5. Thus defined, the *zones* and ***compartments*** constitute the relevant ***subpopulations*** for the application of the recommendations in Part 2 of this ***Terrestrial Code***.

Article 1.3.5.5.

Sequence of steps to be taken in defining a zone/compartment

Sequence of steps to be taken in defining a zone/compartment and having it recognised for trade purposes

There is no single sequence of steps which must be followed in defining a *zone* or a *compartment*. The steps that the *Veterinary Services* of *importing* and *exporting countries* choose and implement will generally depend on the circumstances existing within a country and at its borders. The recommended steps are:

1. For zoning

a) The *exporting country* identifies a geographical area within its territory which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific *disease*/specific *diseases*, based on *surveillance* and *monitoring*.

b) The *exporting country* identifies the procedures which are being, or could be, employed to distinguish such an area epidemiologically from other parts of its territory, in accordance with the measures stipulated in this *Terrestrial Code*.

c) The *exporting country* provides the information above to the *importing country*, and explains that the area can be treated as an epidemiologically separated *zone* for *international trade* purposes.

d) The *importing country* determines whether it may accept such an area as a *zone* for the importation of *animals* and animal products, taking into account:

i) an evaluation of the *exporting country*'s *Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the *disease*(s) concerned; and

iv) other relevant OIE standards.

e) The *importing country* notifies the *exporting country* of the result of its determination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *zone*;

ii) request for further information; or

iii) rejection of the area as a *zone* for *international trade* purposes.

f) An attempt should be made to resolve any differences ~~of opinion~~ over the definition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

g) The *importing country* and the *exporting country* may enter into a formal agreement defining the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant enterprise/industry, the *Veterinary Administration* of the *exporting country* identifies within its territory one or more *establishments* or other premises owned by an enterprise(s) which operates under a common biosecurity management system, and which it considers contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific *disease*/specific *diseases*; and that this status is maintained through a partnership between the relevant enterprise/industry and the *Veterinary Services* of the *exporting country*.

b) The *exporting country* examines the 'biosecurity management manual' produced by the enterprise/industry for such *establishment*(s), and confirms through an audit that:

i) such *establishment*(s) is(are) epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its 'biosecurity management manual' and;

ii) the surveillance and monitoring programme in place is appropriate to verify the free status of such *establishment*(s) with respect to such *disease*(s).

Community written comment:
The disease situation of the area in which a zone/compartment is included, should be considered.
The Community proposes the following wording: "the surveillance and monitoring programme in place is appropriate to verify the free status of such establishment(s) with respect to such disease(s) as well as the situation in the geographical area of the (parts of the) compartments."

c) The *exporting country* identifies such an enterprise to be a *free compartment*, in accordance with the measures stipulated in this *Terrestrial Code*.

d) The *exporting country* provides the information above to the *importing country*, and explains that such an enterprise can be treated as an epidemiologically separated *compartment* for *international trade* purposes.

e) The *importing country* determines whether it may accept such an enterprise as a *compartment* taking into account:

i) an evaluation of the *exporting country*'s *Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the *disease*(s) concerned; and

iv) other relevant OIE standards.

f) The *importing country* notifies the *exporting country* of the result of its examination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *compartment*;

ii) request for further information; or

iii) rejection of such an enterprise as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences ~~of opinion~~ over the definition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

h) The *importing country* and the *exporting country* may enter into a formal agreement defining the *compartment*.

- - - - - - - - - - - - - - -
— text deleted

CHAPTER 2.1.1.

CRITERIA FOR LISTING DISEASES

Community position:
The Community supports this proposal but points out one spelling mistake.

In addition the Community also appreciates that highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry will be included in the OIE disease list and that all members will need to report these outbreaks starting from the end of the General Session.

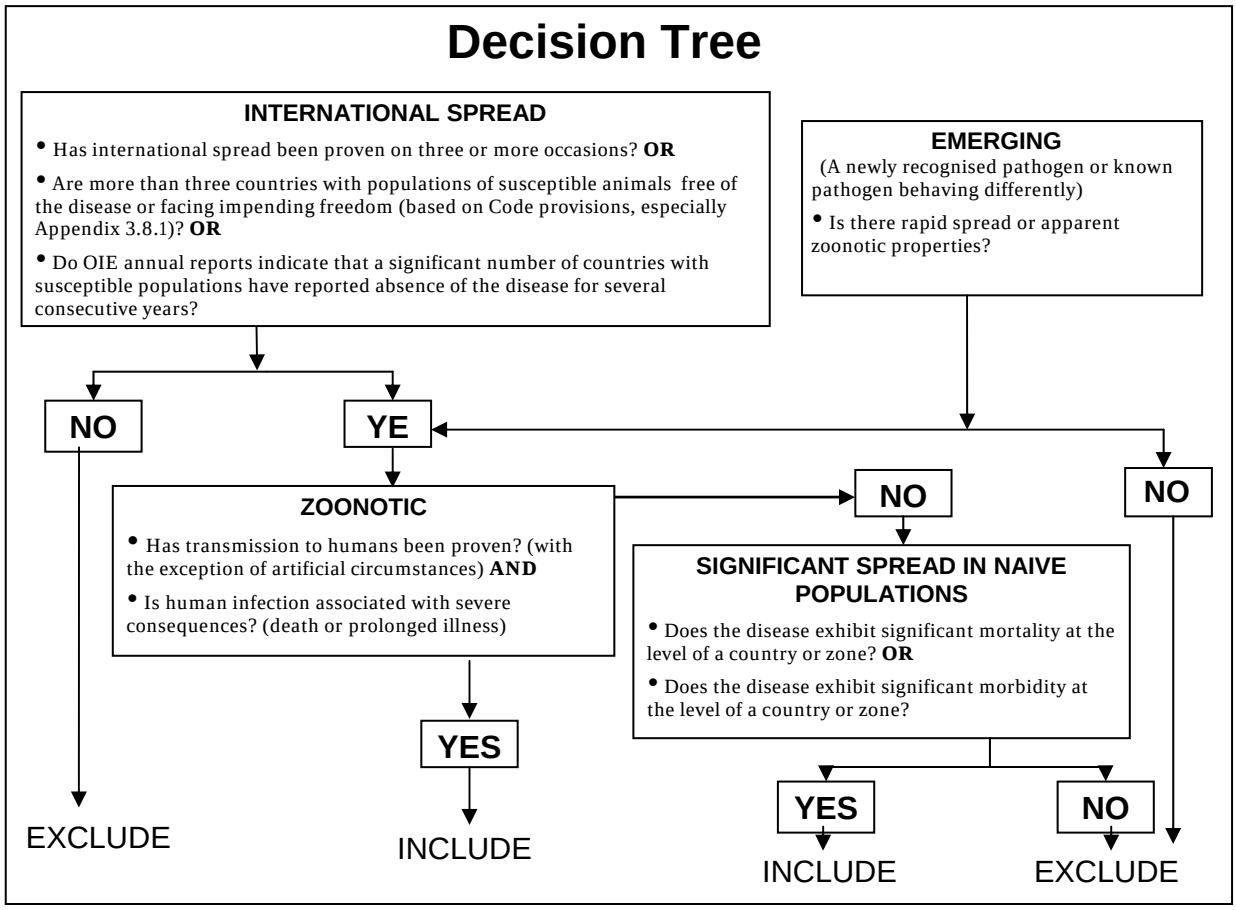
Article 2.1.1.1.

The criteria for the inclusion of a disease in the OIE List are as follows:

Basic criteria	**Parameters (at least one 'yes' answer means that the criterion has been met)**
International Spread	Has international spread been proven on three or more occasions? **OR** Are more than three countries with populations of susceptible animals free of the disease or facing impending freedom (based on the *Terrestrial Code* provisions, especially Appendix 3.8.1)? **OR** Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the disease for several consecutive years?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) **AND** Is human infection associated with severe consequences? (death or prolonged illness)
Significant Spread within Naïve Populations	Does the disease exhibit significant mortality at the level of a country or *zone/ ~~compartment~~*? **~~AND/~~OR** Does the disease exhibit significant morbidity at the level of a country or *zone/ ~~compartment~~*?
Emerging Diseases	Are there ~~rapid spread~~ ~~and/or~~ apparent zoonotic properties or rapid spread

Article 2.1.1.2.

The criteria in Article 2.1.1.1. above are applied according to the decision-making model shown below:



Article 2.1.1.3.

The following diseases are included in the OIE List.

1. The following diseases are included within the category of multiple species diseases:

   - Anthrax
   - Aujeszky's disease
   - Bluetongue
   - Brucellosis (*Brucella abortus*)
   - Brucellosis (Brucella melitensis)
   - Brucellosis (*Brucella suis*)
   - Crimean Congo haemorrhagic fever
   - Echinococcosis/hydatidosis
   - Foot and mouth disease
   - Heartwater

- Japanese encephalitis
- Leptospirosis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

2. The following diseases are included within the category of cattle diseases:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis
- Bovine viral diarrhoea
- Contagious bovine pleuropneumonia.
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Lumpy skin disease
- Malignant catarrhal fever (Wildbeest only)

Community written comment:
The Community believes the OIE is referring to "Wildebeest" not "Wildbeest".

- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

3. The following diseases are included within the category of sheep and goat diseases:

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Peste des petits ruminants
- Salmonellosis (*S.* abortusovis)
- Scrapie
- Sheep pox and goat pox.

4. The following diseases are included within the category of equine diseases:

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Eastern)
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- Surra (*Trypanosoma evansi*)

- Venezuelan equine encephalomyelitis.

5. The following diseases are included within the category of swine diseases:

   - African swine fever
   - Classical swine fever
   - Nipah virus encephalitis
   - Porcine cysticercosis
   - Porcine reproductive and respiratory syndrome
   - Swine vesicular disease
   - Transmissible gastroenteritis.

6. The following diseases are included within the category of avian diseases:

   - Avian chlamydiosis
   - Avian infectious bronchitis
   - Avian infectious laryngotracheitis
   - Avian mycoplasmosis (*M. gallisepticum*)
   - Avian mycoplasmosis (M. synoviae)
   - Duck virus hepatitis
   - Fowl cholera
   - Fowl typhoid
   - Highly pathogenic avian influenza <u>in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 2.7.12</u>
   - Infectious bursal disease (Gumboro disease)
   - Marek's disease
   - Newcastle disease
   - Pullorum disease
   - Turkey rhinotracheitis.

7. The following diseases are included within the category of lagomorph diseases:

   - Myxomatosis
   - Rabbit haemorrhagic disease.

8. The following diseases are included within the category of bee diseases:

   - Acarapisosis of honey bees
   - American foulbrood of honey bees
   - European foulbrood of honey bees
   - Small hive beetle infestation (*Aethina tumida*)
   - *Tropilaelaps* infestation of honey bees
   - Varroosis of honey bees.

9. The following diseases are included within the category of other diseases:

   - Camelpox
   - Leishmaniosis.

- - - - - - - - - - - - - - -
— text deleted

Appendix IX

CHAPTER 2.2.10.

FOOT AND MOUTH DISEASE

Community position:
The Community can support this proposal but the Community would like the minor inconsistencies indicated below taken on board. In addition it would like to point out that it is still very concerned about the requirements in Article 2.2.10.20 as it believes the risk of importing bone in meat from an area which is free of FMD with vaccination may be too high. The recent FMD outbreaks tend to highlight this problem as there have been some confirmed outbreaks and in addition some suspicions with clinical signs but no virus isolation in certain vaccinated areas.

Article 2.2.10.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include animals of the family of Camelidae.

For the purposes of this Chapter, a *case* includes an animal infected with FMD virus (FMDV).

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

1. FMDV has been isolated and identified as such from an animal or a product derived from that animal, or

2. viral antigen or viral RNA specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV, or

3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

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

Article 2.2.10.2.

FMD free country where vaccination is not practised

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a country should:

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

2. send a declaration to the OIE stating 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,

   and supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation and that regulatory measures for the prevention and control of FMD have been implemented;

3. not have imported since the cessation of vaccination any animals vaccinated against FMD.

The country will be included in the list only after the submitted evidence has been accepted by the OIE.

Article 2.2.10.3.

FMD free country where vaccination is practised

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a country should:

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

2. send a declaration to the OIE that 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:

    a) surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

    b) routine vaccination is carried out for the purpose of the prevention of FMD;

    c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

The country will be included in the list only after the submitted evidence has been accepted by the OIE.

If an FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the country should wait for 12 months after vaccination has ceased and provide evidence showing that FMDV circulation has not occurred during that period.

Article 2.2.10.4.

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. Susceptible animals in the FMD *free zone* should be separated from the rest of the country, if infected, and 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 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 <u>within the proposed FMD *free zone*</u>:

    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 Articles 2.2.10.8.;

3. supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation in the <u>proposed</u> 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, if applicable, the *buffer zone* <u>or physical or geographical barriers</u>,

    c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the FMDV *free zone* (in particular if the procedure described in

Article 2.2.10.8. is implemented),

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

The proposed 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.

Article 2.2.10.5.

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. Susceptible animals in the FMD free *zone* where vaccination is practised should be separated from the rest of the country, if infected, and 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 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 an FMD free *zone* or *compartment* 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 circulation in accordance with Appendix 3.8.7. is in operation in the proposed FMD free *zone*;

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, if applicable, the *buffer zone* or physical or geographical barriers,

   c) the system for preventing the entry of the virus into the FMD free *zone* (in particular if the procedure described in Article 2.2.10.8. 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 and FMDV circulation 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 is required and evidence must be provided showing that FMDV infection has not occurred in the said *zone* during that period.

Article 2.2.10.6.

FMD infected country or zone

An FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.

An FMD infected *zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.

Article 2.2.10.7.

Recovery of free status

1. When an FMD *outbreak* or FMDV infection occurs in an FMD free country or *zone* where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is not practised:

   a) 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.7.; or

   b) 3 months after the slaughter of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.7.; or

   c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.7., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 2.2.10.2 or 2.2.10.4. applies.

2. When an FMD *outbreak* or FMDV infection occurs in an FMD free country or *zone* where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is practised:

   a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation, or

   b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

Article 2.2.10.8.

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

FMD susceptible animals should only leave the infected *zone* if moved by mechanised transport to the

nearest designated abattoir located in the *buffer zone* directly to slaughter.

In the absence of an abattoir in the *buffer zone*, live FMD susceptible animals can be transported to the nearest abattoir in a free *zone* directly to 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* during the time it is handling the meat of animals from the *infected zone*;

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

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.

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 2.2.10.11.

Article 2.2.10.9.

When importing from FMD free countries or *zones* where vaccination is not practised, *Veterinary Administrations* should require:

for FMD susceptible animals

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

1. showed no clinical sign of FMD on the day of shipment;

2. were kept in an FMD free country or *zone* where vaccination is not practised since birth or for at least the past 3 months.

Community written comment:
The Community notes that the Scientific Commission has been asked to further examine the need for such a requirement in Articles 2.2.10.9. and 2.2.10.10.

3. have not been vaccinated.

Article 2.2.10.10.

When importing from FMD free countries or *zones* where vaccination is practised, *Veterinary*

Administrations should require:

for domestic ruminants and pigs

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

1. showed no clinical sign of FMD on the day of shipment;

2. were kept in an FMD free country since birth or for at least the past 3 months; and

Community written comment:
The words "or *zone*" should be added after country.

3. have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to an FMD free country or *zone* where vaccination is not practised.

Article 2.2.10.11.

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

for domestic ruminants and pigs

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

1. showed no clinical sign of FMD on the day of shipment;

2. were kept in the *establishment* of origin since birth, or

   a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,

   and that FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and

3. were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *establishment* during that period; or

4. were kept in a *quarantine station* for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *quarantine station* during that period;

5. were not exposed to any source of FMD infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 2.2.10.12.

When importing from FMD free countries or *zones* where vaccination is not practised, *Veterinary Administrations* should require:

for fresh semen of domestic ruminants and pigs

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

1. the donor animals:

    a) showed no clinical sign of FMD on the day of collection of the semen;

    b) were kept in an FMD free country or *zone* where vaccination is not practised for at least 3 months prior to collection;

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

Article 2.2.10.13.

When importing from FMD free countries or *zones* where vaccination is not practised, *Veterinary Administrations* should require:

for frozen semen of domestic ruminants and pigs

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

1. the donor animals:

    a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

    b) were kept in an FMD free country or *zone* where vaccination is not practised for at least 3 months prior to collection;

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

Article 2.2.10.14.

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

for semen of domestic ruminants and pigs

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

1. the donor animals:

    a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

    b) were kept in a country or *zone* free from FMD for at least 3 months prior to collection;

    c) if destined to an FMD free country or *zone* where vaccination is not practised:

        i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3. the semen:

a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant;

b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.15.

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

for semen of domestic ruminants and pigs

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

1. the donor animals:

a) showed no clinical sign of FMD on the day of collection of the semen;

b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3. the semen:

a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant;

b) was subjected, with negative results, to a test for FMDV infection if the donor animal has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.16.

Irrespective of the FMD status of the *exporting country* or *zone*, *Veterinary Administrations* should authorise

without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.10.17.

When importing from FMD free countries or *zones* where vaccination is not practised, *Veterinary Administrations* should require:

for *in vitro* produced embryos of cattle

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

1. the donor females:
    a) showed no clinical sign of FMD at the time of collection of the oocytes;
    b) were kept in a country or *zone* free from FMD at the time of collection;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.18.

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

for *in vitro* produced embryos of cattle

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

1. the donor females:
    a) showed no clinical sign of FMD at the time of collection of the oocytes;
    b) were kept in a country or *zone* free from FMD for at least 3 months prior to collection;
    c) if destined for an FMD free country or *zone* where vaccination is not practised:
        i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or
        ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;
2. no other animal present in the *establishment* has been vaccinated within the month prior to collection;
3. fertilization was achieved with semen meeting the conditions referred to in Articles 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;

4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.19.

When importing from FMD free countries or *zones* where vaccination is not practised, *Veterinary Administrations* should require:

for *fresh meat* of FMD susceptible animals

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 not practised since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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 2.2.10.20.

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

for *fresh meat* of cattle and buffalo (*Bubalus bubalis*) (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 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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 2.2.10.21.

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

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

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 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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 2.2.10.22.

When importing from FMD infected countries or *zones*, where an official control programme exists, involving compulsory systematic vaccination of cattle, *Veterinary Administrations* should require:

for *fresh meat* of cattle and buffalo (*Bubalus bubalis*) (excluding feet, head and viscera)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:

1. comes from animals which:

   a) have remained in the *exporting country* for at least 3 months prior to slaughter;

   b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to slaughter;

   d) were kept for the past 30 days in an *establishment,* and that FMD has not occurred within a 10-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the *approved abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

   f) have been slaughtered in an *approved abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before slaughter and the shipment for export has been dispatched;

   g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after slaughter;

2. comes from deboned carcasses:

   a) from which the major lymph nodes have been removed;

   b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.2.10.23.

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

for *meat products* of domestic ruminants and pigs

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

1. the entire consignment of *meat* comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with

favourable results;

2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.1.;

3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 2.2.10.24.

When importing from FMD free countries or *zones* (where vaccination either is or is not practised), *Veterinary Administrations* should require:

for *milk* and *milk products* intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in the country or *zone* since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.

Article 2.2.10.25.

When importing from FMD infected countries or *zones* where an official control programme exists, *Veterinary Administrations* should require:

for *milk*, cream, milk powder and *milk products*

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

1. these products:

   a) originate from herds or flocks which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 2.2.10.26.

When importing from FMD infected countries, *Veterinary Administrations* should require:

for blood and meat-meals (from domestic or wild ruminants and pigs)

the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core ~~internal~~ temperature of 70°C for at least 30 minutes.

Article 2.2.10.27.

When importing from FMD infected countries, *Veterinary Administrations* should require:

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

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

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.;

2. the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Administrations can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 2.2.10.28.

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

for straw and forage

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

1. are free of grossly identifiable contamination with material of animal origin;
2. have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,
   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

3. have been kept in bond for at least 3 months (under study) before being released for export.

Article 2.2.10.29.

When importing from FMD free countries or *zones* (where vaccination either is or is not practised), *Veterinary Administrations* should require:

for skins and trophies derived from FMD susceptible wild animals

the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been kept in such a country or *zone* since birth, or which have been imported from a country or *zone* free of FMD (where vaccination either is or is not practised).

Article 2.2.10.30.

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

for skins and trophies derived from FMD susceptible wild animals

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 3.6.2.7.

~~*[Note:* International veterinary certificates *for animal products coming from infected countries or zones may not be required if the products are transported in an approved manner to premises controlled and approved by the* Veterinary Administration *of the* importing country *for processing to ensure the destruction of the FMD virus in conformity with the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.]~~

Community written comments
The Community does not agree with this deletion as it is possible to safely canalise wool (for example) which is clean, dry and packaged from an FMD infected country to a processing plant. It therefore asks the OIE to reconsider the need for this deletion.

- - - - - - - - - - - - - - -
— text deleted

APPENDIX 3.8.7.

GUIDELINES FOR THE SURVEILLANCE OF FOOT AND MOUTH DISEASE

Community position:
The Community fully supports this proposal as it believes the use of compartmentalisation for FMD is too high a risk to accept at this time and points out that this is in line with the advice from the Scientific Commission.

Article 3.8.7.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of foot and mouth disease (FMD) in accordance with Appendix 3.8.1. applicable to countries seeking recognition from the OIE for freedom from FMD, either with or without the use of vaccination. This may be for the entire country or a *zone* ~~or *compartment*~~ within the country. Guidance for countries seeking reestablishment of freedom from FMD for the whole country or a *zone* ~~or a *compartment*~~, either with or without vaccination, following an *outbreak*, as well as guidelines for the maintenance of FMD status are provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.2.10. Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on FMD" available from the OIE Central Bureau.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of infection. It is incumbent upon the applicant country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of FMDV infection (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV infection/circulation.

For the purposes of this Appendix, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 3.8.7.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1 should be under the responsibility of the *Veterinary Administration*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory for FMD diagnoses as described in the *Terrestrial Manual.*
2. The FMD surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or *zone* (for example, bordering a game park in which infected wildlife are present).

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV infection/circulation should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.7.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should cover all the susceptible species within the country or *zone* to be recognised as free from FMDV infection/circulation.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of FMDV infection/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of FMDV infection/circulation in accordance with Appendix 3.8.1. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member Country wishes to apply for recognition of a specific *zone* ~~*or compartment*~~ within the country as being free from FMDV infection/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* ~~*or compartment*~~.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection/circulation if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, surveillance design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as herds which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined. The design of surveillance programmes to prove the absence of FMDV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs of FMD by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of disease if a sufficiently large number of clinically susceptible animals is examined.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical surveillance for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD surveillance. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

3. Virological surveillance

Virological surveillance using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;
b) to confirm clinically suspect cases;
c) to follow up positive serological results;

d) to test "normal" daily mortality, to ensure early detection of infection in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological surveillance aims at detecting antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

a) natural infection with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD surveillance. However, the principles of survey design described in this Appendix and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain infection. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV infection is not present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.

Article 3.8.7.4.

Countries applying for freedom from FMD for the whole country or a zone ~~or a compartment~~ where vaccination is not practised

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for recognition of FMD freedom for the country or a *zone* ~~or a *compartment*~~ where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of FMDV infection, during the preceding 12 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 3.8.7.5.

Countries~~,~~ or zones ~~or compartments~~ applying for freedom from FMD where vaccination is practised

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for recognition of country or *zone* ~~or compartment~~ freedom from FMD with vaccination should show evidence of an effective surveillance programme planned and implemented according to general conditions and methods in this Appendix. Absence of clinical disease in the country~~,~~ or *zone* ~~or compartment~~ for the past 2 years should be demonstrated. Furthermore, surveillance should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of herd immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should, in general, be to vaccinate at least 80% of the susceptible population. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country~~,~~ or *zone* ~~or compartment~~, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 3.8.7.6.

Countries~~,~~ or zones ~~or compartments~~ re-applying for freedom from FMD where vaccination is either practised or not practised, following an outbreak

In addition to the general conditions described in Chapter 2.2.10., a country re-applying for country~~,~~ or *zone* ~~or compartment~~ freedom from FMD where vaccination is practised or not practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection/circulation. This will require serological surveillance incorporating, in the case of a country~~,~~ or *zone* ~~or compartment~~ practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV infection following an *outbreak*:

1. slaughter of all clinically affected and in-contact susceptible animals;

2. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;

3. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;

4. vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 2.2.10.7.

In all circumstances, a Member Country re-applying for country~~,~~ or *zone* ~~or compartment~~ freedom from FMD with vaccination or without vaccination should report the results of an active surveillance programme implemented according to general conditions and methods in this Appendix.

Article 3.8.7.7.

The use and interpretation of serological tests (see Figure 1)

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. Animals vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected animals that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD surveillance. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV infection/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical surveillance. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV infection/circulation. NSP-ELISAs may be used for screening sera for evidence of infection/circulation irrespective of the vaccination status of the animal. All herds with seropositive reactors should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of FMDV infection/circulation for each positive herd. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

3.1.1.1. 1. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination

Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor animal at hand, of susceptible animals of the same epidemiological unit and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow up investigations provide no evidence for FMDV infection, the reactor animal shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor animal should be classified as FMD positive.

3.1.1.2. 2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

In case of vaccinated populations one has to exclude that positive test results are indicative of virus circulation. To this end the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on FMD vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategy(ies) should be applied:

a) Following clinical examination, a second serum sample should be taken from the animals tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. Antibody titres against NSP at the time of retest should be statistically either equal to or lower than those observed in the initial test if virus is not circulating.

   The animals sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

b) Following clinical examination, serum samples should be collected from representative numbers of cattle that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating.

d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated ruminants (sheep, goats) are present, they could act as sentinels to provide additional serological evidence.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

– characterization of the existing production systems;

– results of clinical surveillance of the suspects and their cohorts;

– quantification of vaccinations performed on the affected sites;

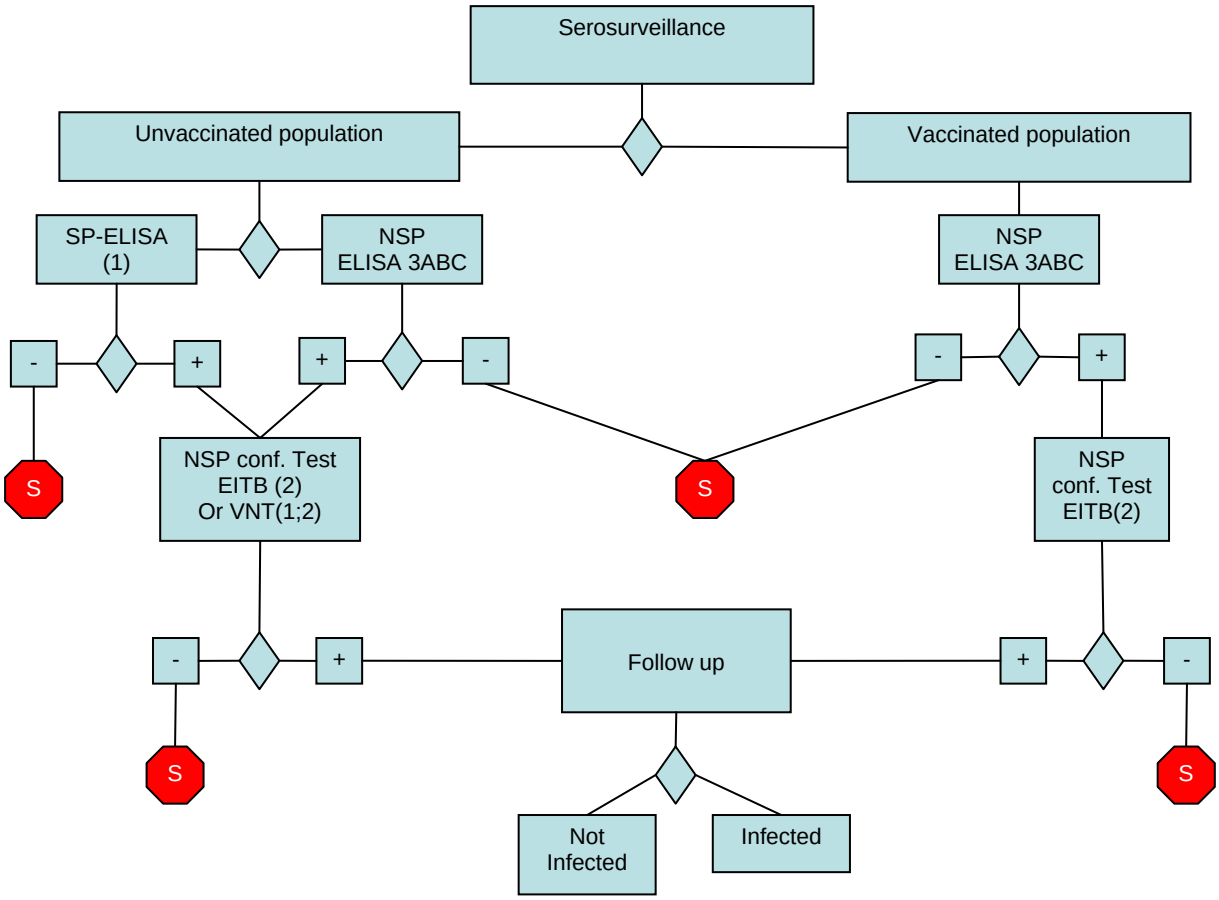
– sanitary protocol and history of the *establishments* with positive reactors;

– control of animal identification and movements;

– other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the surveillance programme.

Figure 1 ***Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys***



Key:

ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
~~OP~~	~~Oesophageal–pharyngeal sample~~
SP	Structural protein test
S	No evidence of FMDV

- - - - - - - - - - - - - - - — text deleted

Appendix XI

CHAPTER 2.2.13.

BLUETONGUE

Community position:
The Community supports this proposal however it would still like to draw the attention of the OIE to its request in Article 2.2.13.8 below concerning the Community request that it would like the OIE to reassess this 60 day period in the light of data which could become available in the future on newly developed inactivated BT vaccines and has some other comments below which it would like taken on board.

Article 2.2.13.1.

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

The global BTV distribution is currently between latitudes of approximately 50°N and 34~~5~~°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 (in accordance with Appendix 3.8.X.) ~~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 Appendix 3.8.X.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar surveillance. The surveillance 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, or a bluetongue surveillance programme (in accordance with Appendix 3.8.X.) in the country or *zone* not having free status supports a lesser distance.

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

Article 2.2.13.2.

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°N or south of 34~~5~~°S, and is not adjacent to a country or *zone* not having a free status; or

   b) a surveillance and monitoring programme in accordance with Appendix 3.8.X. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

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

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 60 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 in accordance with Appendix 3.8.X., 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 in accordance with Appendix 3.8.X. 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.

Community written comments:
The Community proposes the following addition:

c) any antibody seropositive animals are tested negative for viral RNA,

This will bring the Chapter into line with the wording in the Diagnostic Manual which says *"Regarding international trade, PCR has allowed the identification of BT antibody-positive animals that are negative for viral nucleic acid, permitting their importation"* it is possible to conclude that antibody seropositive animals (whether due to contact with the field virus or with the vaccine virus), once checked that they are negative for viral RNA, are safe animals, and their movement should be allowed to free zones without altering the health status of the importing zone.

4. A BTV free country or *zone* adjacent to an infected country or *zone* should include a *zone* in which surveillance is conducted in accordance with Appendix 3.8.X. Animals within this *zone* must be subjected to continuing surveillance. The boundaries of this *zone* must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 2.2.13.3.

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 2.2.13.7., 2.2.13.10. and 2.2.13.14., 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 2.2.13.7., 2.2.13.10. and 2.2.13.14., 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 2.2.13.4.

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 2.2.13.5.

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 2.2.13.6.

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:

1. the animals were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or

2. the animals 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* and remained in the BTV free country or *zone* until shipment; or

3. the animals 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* and remained in the BTV free country or *zone* until shipment;

or

4. the animals:

   a) were kept in a BTV free country or *zone* for at least 7 days;

   b) were vaccinated in accordance with the *Terrestrial Manual* 60 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 Appendix 3.8.1.;

   c) were identified as having been vaccinated; and

   d) remained in the BTV free country or *zone* until shipment;

AND

5. 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.

Article 2.2.13.7.

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 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*, with negative results, carried out at least 28 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*, with negative results, carried out at least 14 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* 60 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 in accordance with Appendix 3.8.X., were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

5. 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 2.2.13.8.

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 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, with negative results, carried out at least 28 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*, with negative results, carried out at least 14 days after introduction into the *quarantine station;* or

4. were vaccinated in accordance with the *Terrestrial Manual* at least 60 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme in accordance with Appendix 3.8.1., and were identified in the accompanying certification as having been vaccinated; or

5. are not vaccinated, a surveillance and monitoring programme in accordance with 3.8.1. 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 60 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 in accordance with Appendix 3.8.1.

Community written comment:
The Community would like the OIE to reassess this 60 day period in the light of data which could become available in the future on newly developed inactivated BT vaccines.

Article 2.2.13.9.

Community written comment:

The Community would like the OIE to reassess the possibility to allow importation for semen//embryos/oocytes when the donors were vaccinated in accordance with the *Terrestrial Manual* at least 60 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme in accordance with Appendix 3.8.1., and were identified in the accompanying certification as having been vaccinated;

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 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, between 21 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* 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 Appendix 3.2.1.

Article 2.2.13.10.

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 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, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* 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 Appendix 3.2.1.

Article 2.2.13.11.

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 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, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* 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 Appendix 3.2.1.

Article 2.2.13.12.

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 2.2.13.13.

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 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, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative;

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

Article 2.2.13.14.

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 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, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* 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 Appendix 3.3.1.

Article 2.2.13.15.

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 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, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* 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 Appendix 3.3.1.

Article 2.2.13.16.

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.

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 modelling information to identify low risk ports and transport routes.

- - - - - - - - - - - - - - -

— text

APPENDIX 3.X.X.

GUIDELINES FOR THE SURVEILLANCE OF BLUETONGUE

Community position:
The Community supports this proposal but would like to suggest that sentinel animals are individually identified (see Article 3.x.x.4 paragraphs 2 and 4).

Article 3.X.X.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of bluetongue (BT) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared BT status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of BT status is also provided. This Appendix complements Chapter 2.2.13.

BT is a vector-borne infection transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of disease risk that incorporates vector competence, abundance, biting rates, survival rates and extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context. Therefore, surveillance for BT should focus on transmission in domestic ruminants.

Susceptible wild ruminant populations should be included in surveillance only if necessary for trade.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is incumbent upon Member Countries to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the surveillance strategies for defining their infection status (free, endemic or area of potential spread) to the local conditions. There is considerable latitude available to Member Countries to justify their infection status at an acceptable level of confidence.

Surveillance for BT should be in the form of a continuing programme.

Article 3.X.X.2.

Case definition

For the purposes of surveillance, a *case* refers to an animal infected with BT virus (BTV).

For the purposes of *international trade*, a difference must be made between a case as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Chapter 2.2.13 of the *Terrestrial Code*.

The purpose of surveillance is the detection of virus circulation in a country or *zone* and not the status of an individual animal or herds. Surveillance deals not only with the occurrence of clinical signs caused by

BTV, but also with the presence of infection with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

1. BTV has been isolated and identified as such from an animal or a product derived from that animal, or

2. viral antigen or viral RNA specific to one or more of the serotypes of BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV.

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

Article 3.X.X.3.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of BT to a laboratory for BT diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2. The BT surveillance programme should:

   a) include an early warning system for reporting suspicious cases. Farmers and workers, who have day-to-day contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of BT should be investigated immediately and samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance;

   b) conduct random or targeted serological and virological surveillance appropriate to the infection status of the country or *zone*.

With regards to BT, compartment refers to establishments where animals are kept in a confirmed vector free environment to prevent BTV infection. Generally, the conditions to prevent exposure of susceptible animals to BTV infected vectors will be difficult to apply. However, under specific situations like artificial insemination centres or quarantine stations such conditions may be met. The testing requirements for

animals kept in these facilities are described in Articles 2.2.13.11 and 2.2.13.15.

Article 3.X.X.4.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country, *zone* or *compartment*. Active and passive surveillance for BTV infection should be ongoing. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone*.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of BTV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A country should justify the surveillance strategy chosen as being adequate to detect the presence of BTV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological surveillance is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member Country wishes to declare freedom from BTV infection in a specific *zone*, the design of the surveillance strategy would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and the different species in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined. The design of surveillance programmes to prove the absence of BTV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of BT at the flock/herd level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated, particularly during a newly introduced infection. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

BT suspects detected by clinical surveillance should always be confirmed by laboratory testing.

2. Serological surveillance

An active programme of surveillance of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species.

Surveillance may include serological surveys, for example abattoir surveys, , or a combination of methods.

Community written comments:
The Community proposes the following wording after the words abattoir surveys"…the use of sentinel animals (which must be individually identifiable)….."

The objective of serological surveillance is to detect antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

a) natural infection with BTV,

b) vaccination against BTV,

c) maternal antibodies,

d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV surveillance. However, the principles of survey design described in these guidelines and the requirements for a statistically valid survey for the presence of BTV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV infection is present in a *country*, *zone* or *compartment*. It is, therefore, essential that the survey is thoroughly documented.

Serological surveillance in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous surveillance and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable to select herds and/or animals for testing.

A surveillance *zone* within a free country or *zone* should separate it from a potentially infected country or *zone*. Serological surveillance in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *zone*, based upon geography, climate, history of infection and other relevant factors.

Serological surveillance in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of samples of BTV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological surveillance using tests described in the *Terrestrial Manual* can be conducted:

a) to identify virus circulation in at risk populations,

b) to confirm clinically suspect cases,

c) to follow up positive serological results,

d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel herds

Sentinel herds are a form of targeted surveillance with a prospective study design. They are the preferred strategy for BTV surveillance. They comprise groups of unexposed animals managed at fixed locations and sampled regularly to detect new BTV infections.

The primary purpose of a sentinel herd programme is to detect BTV infections occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of infected *zones* to detect changes in distribution of BTV. In addition, sentinel herd programmes allow incidence rates to be determined and the timing of infections to be observed.

A sentinel herd programme should use animals of known source and history of exposure, control management variables such as use of insecticides and be flexible in its design in terms of sampling frequency and choice of tests.

Community written comments:
The Community proposes the following an additional sentence as follows "Sentinel animals must be individually identifiable."

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors, sentinel groups should comprise animals selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel herd programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of infection. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV infections are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

The definitive measure of a country or *zone*'s BTV infection status is detection and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by vector species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector surveillance is to define high, medium and low-risk areas and local details of seasonality by determining the species present in an area, their seasonal incidence and profile, and their abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant animals.

The number of traps to be used in a vector surveillance system and the frequency of their use will depend on the availability of resources but is also dependent upon the size or ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel herds is advisable.

The use of a vector surveillance system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Other surveillance strategies (e.g. the use of sentinel herds of domestic ruminants) are preferred to detect virus circulation.

Article 3.X.X.5.

Documentation of BTV infection free status

1. Countries declaring freedom from BTV infection for the country, zone or compartment

In addition to the general conditions described in Chapter 2.2.13. of the Terrestrial Code, a Member Country declaring freedom from BTV infection for the entire country, or a zone or a compartment should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of BTV infection during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a laboratory able to undertake identification of BTV infection through virus detection and antibody tests described in the Terrestrial Manual. This surveillance should be targeted to non-vaccinated animals. Clinical surveillance may be effective in sheep while serological surveillance is more appropriate in cattle.

2. Additional requirements for countries, *zones* or compartments that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The

level of flock or herd immunity required to prevent transmission will depend on the flock or herd size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV infection in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* that practice vaccination there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the surveillance programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Article 3.X.X.6.

The use and interpretation of serological and virus detection tests

1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do animals vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype (s), however BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV infection, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active infection of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

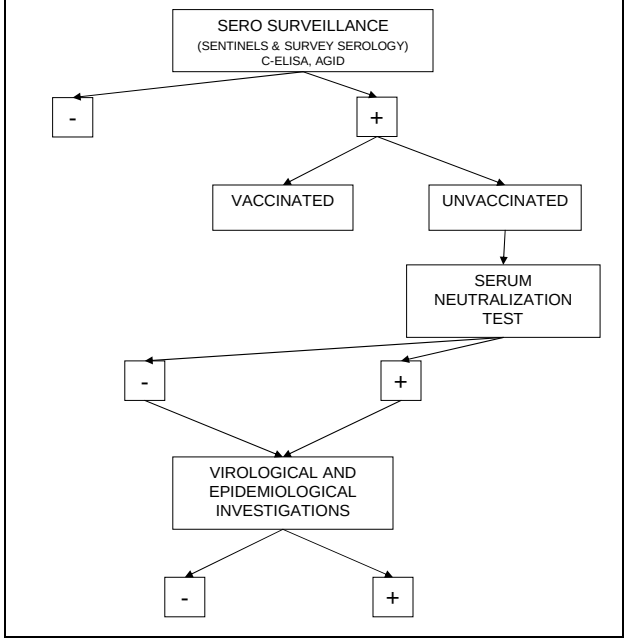


Figure 1

Application of laboratory tests in serological surveillance

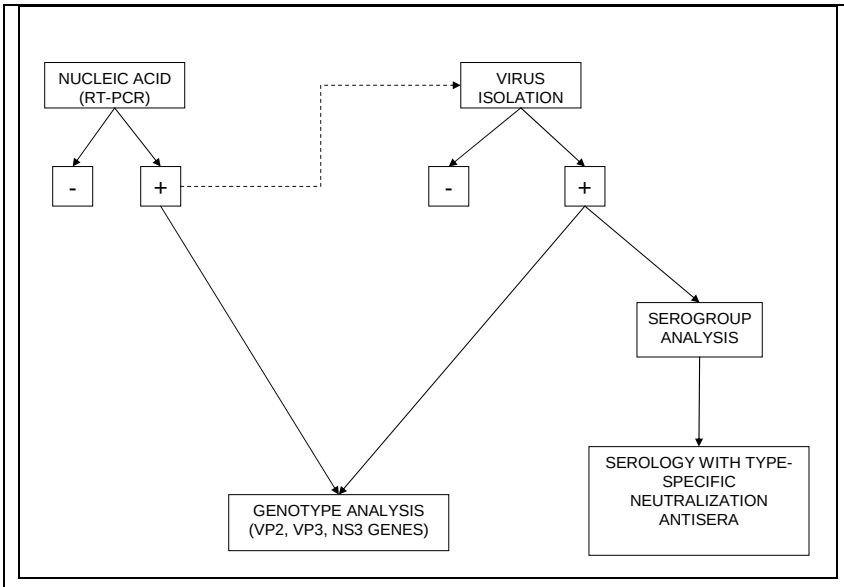


Figure 2

Application of laboratory tests in virological surveillance

Appendix XV

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Community position:
The Community supports the proposal on the classical swine fever chapter 2.6.7. It welcomes especially the introduction of the concept of compartmentalisation and the use of marker vaccination against classical swine fever. The present text however needs to be improved in order to become fully clear and coherent. e.g. some articles or provisions are redundant and can be rearranged. Inconsistencies as regards the conflicting periods of recovery of a free status and the residency of animals in a free country, zone or compartment need to be addressed. The comments have been incorporated below

Community written comments:

The text could be significantly improved by deleting articles 2.6.7.5 and 2.6.7.7. The relevant contents of article 2.6.7.7 can be added to article 2.6.7.4 where appropriate and article 2.6.7.5 seems even more redundant in this case.

The Community supports also the proposal on article 2.6.7.6. on the recovery of free status but points out the inconsistency that the status may be restored after 30 days but according article 2.6.7.8. (2) and other following articles, animals must have been kept since birth or for at least 3 months in a free country, zone of compartment. The Community acknowledges the efforts to take into account the possible use of vaccination against CSF with marker vaccine. Although the Community's policy of stamping-out CSF only foresees the use of emergency vaccination in domestic and wild pigs as an additional tool to eradicate the disease, the Community does not reject the principle that a country, zone or compartment may be considered as free from CSF if vaccination with a marker vaccine is carried out. The conditions to be considered free from CSF in these circumstances have however to be clearly defined. For this reason, Appendix 3.8.8 on surveillance and the Diagnostic Manual need to be reviewed and expanded and to clarify what in practice is meant by "where there are validated means of distinguishing between vaccinated and infected pigs" in this Chapter. For the sake of clarity the Community considers that the text should mention clearly the term "marker vaccination" where appropriate.

Article 2.6.7.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig~~s~~ includes all varieties of *Sus scrofa*, both domestic breeds and wild boar. ~~A distinction is made between farmed and permanently captive pigs, and free-living pigs. Farmed and permanently captive pigs of any breed will hereafter be referred to as domestic pigs. Free-living pigs of any breed will hereafter be referred to as wild pigs. Extensively kept pigs may fall into either of these categories or may alternate between the two.~~ For

the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and owned free-range pigs) and wild pigs (including feral pigs).

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of disease. Pigs exposed postnatally have an *incubation period* of 7-10 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections.

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

Article 2.6.7.2.

The CSF status of a ~~country or *zone*~~ country, *zone* or *compartment* can only be determined after considering the following criteria ~~both~~ in domestic and wild pigs, as applicable:

1. a *risk assessment* has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;

2. CSF should be notifiable in the whole country, and all clinical signs suggestive of CSF should be subjected to field and/or laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;

4. the *Veterinary Administration* should have current knowledge of, and authority over, all domestic ~~*establishments* containing~~ pigs in the ~~whole~~ country, *zone* or *compartment*;

5. the *Veterinary Administration* should have current knowledge about the population and habitat of wild pigs in the ~~whole~~ country or *zone*.

~~Article 2.6.7.3.~~

~~For the purposes of the *Terrestrial Code*:~~

~~'CSF infected *establishment*' means a domestic pig holding in which the presence of the infection has been confirmed by field and/or laboratory investigations.~~

~~'Country, *zone* or *compartment* with CSF infection in domestic pigs' means a country, *zone* or *compartment* containing a CSF infected *establishment*.~~

~~The size and limits of a CSF domestic pig control area must be based on the control measures used and the presence of natural and administrative boundaries, as well as an assessment of the risks for disease spread.~~

Article 2.6.7.4.

Article 2.6.7.4.

~~Country or zone~~ Country, *~~zone~~* or *~~compartment~~* ~~free of CSF in domestic and wild pigs~~

~~1.~~ ~~Historically free status~~

~~A country or *zone* country, *zone* or *compartment* may be considered free from the disease in domestic and wild pigs after conducting a *risk assessment* as referred to in Article 2.6.7.2. but without formally applying a specific surveillance programme (historical freedom) if the country or *zone* complies with if~~

~~the provisions of Appendix 3.8.18 are complied with.~~

~~2. Free status as a result of an eradication a specific surveillance programme~~

~~A country or *zone* country, *zone* or *compartment* which does not meet the conditions of point 1) above may be considered free from CSF in domestic and wild pigs after the conducting of a *risk assessment* as referred to in Article 2.6.7.2. and surveillance in accordance with Appendix 3.8.8. is in place, and when:~~

~~a) it CSF is a notifiable disease;~~

~~AND EITHER~~

~~b) no *outbreak* has been observed in domestic pigs for at least 12 months; or~~

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

~~c) where a *stamping-out policy* with vaccination is practised, either~~

~~i) no *outbreak* has been observed in domestic pigs for at least 6 months after the last vaccinated pig was slaughtered; or~~

~~ii) where there are validated means of distinguishing between vaccinated and infected pigs, no *outbreak* has been observed in domestic pigs for at least 6 months;~~

~~c)bis where a vaccination strategy is practised has been adopted, with or without a *stamping-out policy*,~~

~~i) vaccination against CSF has been banned in all domestic pigs in the country or *zone* country, *zone* or *compartment* for at least 12 months one year, unless there are validated means of distinguishing between vaccinated and infected pigs;~~

~~ii) if vaccination has been practised within occurred in the past 5 years, surveillance in accordance with Appendix 3.8.8. has been in place for at least 6 months to demonstrate the absence of infection within the population of domestic pigs 6 months to one year old; and~~

~~iii) no *outbreak* has been observed in domestic pigs for at least 12 months;~~

~~AND~~

~~d) based on surveillance in accordance with Appendix 3.8.8, CSF infection is not known to occur in the any wild pig population in the country, *zone* or *compartment* and surveillance of wild pigs indicates that there is no residual infection.~~

CSF free country, *zone* or *compartment*

1. CSF free status in the absence of an outbreak

a) Historically free status

A country, *zone* or *compartment* may be considered free from the disease after conducting a *risk assessment* as referred to in Article 2.6.7.2. but without formally applying a specific surveillance programme, if the provisions of Article 3.8.1.6 are complied with.

b) Free status as a result of a specific surveillance programme

A country, *zone* or *compartment* which does not meet the conditions of point 1) above may be considered free from CSF when a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, surveillance in accordance with Appendix 3.8.8. has been in place for at least

12 months, and when no *outbreak* has been observed for at least 12 months.

2. CSF free status following an outbreak

A country, *zone* or *compartment* which does not meet the conditions of point a) or b) above may be considered free from CSF if surveillance in accordance with Appendix 3.8.8. has been in place and after a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, and

a) where a *stamping-out policy* without vaccination is practised and no *outbreak* has been observed in domestic pigs for at least 6 months;

OR

b) where a *stamping-out* policy with vaccination is practised, and either:

i) vaccinated pigs are slaughtered, and no *outbreak* has been observed in domestic pigs for at least 6 months after the last vaccinated pig was slaughtered; or

ii) where there are validated means of distinguishing between vaccinated and infected pigs, no *outbreak* has been observed in domestic pigs for at least 6 months;

OR

c) where a *vaccination* strategy is practised without a *stamping-out policy*:

i) vaccination has been banned in all domestic pigs in the country, *zone* or *compartment* for at least 12 months, unless there are validated means of distinguishing between vaccinated and infected pigs;

ii) if vaccination has been practised within the past 5 years, surveillance in accordance with Appendix 3.8.8. has been in place for at least 6 months to demonstrate the absence of infection within the population of domestic pigs 6 months to one year old; and

iii) no *outbreak* has been observed in domestic pigs for at least 12 months;

AND

in all cases, based on surveillance in accordance with Appendix 3.8.8, CSF infection is not known to occur in any wild pig population in the country or *zone.*

Community written comments:
The Community proposes to simplify the text by deleting overlapping articles.

It is proposed to delete article 2.6.7.7. and to replace article 2.6.7.4. (2)(d) with the text of article 2.6.7.7. point 2 to 4. The Community proposes to modify the very last sentence in 2) by adding as follows:

i) there has been no clinical, nor virological evidence of CSF in wild pigs during the past 12 months;

ii) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;

iii) there has been no vaccination in wild pigs for the past 12 months;

iv) the feeding of swill to wild pigs 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.;"

Article 2.6.7.5.

Country ~~or zone~~ free of CSF in domestic pigs but with a ~~infection in the~~ wild pig population

Community written comments:

The Community proposes to delete this article because the possibility is covered by the proposed modified article 2.6.7.4.

Requirements in point ~~2) a) to c)bis~~ 2a to 2c of Article 2.6.7.4. as relevant, are complied with. As ~~but~~ CSF infection ~~is known to occur~~ may be present in the wild pig~~s~~ population, the following additional conditions are complied with ~~for the free status are that in the country or *zone*~~:

1. a programme for the management of CSF in wild pigs is in place~~, and CSF wild pig control areas are delineated around every CSF *case* reported in wild pigs~~, taking into account the measures in place to manage the disease in the wild pig population, the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risk of disease spread;

2. ~~biosecurity measures are~~ zoning or compartmentalisation is applied to prevent transmission of CSF from wild pigs to domestic pigs~~;~~

~~3. surveillance in accordance with Appendix 3.8.8. is carried out in the domestic pig population, with negative results~~.

Article 2.6.7.6.

Recovery of free status

Should a CSF *outbreak* occur in ~~an *establishment* of~~ a free ~~country or *zone*~~ country, *zone* or *compartment* ~~(free in domestic and wild pigs, or free in domestic pigs only)~~, the status of the country~~, or~~ *zone* or *compartment* may be restored ~~at least~~ not less than 30 days after completion of a *stamping-out policy* where surveillance in accordance with Appendix 3.8.8. has been carried out with negative results. ~~which should include the following measures:~~

~~1. a CSF domestic pig control area (including an inner protection area of at least 3-kilometre radius and an outer surveillance area of at least 10-kilometre radius) should be delineated around the *outbreak*, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;~~

~~2. all the pigs have been killed and their carcasses destroyed, and *disinfection* has been applied within the *establishment*;~~

~~3. in the protection area around a CSF *outbreak*:~~

~~a) a *risk assessment* should be carried out to determine the likelihood of CSF infection in neighbouring *establishments*; when a significant risk is indicated, a *stamping-out policy* of all domestic pigs within a radius of at least 0.5 kilometre may be applied;~~

~~b) an immediate clinical examination of all pigs in all pig *establishments* situated within the protection area has been carried out;~~

~~4. in the surveillance area around a CSF *outbreak*, all sick pigs should be subjected to laboratory tests for CSF;~~

~~5. surveillance in accordance with Appendix 3.8.8. has been carried out in all pig *establishments* that have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within the CSF domestic pig control area, demonstrating that these *establishments* are not infected;~~

~~6. measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, *vehicles*, etc. have been implemented.~~

If emergency vaccination has been practised ~~within the CSF domestic pig control area~~, recovery of the free status cannot occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.7.

Country or zone free of CSF in wild pigs

Community written comments:
The Community proposes to simplify the text by deleting overlapping articles. It is proposed to delete article 2.6.7.7. and to add point 2 to 4 to article 2.6.7.4.

A country or *zone* may be considered free from CSF in wild pigs when:

1. the domestic pig population in the country or *zone* is free from CSF infection;

2. surveillance in accordance with Appendix 3.8.8. has been in place to determine the CSF status of the wild pig population in the country, and in the country or *zone*:

   a) there has been no clinical, nor virological evidence of CSF in wild pigs during the past 12 months;

   b) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;

3. there has been no vaccination in wild pigs for the past 12 months;

4. the feeding of swill to wild pigs 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.;

5. imported wild pigs comply with the relevant requirements set forth in the present chapter.

A ~~zoning~~ compartmentalisation approach within the country or *zone* can only be adopted if there is a wild pig sub-population that is isolated through a biosecurity management system from other wild pigs.

Article 2.6.7.8.

When importing from ~~countries or *zones*~~ countries, *zones* or *compartments* free of CSF ~~in domestic and wild pigs~~, *Veterinary Administrations* should require:

for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a ~~country or *zone*~~ country, *zone* or *compartment* free of CSF ~~in domestic and wild pigs~~ since birth or for at least the past 3 months;

3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.9.

When importing from countries free of CSF in domestic pigs but with a wild pig population ~~countries or *zones* free of CSF in domestic pigs but with infection in the wild pig population~~, *Veterinary Administrations* should require:

for domestic pigs

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

1. were kept in a country or *zone* free of CSF in domestic pigs since birth or for at least the past 3 months;

2. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

3. come from ~~an *establishment*~~ a free *zone* or compartment ~~which is not located in a CSF wild pig control area as defined in Article 2.6.7.5., and has undergone surveillance to verify absence of CSF in accordance with Appendix 3.8.8.;~~

4. ~~have had no contact with pigs introduced into the *establishment* during the past 40 days;~~

~~5.~~ showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.10.

When importing from countries or *zones* with CSF infection in domestic pigs, *Veterinary Administrations* should require:

for domestic pigs

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

1. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

2. were kept since birth or for the past 3 months, in ~~an *establishment*~~ a free *compartment* ~~not situated in a CSF domestic or wild pig control area as defined in Article 2.6.7.5. and in Article 2.6.7.6.~~;

~~3. were isolated in a *quarantine station* for at least 40 days;~~

~~4. were subjected during that period of quarantine to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;~~

5. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.11.

When importing from countries or *zones* free of CSF ~~in domestic and wild pigs~~, *Veterinary Administrations* should require:

for wild pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. have been captured in a country or *zone* free from CSF ~~in domestic and wild pigs~~;

3. have not been vaccinated against CSF, unless there are validated means of distinguishing between vaccinated and infected pigs;

and, if the *zone* where the animal has been captured is adjacent to a *zone* with infection in wild pigs:

4. were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.

Article 2.6.7.12.

When importing from ~~countries or *zones*~~ countries, *zones* or *compartments* free of CSF ~~in domestic and wild pigs~~, *Veterinary Administrations* should require:

for semen of domestic pigs

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

1. the donor animals:

   a) were kept in a ~~country or *zone*~~ country, *zone* or *compartment* free of CSF ~~in domestic and wild pigs~~ since birth or for at least ~~the past~~ 3 months prior to collection;

   b) showed no clinical sign of CSF on the day of collection of the semen;

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

Article 2.6.7.13.

When importing from countries ~~or *zones*~~ free of CSF in domestic pigs but with ~~infection in the~~a wild pig population, *Veterinary Administrations* should require:

for semen of domestic pigs

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

1. the donor animals:

   a) were kept in a country, *zone* or *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection ~~have been kept in an *artificial insemination centre* which is not located in a CSF wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix 3.8.8.~~;

   b) ~~were isolated in the *artificial insemination centre* for at least 40 days prior to collection;~~

~~c)~~ showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;

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

Article 2.6.7.14.

When importing from countries or *zones* considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

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

1. the donor animals:

   a) were kept in a *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection;

   a)bis showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days ~~3 months~~;

   b) have not been vaccinated against CSF, and were subjected to a serological test performed at least 21 days after collection, with negative results;

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

Article 2.6.7.15.

When importing from countries, ~~or~~ *zones* or *compartments* free of CSF ~~in domestic and wild pigs~~, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;

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

Article 2.6.7.16.

When importing from countries ~~or *zones*~~ free of CSF in domestic pigs but with ~~infection in the~~a wild pig population, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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

1. the donor females:

   a) were kept in a country, *zone* or *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection ~~were kept for at least 40 days prior to collection in an *establishment*~~

~~which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix 3.8.8.~~;

b) showed no clinical sign of CSF on the day of collection of the embryos;

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

Article 2.6.7.17.

When importing from countries or *zones* considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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

1. the donor females:

   a) were kept in a *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection; ~~were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix 3.8.8.~~;

   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following ~~21~~ 40 days;

   c) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection;

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

Article 2.6.7.18.

When importing from countries, ~~or~~ *zones* or *compartments* free of CSF ~~in domestic and wild pigs~~, *Veterinary Administrations* should require:

for *fresh meat* of domestic pigs

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

1. have been kept in a country, ~~or~~ *zone* or *compartment* free of CSF ~~in domestic and wild pigs~~ since birth or for at least the past 3 months;

2. have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.19.

When importing from countries or *zones* free of CSF in domestic pigs but with ~~infection in the~~a wild pig population, *Veterinary Administrations* should require:

for *fresh meat* of domestic pigs

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

1. were kept in a country, ~~or~~ *zone* or *compartment* free of CSF in domestic pigs since birth or for at least the past 3 months;

2. ~~were kept in an *establishment* which was not located in a CSF wild pig control area and had undergone surveillance to verify absence of CSF in accordance with Appendix 3.8.8.;~~

~~3.~~ have been slaughtered in an *approved abattoir* ~~not located in a CSF control area~~, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.20.

When importing from countries or *zones* free of CSF ~~in domestic and wild pigs~~, *Veterinary Administrations* should require:

for *fresh meat* of wild pigs

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

1. the entire consignment of meat comes from animals which:

   a) have been killed in a country or *zone* free of CSF ~~in domestic and wild pigs~~;

   b) have been subjected to post-mortem inspection in an approved examination centre, and have been found free of any sign suggestive of CSF;

and, if the *zone* where the animal has been killed is adjacent to a *zone* with infection in wild pigs:

2. a sample has been collected from every animal shot, and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 2.6.7.21.

Veterinary Administrations of *importing countries* should require:

for *meat products* of pigs (either domestic or wild), or for products of animal origin (from *fresh meat* of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use, or for trophies derived from wild pigs

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

1. have been prepared:

   a) exclusively from *fresh meat* meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary Administration* for export purposes;

      ii) ~~regularly inspected by the *Veterinary Authority*;~~

      ~~iii)~~ ~~not situated in a CSF control area;~~

~~iv)~~ processing only meat meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes ~~and regularly inspected by the *Veterinary Authority*~~ so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2.

Article 2.6.7.22.

Veterinary Administrations of *importing countries* should require:

for products of animal origin (from pigs, but not derived from *fresh meat*) intended for use in animal feeding and for agricultural or industrial use

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

1. have been prepared:

   a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary Administration* for export purposes;

      ii) ~~regularly inspected by the *Veterinary Authority*;~~

      ~~iii) not situated in a CSF control area;~~

      ~~iv)~~ processing only products meeting the conditions laid down in point a) above;

OR

2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes ~~and regularly inspected by the *Veterinary Authority*~~ so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2.

Article 2.6.7.23.

Veterinary Administrations of *importing countries* should require:

for bristles (from pigs)

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

1. come from a country, ~~or~~ *zone* or *compartment* free of CSF ~~in domestic and wild pigs~~; or

2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes ~~and regularly inspected by the *Veterinary Authority*~~ so as to ensure the destruction of the CSF virus.

Article 2.6.7.24.

Veterinary Administrations of *importing countries* should require:

for litter and manure (from pigs)

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

1. come from a country, ~~or~~ *zone* or *compartment* free of CSF ~~in domestic and wild pigs~~; or

2. ~~come from *establishments* situated in a country or *zone* free of CSF in domestic pigs but with infection in wild pigs, but not located in a CSF control area; or~~

3. have been processed in an establishment approved by the *Veterinary Administration* for export purposes ~~and regularly inspected by the *Veterinary Authority*~~ so as to ensure the destruction of the CSF virus. - - - - - - - - - - - - -

CHAPTER 2.7.12.

AVIAN INFLUENZA

Community position:
The Community thanks the Code Commission for taking its comments on the AI Code Chapter into account. The Community believes this AI Code Chapter and the guidelines for surveillance on AI are good tools to enable safe trade with poultry and other birds and product derived from them in relation to AI and can support this proposal. However recent experiences have shown that there are problems in international trade in relation to the use of vaccination against AI. The Community hopes that from this General Session a clear signal in respect of the research into and use of vaccination against AI with minimal trade impact will have been sent out.

Article 2.7.12.1.

1. For the purposes of this *Terrestrial Code*, avian influenza in its notifiable form (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

   a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI.

   b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. Poultry is defined as 'all domesticated birds ~~reared or kept in captivity~~ used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds'.

3. For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs.

4. The following defines the occurrence of infection with NAI virus:

   a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or

b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry; or

c) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination have been detected in poultry. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of NAI infection.

For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the poultry have shown no evidence of NAI infection, based on surveillance in accordance with Appendix 3.8.9.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.7.12.2.

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for NAI occurrence and their historic perspective;

2. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, laboratory investigations;

3. appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with Appendix 3.8.9.

Article 2.7.12.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection has been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix 3.8.9. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

2. In the case of LPNAI infections, poultry may be kept for slaughter for human consumption subject to specified conditions specified in Article 2.7.12.19 or 2.7.12.20 or a *stamping-out policy* may be applied; in either case, 3 months after the disinfection of all affected establishments, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when it has been shown that HPNAI infection has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown, when, based on surveillance in accordance with Appendix 3.8.9., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus. The surveillance may need to be adapted to parts of the country or *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.5.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for live poultry (other than day-old poultry)

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

1. the poultry showed no clinical sign of NAI on the day of shipment;
2. the poultry were kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. the required surveillance has been carried out on the *establishment* within at least the past 21 days;
4. if vaccinated, the poultry have been vaccinated in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the poultry (including the dates of vaccination, and the vaccine used should be included in the veterinary certificate.~~

Article 2.7.12.6.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for live birds other than poultry

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

1. the birds showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;
3. the birds were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from infection with a virus which would be considered NAI in poultry;
4. the birds are transported in new containers;

5. if the birds have been vaccinated, the relevant information is attached.

Article 2.7.12.7.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for day-old live poultry

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

1. the poultry were kept in an NAI free country, *zone* or *compartment* since they were hatched;

2. the poultry were derived from parent flocks which had been kept in an NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the poultry and the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.8.

When importing from an HPNAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for day-old live poultry

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

1. the poultry were kept in an HPNAI free country, *zone* or *compartment* since they were hatched;

2. the poultry were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the poultry are transported in new containers.

4. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the poultry and the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.9.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for *hatching eggs*

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

1. the eggs came from an NAI free country, *zone* or *compartment*;

2. the eggs were derived from parent flocks which had been kept in an NAI free country, *zone* or

compartment for at least 21 days prior to and at the time of the collection of the eggs.

3. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.10.

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

for *hatching eggs*

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

1. the eggs came from an HPNAI free country, *zone* or *compartment*;

2. the eggs were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material;

4. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.11.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country, *zone* or *compartment*.

Article 2.7.12.12.

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

for eggs for human consumption

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

1. come from a HPNAI free country, *zone* or *compartment*;

2. ~~come from *establishments* in which there has been no evidence of NAI in the past 21 days;~~

~~3.~~ have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material.

Article 2.7.12.13.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country, *zone* or *compartment*.

Article 2.7.12.14.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for egg products

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

1. the egg products are derived from eggs which meet the requirements of Articles 2.7.12.9., 2.7.12.10., 2.7.12.11., or 2.7.12.12.; or

2. the egg products were processed to ensure the destruction of NAI virus ~~(under study)~~ in accordance with Appendix 3.6.X~~; and the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.~~

3. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.15.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;

2. were kept in an NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

~~Information concerning the vaccination status of the donor poultry (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.16.

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

for poultry semen

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

~~1) came from an HPNAI free country, *zone* or *compartment*;~~

~~2) were kept in an NAI free *establishment* for at least 21 days prior to and at the time of semen collection.~~

1. showed no clinical sign of HPNAI on the day of semen collection;

2. were kept in an HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

~~Information concerning the vaccination status of the donor flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.17.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for semen of birds other than poultry

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

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;

2. showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

3. were tested between 7 and 14 days prior to semen collection and shown to be free of NAI infection.

Article 2.7.12.18.

When importing from an NAI free country, *zone* or *compartment*, *Veterinary Administrations* should require:

for *fresh meat* of poultry

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

1. which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

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

Article 2.7.12.19.

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

for *fresh meat* of poultry

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

1. which have been kept in an HPNAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days ~~which have been kept in an *establishment* since they were hatched or for at least the past 21 days and in which there has been no evidence of NAI in the past 21 days~~;

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

Article 2.7.12.20.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for *meat products* of poultry

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

1. the *commodity* is derived from *fresh meat* which meet the requirements of Articles 2.7.12.18. or 2.7.12.19.; or

2. the *commodity* has been processed ~~to a core temperature of 70ºC for one second (or to an equivalent process),~~ to ensure the destruction of NAI virus ~~(under study)~~ in accordance with Appendix 3.6.X;

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.21.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

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

1. these *commodities* come from ~~birds~~ poultry which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days; or

2. these *commodities* have been processed to ensure the destruction of NAI virus (under study) ~~in accordance with Appendix 3.6.X.~~;

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.22.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for feathers and down (from poultry)

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

1. these *commodities* come from ~~birds~~ poultry which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days; or

2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.23.

Regardless of the NAI status of the country, *zone* or *compartment*, *Veterinary Administrations* should require for the importation of:

meat or other products from birds other than poultry

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

1. the *commodity* has been processed to ensure the destruction of NAI virus (under study);

2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

- - - - - - - - - - - - - - -
— text deleted

APPENDIX 3.8.9.

GUIDELINES FOR THE SURVEILLANCE OF AVIAN INFLUENZA

Community position:
The Community can support this proposal but would like the written comments below taken on board at the next Code Commission meeting.

Article 3.8.9.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of notifiable avian influenza (NAI) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared NAI status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of NAI status are provided. This Appendix complements Chapter 2.7.12.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in Chapter 2.7.12. refers to the infection in poultry only and this Appendix was developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 3.8.9.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or infection with NAIV should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a laboratory for NAI diagnosis as described in the *Terrestrial Manual*;

c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2. The NAI surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. All suspected cases of NAI should be investigated immediately. ~~Where~~ As suspicion cannot be resolved by epidemiological and clinical investigation alone, ~~as is frequently the case with low pathogenicity notifiable avian influenza (LPNAI) virus infections,~~ samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to an NAI infected country, *zone* or *compartment*, places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other sources of NAIV.

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.9.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible poultry species within the country, *zone* or *compartment*. Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every 6 months. Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of NAIV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with virological methods.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A country should justify the surveillance strategy chosen as adequate to detect the presence of NAIV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from NAIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and the different species in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as flocks which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined. The design of surveillance programmes to prove the absence of NAIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable ~~to be accepted by the OIE or international trading partners~~, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of NAIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until evidence to the contrary is produced.

Identification of suspect flocks is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

Virological surveillance using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological surveillance aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural infection with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent flock are usually found in the yolk and can persist in progeny for up to 4 weeks;

d) positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive flocks may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or infection. As clustering may signal infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive flocks is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The surveillance strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the surveillance strategy should be based on virological and/or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. The interpretation of serological results in the presence of vaccination is described in 3.8.9.7.

Article 3.8.9.4.

Documentation of NAI or HPNAI free status

1. Countries declaring freedom from NAI or HPNAI for the country, *zone* or compartment

In addition to the general conditions described in Chapter 2.7.12. of the *Terrestrial Code*, a Member Country declaring freedom from NAI or highly pathogenic notifiable avian influenza (HPNAI) for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a laboratory able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, *zones* or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a disease control programme. The level of flock immunity required to prevent transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 3.8.9.5.

Countries, zones or compartments ~~re-declaring~~ regaining freedom from NAI or HPNAI following an outbreak

In addition to the general conditions described in Chapter 2.7.12., a country ~~re-declaring for~~ regaining country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of surveillance results.

Community written comment:

The first sentence should read "….a country ~~re-declaring for~~ regaining freedom for country, *zone* or *compartment* from NAI or HPNAI virus infection….."

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 3.8.9.6.

NAI free establishments within HPNAI free compartments

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these guidelines. The frequency of testing should be based on the risk of infection and at a maximum interval of 21 days.

Community written comment:
The heading should read" NAI free establishments within a HPNAI free compartment" and in addition the text needs to be clarified as its unclear what is the purpose of free establishments in a free compartment either the whole compartment is free or it isn't. So the Community suggests to add "In this compartment all the establishments must have the same NAI free status" as in this case the status is NAI free in all the establishments in a defined compartment.

Article 3.8.9.7.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Appendix. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16~~5~~ haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. ~~Poultry vaccinated with inactivated whole AI vaccines may develop low titres of antibodies to NSP, but the titre in infected birds will be markedly higher. Alternatively, usage of a vaccine strain with a different NA subtype than the field virus can allow differentiation of vaccinated from infected birds (DIVA) by detection of subtype specific NA antibodies of the field virus.~~ Vaccines used should comply with the standards of the *Terrestrial Manual*.

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of NAI infection/circulation for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

3.1.1.3. 1. The follow up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on NAI-vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

   i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

   ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;

   iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

3.1.1.4. 2. The follow up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for infection by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterization of the existing production systems;

b) results of clinical surveillance of the suspects and their cohorts;

c) quantification of vaccinations performed on the affected sites;

d) sanitary protocol and history of the affected *establishments*;

e) control of animal identification and movements;

f) other parameters of regional significance in historic NAIV transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme.

Figure 1. - Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys

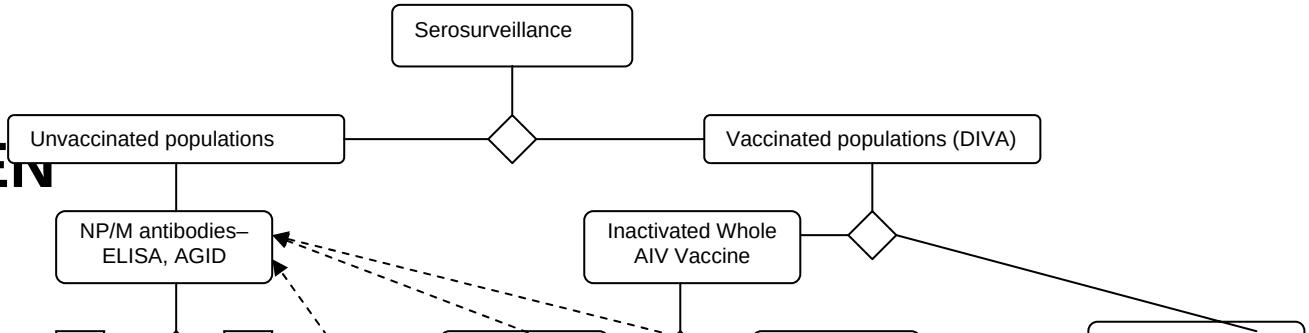
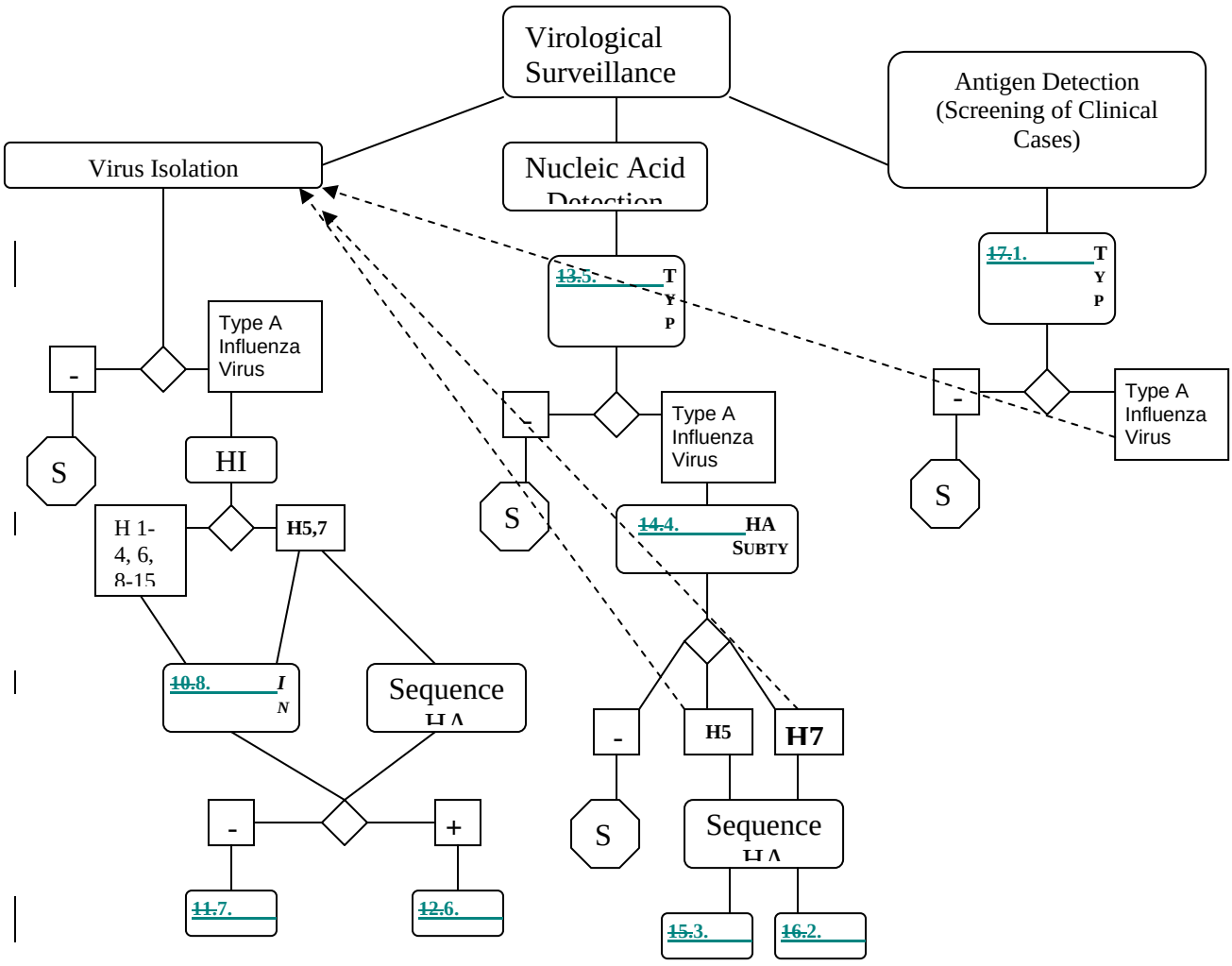


Figure 2. - Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods



The above diagram indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:

AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAIV

- - - - - - - - - - - - - - — text deleted

Appendix XVIII

APPENDIX 3.~~8~~6.X.

GUIDELINES FOR THE INACTIVATION OF THE AVIAN INFLUENZA VIRUS

Community position:

The Community can support the proposal.

Article 3.~~8~~6.X.1.

Egg and egg products

The following times for industry standard ~~procedures~~ temperatures are suitable for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus present in egg and egg products:

	Temperature (°C)	Time
Whole egg	60	~~210~~ 188 seconds
Whole egg blends	60	~~372~~ 188 seconds
Whole egg blends	61.1	~~210~~ 94 seconds
Liquid egg white	55.6	~~372~~ 256 seconds
Liquid egg white	56.7	~~210~~ 228 seconds
10% salted yolk	62.2	~~372~~ 138 seconds
~~10% salted yolk~~	~~63.3~~	~~210 ≤138 seconds~~
Dried egg white	67	~~15~~ 0.83 days
Dried egg white	54.4.	21.38 days

Article 3.~~8~~6.X.2.

Meat

A procedure which produces a core temperature of 70ºC for one second is suitable for the inactivation of HPNAI virus present in meat.

Appendix XIX

APPENDIX 3.2.1.

BOVINE AND SMALL RUMINANT SEMEN

Community position:
The Community can support this proposal and thanks the OIE for taking some points into account but would still like the comments below taken into account in the next OIE expert meeting on this subject.

Article 3.2.1.1.

General considerations

The purposes of official sanitary control of semen production are to:

1. maintain the health of animals on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other animals or humans with pathogens transmissible by semen;

2. ensure that semen is hygienically collected, processed and stored.

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

Article 3.2.1.2.

Conditions applicable to artificial insemination centres

1. The *artificial insemination centre* is comprised of:

   a) animal accommodation areas (including one isolation facility for sick animals) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;

   b) a semen laboratory and semen storage areas;

   c) administration offices.

   A *quarantine station* may also be attached to the centre, provided that it is on a different location from that of those two first parts.

2. The centre should be officially approved by the *Veterinary Administration*.

3. The centre should be under the supervision and control of the *Veterinary Authority* which will be responsible for regular audits, at an interval of no more than 6 months, of protocols, procedures and prescribed records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

4. The centre should be under the direct supervision and control of a veterinarian designated by the *artificial insemination centre* and accredited by the *Veterinary Administration* for relevant official tasks.

Article 3.2.1.3.

Conditions applicable to semen collection facilities

1. The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage, and for the isolation of ~~suspect~~ animals suspected of being infected.

2. Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species of animals may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All animals resident at the semen collection facilities must meet the minimum health requirements for donors.

3. The donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be in place to prevent the entry of wild animals susceptible to OIE-listed ruminant diseases transmissible via semen.

4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.

5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises must be examined and treated if necessary to ensure that they cannot introduce disease.

6. *Vehicles* used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.

7. The semen collection area should be cleaned daily after collection. The animals' accommodation and semen collection areas should be cleaned and disinfected at least once a year.

8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 3.2.1.4.

Conditions applicable to semen laboratories

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.

2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.

3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.

4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.

5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.

7. The storage rooms and individual semen containers should be easy to clean and disinfect.

8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 3.2.1.5.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals ~~can~~ should enter an *artificial insemination centre* only if they fulfil the following requirements ~~laid down by the *Veterinary Administration*~~.

1. Pre-quarantine

   The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

   a) Bovine brucellosis

      The animals should comply with point 3 or 4 of Article 2.3.1.5. of the *Terrestrial Code*.

   b) Bovine tuberculosis

      The animals should comply with point 2, 3 or 4 of Article 2.3.3.4. of the *Terrestrial Code*.

   c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

      The animals should be subjected to the following tests:
      i) a virus isolation test or a test for virus antigen, with negative results;
      ii) a serological test to determine the serological status of every animal.

   d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis (IBR/IPV) If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should either:

      i) come from an IBR/IPV free herd as defined in Article 2.3.5.3.; or
      ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

   e) Bluetongue

      The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre,* bulls and teaser animals should be kept in a *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station,* except for *Campylobacter fetus* subsp. *venerealis* and *Trichomonas foetus,* for which testing may commence after 7 days in quarantine. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

a) Bovine brucellosis

~~If the country is not free from brucellosis,~~ the animals should be subjected to a serological test with negative results.

Community written comment:
The Community is pleased the proposed amendment was taken into account as requested.

b) BVD-MD

i) All animals should be tested for viraemia as described in point 1c) above.

Only when all the animals in quarantine test negative for viraemia may the animals enter the semen collection facilities upon completion of the 28-day quarantine period.

ii) After 21 days in quarantine, all animals should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.

iii) Only if no sero-conversion occurs in the animals which tested seronegative before entry into the *quarantine station,* may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If sero-conversion occurs, all the animals that remain seronegative should be kept in quarantine over a prolonged time until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine should be tested once on a preputial specimen, with a negative result.

ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Trichomonas foetus*

i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine, should be tested once on a preputial specimen, with a negative result.

ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the *quarantine station* and the other animals of the same group should remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive animal.

f) Bluetongue

The animals should comply with Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each animal should be subjected to a virus isolation or virus antigen ~~ELISA~~ test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

Community written comment:
The Community thanks the OIE for deleting the word ELISA However it would like to point out the suitable method is RT-PCR. Virus isolation can be used, but raw semen is cytotoxic and must be diluted in culture medium. Extended semen can usually be inoculated directly on to cell monolayers, but may occasionally cause cytotoxicity. Also, note that the target population for this test, seropositive bulls with localized persistent infection, are likely to have low levels of virus in semen and this is an additional reason to use RT-PCR for this purpose.
If the OIE wishes to refer to what is recommended in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, the alternative wording above may be used. Note, however, that the Manual (chapter 2.10.6) is not exhaustive on this particular matter (detection of virus in semen) and we therefore recommend a revision where this aspect is included.

4. Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 2.3.5.7.

5. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country of origin is not free:

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.

d) *Campylobacter fetus* subsp. *venerealis*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

f) *Trichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

g) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should comply with the provisions in point 2)c) of Article 2.3.5.3.

Article 3.2.1.6.

Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals can enter an *artificial insemination centre* only if they fulfil the <u>following</u> requirements ~~laid down by the *Veterinary Administration*~~.

1. <u>Pre-quarantine</u>

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

a) Caprine and ovine brucellosis

The animals should comply with Article 2.4.2.6.

b) Ovine epididymitis

The animals should comply with Article 2.4.1.3.

c) Contagious agalactia

The animals should comply with points 1 and 2 of Article 2.4.3.1.

d) Peste des petits ruminants

The animals should comply with points 1, 2, and 4 ~~and~~or 5 of Article 2.4.9.7.

e) Contagious caprine pleuropneumonia

The animals should comply with Article 2.4.6.5. or Article 2.4.6.7., depending on the CCPP status of the country of origin of the animals.

~~f) Caseous lymphadenitis~~

~~The animals should be free from clinical signs for the past 12 months.~~

g) Paratuberculosis

The animals should be free from clinical signs for the past 2 years.

h) Scrapie

If the animals do not originate from a scrapie free country or *zone* as defined in Article 2.4.8.3., the animals should comply with points 1 and 2 of Article 2.4.8.8.

i) Maedi-visna

The animals should comply with Article 2.4.5.2.

j) Caprine arthritis/encephalitis

In the case of goats, the animals should comply with Article 2.4.4.2.

k) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

l) Tuberculosis

In the case of goats, the animals should be subject to a single or comparative tuberculin test, with negative results.

~~m) Border disease~~

~~The animals should be subject to a viral agent isolation test with negative results.~~

Community written comment:
The Community cannot support the proposed amendment for the following reasons:

The virus is present in semen of persistently infected (PI) and apparently healthy animals; PI animals can spread infection horizontally, and there is evidence that infected ewes can infect the fetus (vertical transmission). Unlike BVD, Border Disease has not been thoroughly or extensively researched. According to EU laboratory experts, the probability of infected semen causing disease in recipients is lower than in the case of BVD and cattle. Nevertheless, it cannot be discounted. Border disease is in IETS category IV, hence the risk of producing infected embryos cannot be discounted either.

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, with negative results:

a) Caprine and ovine brucellosis

The animals should be subject to testing as described in point 1 b) or c) of Article 2.4.2.8.

b) Ovine epididymitis

The animals and semen should be subject to testing as described in points 1 d) and 2 of Article 2.4.1.4.

c) Maedi-visna and caprine arthritis/encephalitis ~~or CAE~~

The animals should be subjected to a serological test.

d) Bluetongue

The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country of origin is not free:

a) caprine and ovine brucellosis;

b) ovine epididymitis;

c) Maedi-visna and caprine arthritis/encephalitis ~~or CAE~~;

d) tuberculosis (for goats only);

e) bluetongue.

Article 3.2.1.7.

General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 3.2.1.8.

Conditions applicable to the management of bulls, rams and bucks

The objective is to keep the animals in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the animal should be kept under hygienic conditions. If housed, the litter must be kept clean and renewed as often as necessary.

2. The coat of the animal should be kept clean.

3. For bulls, the length of the tuft of hairs at the preputial orifice, which is invariably soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.

4. The animal should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.

5. In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.

6. When the animal is brought into the collection area, the technician must make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves, for such materials are always heavily contaminated.

Measures similar to the above should be adapted to rams and bucks.

Article 3.2.1.9.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be easy to clean and to disinfect. A dusty floor should be avoided.

2. The hindquarters of the teaser, whether a dummy or a live teaser animal, must be kept clean. A dummy must be cleaned completely after each period of collection. A teaser animal must have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.

3. The hand of the person collecting the semen must not come into contact with the animal’s penis. Disposable gloves should be worn by the collector and changed for each collection.

4. The artificial vagina must be cleaned completely after each collection. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of ~~70° ethyl or 98-99° isopropyl~~ alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

5. The lubricant used should be clean. The rod used to spread the lubricant must be clean and should not be exposed to dust between successive collections.

6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.

7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.

8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.

9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 3.2.1.10.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1. Diluents

   a) All receptacles used should have been sterilised.

   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.

   c) If the constituents of a diluent are supplied in commercially available powder form, the water used must have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

   d) When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives must also be sterilized before use.

   e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.

   f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: either

gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg) or penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.

b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.

c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be ~~sterilised~~ disinfected with alcohol, ethylene oxide, steam or other approved ~~sterilisation~~ disinfection techniques

d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

Semen for export should be stored separately from other genetic material not meeting these guidelines in fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)*.

Prior to export, semen straws or pellets should be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing ~~Containers should be sealed~~ with an official numbered seal ~~under the responsibility of the Veterinary Administration~~ before export and accompanied by an international veterinary certificate listing the contents and the number of the official seal.

Community written comment:
The Community believes the requirement for an official veterinarian to supervise these procedures is too onerous as a designated veterinarian to carry out official duties is required according to Article 3.2.1.2 point 4 and it suggests the following wording:

"Prior to export, semen straws or pellets should be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of the designated centre *v*eterinarian. The contents of the container or flask should be verified by the centre veterinarian prior to sealing according to the instructions from the *Official Veterinarian.*"

* The ICAR international standards on straws are contained in *Recording Guidelines* - Appendices to the international agreement of recording practices. Section 9, Appendix B

relating to semen straw identification.

- - - - - - - - - - - - - - - -

— text deleted

Appendix XXIV

APPENDIX X.X.X.
GUIDELINES FOR THE CONTROL OF BIOLOGICAL HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE THROUGH ANTE- AND POST-MORTEM MEAT INSPECTION

Community position:
The Community can support this proposal but would like the comments below taken into account at the next meeting of the Code Commission to improve the text. However in addition the Community believes that there should be an inclusion of some responsibilities for the breeders or for the slaughterhouse operators. The primary responsibility for ensuring compliance with food laws and in particular for the safety of food rests with the food industry. This also applies to the feed industry.

Introduction
Foodborne disease and zoonoses are important public health problems and ~~important~~ causes of decreased economic productivity in developed and developing countries. Similarly, transmission of hazards of animal health importance via the ~~food~~ meat production chain and associated by-products can result in significant economic loss in livestock. Inspection of animals at slaughter can provide a valuable contribution to surveillance for certain diseases of animal and public health importance. Control and/or reduction of biological hazards of animal and public health importance by ante- and post-mortem meat inspection are a core responsibility of *Veterinary Services*

3.2. Design and management of inspection programmes

At the end of this chapter the following two sentences should be added:
A priority should be the collation and analysis of the information gained from the surveillance of primary production, ante and post mortem inspections in a transparent way. These results should be made available in a timely way.

Purpose
These guidelines provide a basis for future development of OIE standards for animal production food safety.

Community written comments:

The sentence should read as follows:

"These guidelines provide a basis for future development of OIE standards for animal production food safety having regard to the food chain or farm to fork concept."

Hygienic practice throughout the ~~food~~ meat production

The Codex Alimentarius Code of Hygienic Practice for Meat[47] (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to

[47] Code of Hygienic Practice for Meat, CAC/RCP 58-2005

application of sanitary measures throughout the ~~food~~ meat production chain. Ante-mortem inspection is described as a primary component of meat hygiene before slaughter, and post-mortem inspection is described as a primary component of process control in post-slaughter meat hygiene. The CHPM specifically recognises the dual objectives that slaughterhouse inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific hazards ~~or organoleptically detected abnormalities~~, which remain the responsibility of national competent authorities. The animal and public health risks associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of meat hygiene systems that are based on risk assessment. There are few risk assessment models ~~or~~ and little relevant scientific information available on public health hazards derived specifically from animals and their processing, making difficult the development of risk-based standards for food-borne zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

3.2.1.1.

Community written comments:
The last sentence should read:
"It is foreseen that by linking up surveillance data, epidemiologic knowledge with risk assessments major advances can be made in the years to come to develop evidence based risk management policies".

Veterinary Services and meat inspection programmes
Veterinary Services are primarily responsible for the development of ante- and post-mortem meat inspection programmes. Wherever ~~possible~~ practicable, inspection procedures should be risk-based and management systems should reflect international norms and cover the significant hazards to both human and animal health in the livestock being slaughtered, as determined by the *Veterinary Services*. In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of *Veterinary Services* include:

- Risk assessment and risk management
- Establishment of policies and standards
- Design and management of inspection programmes
- Assurance and certification of appropriate delivery of inspection and compliance activities
- Dissemination of information throughout the ~~food~~ meat production chain

Community written comments:
The Community proposes to add the following 2 bullets:
"Design and management of monitoring and surveillance program"

Risk assessment and risk management

Veterinary Services should utilise risk assessment to the greatest extent ~~possible~~ practicable in the development of sanitary measures. *Veterinary Services* should give priority to addressing microbiological

contamination, ~~rather~~ while not neglecting than gross abnormalities detected at ante and post-mortem inspection, as this has been found to be the most important source of hazards.

Community written comment:

A third sentence should be added as follows:
"However, the animal health importance of detecting diseased animals at ante and post mortem inspection should be kept in mind".

Microbiological, serological or other testing at single-animal and herd level as part of ante- and post-mortem inspection should be used to support surveillance, as well as risk assessment of prioritised foodborne hazards. The information gathered should be linked to human disease data to allow an assessment of the effectiveness of various management options, as well as a general evaluation of food sources of foodborne disease.
Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while accommodating the different risk assessment methodologies used in animal and public health.

Establishment of policies and standards

The national competent authority(s) should provide an appropriate institutional environment to allow *Veterinary Services* to develop the necessary policies and standards.
As well as meeting public health objectives, policies and standards relating to ante- and post-mortem inspection should aim to detect and remove hazards of animal health significance from the ~~food~~ meat production chain. This may be achieved by the removal of live animals at ante-mortem inspection or by the removal of specific tissues at post-mortem inspection.

Veterinary Services should integrate their activities to the maximum extent ~~possible and~~ practicable so as ~~to increase the efficacy of policies~~ to prevent duplication of effort and unnecessary costs e.g. within the process of international certification.

Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Veterinary Services* contribute through the direct performance of some veterinary tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector. To this end, *Veterinary Services* provide assurances domestically and to trading partners that safety and suitability standards have been met.
Veterinary Services should allow flexibility in meat inspection service delivery through an officially recognised competent body operating under its supervision and control. In recognition of the contribution of industry to food safety, quality assurance systems may be extended in the case of ante- and post-mortem inspection to systems that integrate industry and *Veterinary Services* activities. Nevertheless, *Veterinary Services* should take into account the factors identified in Chapter 1.3.3 on the Evaluation of *Veterinary Services*. For example, if personnel from the private sector are used to carry out ante- and post-mortem inspection activities under the overall supervision and responsibility of the *Veterinary Services*, the *Veterinary Services* should specify the competency requirements for all such persons and verify their performance.

Assurance and certification

Assurance and certification of appropriate delivery of inspection and compliance activities 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.

Dissemination of information

Organisation and dissemination of information throughout the ~~food~~ meat production chain involves multidisciplinary inputs. To ensure the effective implementation of ante- and post-mortem inspection procedures, *Veterinary Services* should have in place systems for the monitoring of these procedures and the exchange of information gained. Further, there should be an ongoing programme for monitoring of hazards at appropriate points throughout the meat production chain so as to help evaluate the efficacy of controls. Animal identification and traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward ~~to processors~~ through the meat production chain

_____

Appendix XXV

CHAPTER 1.3.7.

ANIMAL IDENTIFICATION AND TRACEABILITY

Community position:
The Community thanks the OIE for taking some of its points into account and can support this proposal. The Community welcomes this draft but understands that this work will be further elaborated by the working group being set up on this subject and would like the comments below taken into account during that process.

Proposed definitions (to be located in Chapter 1.1.1)

Animal identification means the combination of the identification and *registration* of an animal individually, with a unique identifier; or collectively by its *epidemiological unit* or group, with a unique group identifier. ~~Methods of animal identification include tag, brand, tattoo, transponder (microchip), collar, ring and mark.~~

Animal identification system means the inclusion and linking of components such as identification of *establishments*/owners, the person(s) responsible for the animal(s), movements and other records with *animal identification*.

Animal traceability means the ability to follow an animal or group of animals during ~~specified~~ all ~~stage(s)~~ stages of ~~its~~ their ~~life~~ lives.

~~*Individual identification* means the identification of each animal using a unique identifier.~~

~~*Group identification* means the identification of a group of animals using a unique group identifier.~~

~~*Register* means the system by which animal identification and traceability information is securely stored and appropriately accessed by the *Competent Authority*.~~

Registration is the action by which information on animals (such as identification, animal health, movement, certification, epidemiology, *establishments*) is collected, recorded, securely stored and made appropriately accessible and able to be utilised by the *Competent Authority*.

Article 1.3.7.1.

General principles

1. There is a critical relationship between *animal identification* and the traceability of animals and *products of animal origin*.

2. *Animal traceability* and traceability of products of animal origin should have the capability to be linked ~~to food product traceability in order to maintain~~ to achieve traceability throughout the food chain taking into account relevant OIE and Codex Alimentarius standards.

3. *Animal identification* and *animal traceability* are ~~important~~ tools for addressing animal health (including zoonoses), and food safety. These ~~and~~ may significantly improve the effectiveness of: ~~the~~ management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock husbandry, *zoning*/*compartmentalisation*, surveillance, early response and notification systems, animal

movement controls, inspection, certification ~~and assurances of~~ ~~safety~~, fair practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level.

Community written comments:
Bearing in mind ongoing discussions at the WTO/SPS committee on regionalisation, direct reference to "regionalisation" could also appear here as this is still used in CODEX:
The Community proposes the following wording:
"3. *Animal identification* and *animal traceability* are key tools for animal health, including zoonoses, and food safety, and may significantly improve the effectiveness of the management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock management, *zoning* (regionalisation)*/compartmentalisation*, surveillance, early response and notification systems, animal movement controls, inspection, certification, fair practices in trade and the utilisation of veterinary drugs, feed and pesticides at farm level and health measures to facilitate trade".
Other key concepts on usefulness of animal identification and animal traceability could be added, either in a dedicated paragraph or as additional examples:

- **"bio-safety management";**
- **"monitoring of animal/herd health status" (not only "management of disease outbreaks");**
- **quality management ("quality schemes", "conformation of the animal/carcass");**
- **different policy and economic considerations (management of premiums and taxes);**
- **and, last but not least "compensation schemes".**

A new sentence could be added after paragraph 3 to highlight the fact that animal identification/traceability could be used for quality related purposes and consumer information (e.g., organic farming, particular breed of cattle, animal welfare, particular origin, etc):
The Community proposes the following wording:
"Animal identification and animal traceability can also be used as tools to demonstrate the origin of the animal, and consequently of its products (e.g., religious concerns, organic farming, animal welfare concerns), and contribute to reinforce the confidence of the consumer as regards the information provided."

4. The objective(s) and outcomes of *animal identification* and *animal traceability* for a particular country, *zone* or *compartment*, and the approach used, should be clearly defined, following an assessment of the risks to be addressed, and a consideration of the factors listed below. They should be defined through consultation between the *Veterinary Administration* and relevant ~~sector(s)~~ sectors/stakeholders prior to implementation, and periodically reviewed.

Community written comments:
Bearing in mind ongoing discussions at the WTO/SPS committee on regionalisation, reference to "regionalisation" could appear here.
The Community proposes the following wording:
"4. The objective(s) of *animal identification* and *animal traceability* for a particular country, region, compartment or zone, and the approach used, should be clearly defined, following an assessment of the risks to be addressed, and a consideration of the factors listed below. They should be defined in partnership between the

Competent Authority **and relevant sector(s)/stakeholders prior to implementation, and periodically reviewed."**

5. There are various factors which may determine the chosen ~~approach~~ system for *animal identification* and *animal traceability*. Factors such as the outcomes of the risk assessment, the animal and public health situation (including zoonoses), animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic considerations, and cultural aspects, should be taken into account when designing the ~~approach~~ system. Whatever ~~approach~~ system is used, it should comply with relevant OIE standards to ensure that the defined objectives are able to be achieved.

Community written comments:
Bearing in mind ongoing discussions at the WTO/SPS "geographical parameters" could also be mentioned under paragraph 5.
The Community proposes the following wording:
"5. There are various factors which may determine the chosen system for *animal identification* and *animal traceability*.**. Factors such as the outcomes of the risk assessment, the zoning (regionalisation) policy, geographical parameters, the animal health and public health situation (including zoonoses), animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic and environmental considerations, and cultural aspects, should be taken into account when designing the system. ~~approach.~~ Whatever system is used, it should comply with relevant OIE standards to ensure that the defined objectives are able to be achieved."**

6. *Animal identification* and *animal traceability* should be under the responsibility of the *Veterinary Administration*.

7. The *Veterinary Administration* ~~in consultation~~ with relevant governmental agencies and in consultation with the private sector, should establish a legal framework for the implementation and enforcement of *animal identification* and *animal traceability* in the country. In order to facilitate compatibility and consistency, relevant international standards and obligations should be taken into account. This legal framework should include elements such as the objectives, scope, organisational arrangements including the choice of technologies used for identification and registration, obligation of the parties, confidentiality, accessibility issues and the efficient exchange of information.

8. Whatever the specific objectives of the chosen *animal identification system* and *animal traceability*, there is a series of common basic factors ~~that are to all systems~~, and these must be considered before ~~their~~ implementation, such as the legal framework, procedures, the *Competent Authority*, identification of *establishments*/owners, *animal identification* and animal movements.

9. The equivalent outcomes (performance criteria), rather than identical systems (design criteria), should be the basis for comparison of *animal identification systems* and *animal traceability*.

- - - - - - - - - - - - - - -
— text deleted

Appendix XXVI

CHAPTER 2.5.4.

EQUINE INFECTIOUS ANAEMIA

Community position:
The Community can support this proposal but would like the comments below taken on board at the next OIE meeting on this subject.

Article 2.5.4.1.

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

Article 2.5.4.2.

Veterinary Administrations of *importing countries* should require:

for equines ~~imported on a permanent basis~~

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

1. the animals showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment;

2. ~~for breeding animals only,~~ no *case* of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;

3. the animals were subjected to a diagnostic test for EIA with negative results on blood samples collected during the 30 days prior to shipment.

Community written comments:
The following text is suggested:

"1. equine infectious anaemia is a notifiable disease in the exporting country
2. the animals showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment;
3. ~~for breeding animals only,~~ no *case* of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;
4. the animals were subjected to a diagnostic test for EIA with negative results on blood samples taken during the 30 days prior to shipment, or the equine animals are imported on a temporary basis and the blood samples were taken within 90 days of export."

~~Article 2.5.4.3.~~

~~*Veterinary Administrations* of *importing countries* should require:~~

~~for equines imported on a temporary basis~~

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

1. ~~the animals showed no clinical sign of EIA on the day of shipment and during the 48 hours prior to shipment;~~

2. ~~no *case* of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;~~

3. ~~the animals were subjected to a diagnostic test for EIA with negative results during the 30 days prior to shipment (the negative response to the serological test remains valid for 120 days).~~

— text deleted

CHAPTER 2.5.6.

EQUINE PIROPLASMOSIS

Community position:
The Community can support this proposal but would like the comments below taken into account at the next OIE meeting on this subject

Article 2.5.6.1.

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

Article 2.5.6.2.

Veterinary Administrations of *importing countries* should require:
for equines
the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of equine piroplasmosis on the day of shipment;
2. were subjected to diagnostic tests for equine piroplasmosis (~~*Babesia*~~ *Theileria equi* and ~~*B.*~~ *Babesia caballi*) with negative results during the 30 days prior to shipment;
3. were maintained free from ticks during the 30 days prior to shipment.

Community written comments:
The Community proposes the following wording to replace 3 above:
"3. were maintained free from ticks, where necessary by treatment, during the 30 days prior to shipment."

~~treated against ticks within the 7 days prior to shipment (the *importing country* may decide to import only during seasons when ticks are not active on its territory).~~

Article 2.5.6.3.

Veterinary Administrations of *importing countries* should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 2.5.6.2. under the following safeguards:

1. the horses are accompanied by a passport in conformity with the model contained in Appendix 4.1.5.;
2. the *Veterinary Administrations* of *importing countries* require the presentation of an *international veterinary certificate* attesting that the animals:
   a) showed no clinical sign of equine piroplasmosis on the day of shipment;
   b) were treated against ticks within the 7 days prior to shipment;
3. the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the *Veterinary Authority*;
4. the horses are regularly examined for the presence of ticks under the direct supervision of the *Veterinary Authority*.

- - - - - - - - - - - - - - -

— text deleted

Appendix XXVIII

CHAPTER 2.5.7.

EQUINE RHINOPNEUMONITIS

Community position:
The Community can support this proposal but would like to point out that the disease should be called "Equine herpes virus infection" and would like the OIE to take on board the comments below at the next OIE meeting on this subject.

Article 2.5.7.1.

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

Article 2.5.7.2.

Veterinary Administrations of *importing countries* should require:

for equines

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

1. showed no clinical sign of equine rhinopneumonitis on the day of shipment and during the 21 days ~~3 months~~ prior to shipment;

2. were kept for the 21 days ~~3 months~~ prior to shipment in an *establishment* where no *case* of equine rhinopneumonitis was ~~officially~~ reported during that period.

Community written comments:
The points above must be replaced by the following wording:

1. showed no clinical sign of equine herpes virus infection, such as abortion or paralysis, on the day of shipment and during the 21 days ~~3 months~~ prior to shipment;

2. were kept for the 21 days ~~3 months~~ prior to shipment in an *establishment* where no *case* of equine herpes virus infection has ~~officially~~ occurred during that period.

- - - - - - - - - - - - - - -

— text deleted

Appendix XXIX

CHAPTER 2.5.8.
GLANDERS

Community position:
The Community cannot support this proposal. The Community comments on this draft were not taken into account and a number of important points remain to be discussed and our comments can be found in the text below.

Article 2.5.8.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for glanders shall be 6 months.

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

Article 2.5.8.2.

Glanders free country

A country may be considered free from glanders when:

1. glanders is notifiable in the country;

2. no *case* of glanders has been reported during ~~confirmed for at least~~ the past 3 ~~last 2~~ years.

~~When importing equines for immediate slaughter from an infected country (see Article 2.5.8.5.), a glanders free country will not be considered as infected if one of the imported equines is found infected.~~

~~The conditions for such imports will require direct transport of the animals from the place of disembarkation to a designated abattoir and completion of cleansing and *disinfection* of the means of transport, the lairages and the abattoir immediately after use. These conditions should be prescribed and enforced by the *Veterinary Administration.*~~

Community written comments:
The Community asks the scientific background for the extension of the period during which the disease should not have been reported.

The following is suggested:

"2. either historical freedom can be documented, or no case of glanders has been reported for a period of at least 6 months and a surveillance programme is in place demonstrating the absence of the disease in accordance with general surveillance guidelines."

Article 2.5.8.3.

When importing from glanders free countries, *Veterinary Administrations* should require:

for equines

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

1. showed no clinical signs ~~evidence~~ of glanders on the day of shipment;

2. were kept since birth, or for the ~~past~~ 6 months prior to shipment, in the *exporting country*; or

3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and/or the complementfixation test~~ for glanders with negative results, during the 15 days prior to shipment.

Community written comments:
The Community agrees with the proposed modifications.
However, taking into account the above suggestions, the following is suggested:
"2. were kept for the ~~past~~ 6 months prior to shipment, or since birth if less than six months of age, in the *exporting country*; or

3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and/or the complementfixation test~~ for glanders with negative results, carried out on the animals or on samples taken from the animals during the 21 days prior to shipment."

Article 2.5.8.4.

When importing from countries considered infected with glanders, *Veterinary Administrations* should require:
for equines
the presentation of an *international veterinary certificate* attesting that the animals:
1. showed no clinical sign of glanders on the day of shipment;

2. were kept for the 6 months prior to shipment in an *establishment* where no *case* of glanders was ~~officially~~ reported during that period;

3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and the complement fixation test~~ for glanders with negative results, during the 15 days prior to shipment.

Community written comments
The Community agrees with the changes, however the following is suggested:
"2. were kept for the 6 months prior to shipment, or since birth if less than six months of age, in an *establishment* where no *case* of glanders was ~~officially~~ reported during that period, and
3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and the complement fixation test~~ for glanders with negative results, carried out on the animals or on a sample taken from the animals during the 21 days prior to shipment."

Article 2.5.8.5.

When importing from countries considered infected with glanders, *Veterinary Administrations* should require:

for equines for immediate slaughter

the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of glanders on the day of shipment. ~~(See also Article 2.5.8.2.)~~

Community written comments:
The Community does not agree with the proposed modification.
Taking into account recent experience and the zoonotic potential of B. malleus, there should be no specific conditions for the export of equidae for direct slaughter and these equidae should simply have to comply with the conditions in Article 2.5.8.3. and 2.5.8.4. It is therefore proposed to delete this Article.

- - - - - - - - - - - - - - -
— text deleted

Appendix XXX

CHAPTER 2.5.10.

EQUINE VIRAL ARTERITIS

Community position:
The Community cannot support this proposal as presently drafted as no Community comments were taken on board. Our comments can be found below.

Article 2.5.10.1.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for mares, ~~and~~ geldings, and sexually immature equines. The health status of seropositive stallions should be checked to ensure that they do not shed equine arteritis virus in their semen.

Community written comments:
The introduction should read as follows:

"The *infective period* for equine viral arteritis (EVA) shall be 28 days relating to aerosol transmission. However, as this period may be extended in case of virus shedding through semen, the health status of sero-positive stallions should be checked to ensure that they do not shed equine arteritis virus in their semen."

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

Article 2.5.10.2.

Veterinary Administrations of *importing countries* should require:

for uncastrated male equines imported on a temporary basis for breeding or on a permanent basis

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

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;

2. were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ on blood samples at least 14 days apart with negative results, during the 28 days prior to shipment; or

3. were subjected between 6 and 12 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated; or

4. have been subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

    a) were subsequently test mated to two mares within 12 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

    b) were subjected to a ~~virus isolation~~ test for EVA as prescribed in the *Terrestrial Manual* with negative results ~~(under study)~~, carried out on semen collected during the 28 days prior to

shipment.

Community written comments:
The following wording is suggested:

"2. were subjected with negative results to a test for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ on blood samples taken within 14 days prior to shipment; or

3. were subjected between 6 and 9 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on blood samples taken 10 to 14 days apart, with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or

5. have been subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then within 12 months prior to shipment either

a) were subsequently test mated to two mares which were subjected during a 28 days isolation to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

b) were subjected to a ~~virus isolation~~ test for EVA as prescribed in the *Terrestrial Manual* with negative results ~~(under study)~~, carried out on aliquots of two consecutive ejaculates collected 4 to 7 days apart."

Article 2.5.10.3.

Veterinary Administrations of *importing countries* should require:

for uncastrated male equines imported on a temporary basis other than for breeding, and for equines other than uncastrated males

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

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;

2. were subjected, during the 28 days prior to shipment, to two ~~diagnostic~~ tests for EVA as prescribed in the *Terrestrial Manual* on blood samples collected at least 14 days apart, which demonstrated negative results or a stable or declining antibody titres;

3. were subjected, between 6 and 12 months of age, to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample, with negative results, and immediately vaccinated for EVA and regularly revaccinated.

Community written comments:
The Community agrees with the proposed modifications, however suggests the

following:
"1. showed no clinical signs of EVA on the day of shipment and was kept in an establishment where no equidae have shown any signs EVA for 28 days prior to shipment."
Delete paragraphs 2 and 3, as these requirements appear to be irrelevant to the risk posed by non-reproductive equidae.

Article 2.5.10.4.

Veterinary Administrations of *importing countries* should require:

for fresh semen

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

1. were kept for the 28 ~~30~~ days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;

2. showed no clinical sign of EVA on the day of semen collection;

3. were subjected between 6 and 12 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, and immediately vaccinated for EVA and regularly revaccinated; or

4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had not been used for natural breeding from the time of the taking of the blood sample to the time of semen collection; or

5. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

   a) were test mated, within 12 months ~~one year~~ prior to semen collection, to two mares which showed negative results to two ~~diagnostic~~ tests as prescribed in the *Terrestrial Manual* on blood samples collected at the time of test mating and again 28 days after the test mating, or

   b) were subjected to a ~~virus isolation~~ test as prescribed in the *Terrestrial Manual*~~e~~ with negative results ~~(under study)~~, carried out on semen collected within one year prior to collection of the semen to be exported.

Community written comments:
The Community agrees with the proposed modifications, however suggest the following modifications:
"for fresh, chilled and frozen semen:

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

1. were kept for the 28 ~~30~~ days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;

2. showed no clinical sign of EVA on the day of semen collection;

3. were subjected between 6 and 9 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated; or

4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated; or

5. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae from the time of the taking of the blood sample to the time of semen collection; or

6. have been subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then within 12 months prior to semen collection either

a) were subsequently test mated to two mares which were subjected during a 28 days isolation to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

b) were subjected to a ~~virus isolation~~ test for EVA as prescribed in the *Terrestrial Manual* with negative results ~~(under study)~~, carried out on aliquots of two consecutive ejaculates collected 4 to 7 days apart."

Article 2.5.10.5.

Veterinary Administrations of *importing countries* should require:

for frozen semen

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

1. showed no clinical sign of EVA on the day of semen collection;

2. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results not less than 14 days after semen collection; or

3. were subjected, between 6 and 12 months of age, to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, and immediately vaccinated for EVA and regularly revaccinated; or

4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

   a) were test mated, within 12 months ~~one year~~ prior to or as soon as possible after semen collection, to two mares which showed negative results to two ~~diagnostic~~ tests as prescribed in the *Terrestrial Manual* on blood samples collected at the time of test mating and again 28 days after the test mating, or

   b) were subjected to a ~~virus isolation~~ test as prescribed in the *Terrestrial Manual*~~e~~ with negative results ~~(under study)~~, carried out on semen collected within one year prior to collection of the semen to be exported.

Community written comments:
The Community suggests to list together test regimes common to fresh, chilled and

frozen semen, as ejaculates may be split for various confections. Article 2.5.10.5 should only deal with a test regime specific for frozen semen.
The Community suggests to delete paragraph 3 and to amend the current paragraph 4 as follows:

"3. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either

a) were test mated, within 30 days after semen collection, to two mares which showed negative results to two ~~diagnostic~~ tests as prescribed in the *Terrestrial Manual* on blood samples collected during a 28 days isolation at the time of test mating and again 28 days after the test mating, or

b) were subjected to a ~~virus isolation~~ test as prescribed in the *Terrestrial Manual* with negative results ~~(under study)~~, carried out on semen collected within 30 days after collection of the semen to be exported."

- - - - - - - - - - - - - - -
— text deleted

Appendix XXXI

CHAPTER 2.X.X.

AFRICAN HORSE SICKNESS

Community p o s i t i o n :
Although the Community welcomes the review of this chapter, it cannot support this proposal as none of it proposed changes outlined below were taken on board.
In addition the Community cautions about certain requirements that would entail a highly effective surveillance system which so far cannot be delivered in countries affected by the disease.
Certain changes should be better explained, such as shortening security distances or the period of quarantine isolation.
Following the philosophy of the current chapter on AHS there is a protection and surveillance zone with measures foreseen in both zones. The new text would in fact allow uncontrolled movement of equidae right next to the delineated free zone
The new text does not provide a clear understanding about the role of vaccination, and consequently any definition based on absence of cases, i.e. clinical signs, is obsolete.

Article 2.x.x.1.

For the purposes of this *Terrestrial Code*, the *infective period* for African horse sickness (AHS) shall be 40 days for domestic horses.

All countries or *zones* adjacent to a country or *zone* not having free status should determine their AHS status from an ongoing surveillance programme (in accordance with Appendix 3.8.X.). The surveillance 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 AHS.

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

Community written comments:
This article provides a new concept which

- **firstly reduces the security distance from 150 km to 100 km,**
- **secondly does not clarify for the case of a free zone within an infected country where this surveillance should be carried out: on the territory of the free zone or within the perimeters of the infected zone. This clarification could have consequences for the minimum size of a declared free zone.**

In accordance with General Definitions a surveillance zone is part of the free zone and entails intensified surveillance. A buffer zone would not only allow increased surveillance but also movement controls and vaccination

Article 2.x.x.2.

AHS free country or zone

1. A country or a *zone* may be considered free from AHS when the disease is notifiable in the whole country and either:

a) the country or *zone* is not adjacent to a country or *zone* not having a free status; or

Community written comments:
Point (a) should read as follows:

"1. A country or a *zone* may be considered free from AHS when the disease is notifiable in the whole country, systematic prophylactic vaccination is prohibited and either:

a) the country or *zone* has not reported any case of AHS during at least the previous 2 years and is not adjacent to a country or *zone* not having a free status; or"

b) *historical freedom* as described in Appendix 3.8.1. has demonstrated no evidence of AHS in the country or *zone*; or

c) a surveillance programme as described in Appendix 3.8.X. has demonstrated no evidence of AHS in the country or *zone* during the past 2 years, including in wildlife; or

Community written comments:
Reference should be made to Appendix 3.8.1 and Appendix 3.8….(*which is understood as specific guidelines for AHS*).

d) a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent AHS vectors in the country or *zone*.

Community written comments:
Point (d) should read as follows:
"d) the country or *zone* has not reported any case of AHS during at least the previous 3 months and a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent AHS vectors in the country or *zone*."

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

3. An AHS free country or *zone* in which surveillance has found evidence that *Culicoides* likely to be competent AHS vectors are present will not lose its free status through the importation of vaccinated or seropositive domestic horses from infected countries or *zones*, provided:

a) the animals have been vaccinated, in accordance with the *Terrestrial Manual,* at least 40 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme as described in Appendix 3.8.X., and that the animals are identified in the accompanying certification as having been vaccinated; or

b) the animals are not vaccinated, and a surveillance programme as described in Appendix X.X.X. has been in place in the source population for a period of at least 40 days immediately prior to dispatch, and no evidence of AHS has been detected.

Community written comments:
Alternatively, a quarantine system under vector protection should be foreseen.

4. An AHS free country or *zone* should be protected from an adjacent infected country or *zone* by a *buffer*

zone in which surveillance is conducted as described in Appendix X.X.X.

Community written comments:
Paragraph 4 appears to be misplaced, as it should be the third paragraph of Article 2.x.x.1.

Article 2.x.x.3.

AHS seasonally free zone

1. An AHS 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 AHS transmission or of adult *Culicoides* likely to be competent AHS vectors.

2. For the application of Articles 2.x.x.7., 2.x.x. 10. and 2.x.x. 14., the seasonally free period is taken to commence the day following the last evidence of AHS transmission (as demonstrated by the surveillance programme), or of the cessation of activity of adult *Culicoides* likely to be competent AHS vectors.

3. For the application of Articles 2.x.x.7., 2.x.x. 10. and 2.x.x. 14., the seasonally free period is taken to conclude either:

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

   b) 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 AHS vectors.

Community written comments:
It is unclear how reliable such sudden changes would be certified.

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

5. An AHS seasonally free *zone* in which surveillance and monitoring has found evidence that *Culicoides* likely to be competent AHS vectors are present will not lose its free status through the importation of vaccinated or seropositive domestic horses from infected countries or *zones*, provided:

   a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 40 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme as described in Appendix 3.8.X., and that the animals are identified in the accompanying certification as having been vaccinated; or

   b) the animals are not vaccinated, and a surveillance programme as described in Appendix X.X.X. has been in place in the source population for a period of at least 40 days immediately prior to dispatch, and no evidence of AHS has been detected.

Article 2.x.x.4.

AHS infected country or zone

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

Community written comments:
This definition of an AHS-infected country appears to be incomplete.

For example, where AHS was reported in a country during a period of absence of vectors, for example in the northern hemisphere in winter, the restrictions should not apply for 2 years.

It would be preferable that there is an additional option which allows a country or zone to regain the free status after a shorter time subject to surveillance and documented proof that during the time the animal in question was infective, it was effectively protected from vector Culicoides, either because it was the vector free season or the vector is absent in the country or the animal was actively protected from vectors (quarantine).

As the text stands at the moment, it could be that South Africa with a good vaccination is declared free and Greenland with an accident of AHS is considered infected.

Community suggestions:

"An AHS infected country or *zone* is a clearly defined area where evidence of AHS has been reported during the past 2 years or until at least 6 months have elapsed following the last case and a surveillance programme demonstrates the absence of the virus in the target and vector population."

Article 2.x.x.5.

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

1. equines;
2. equine semen;
3. equine embryos;
4. *pathological material* and biological products (from these species) (see Chapter 1.4.5. and Section 1.5.).

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

Article 2.x.x.6.

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

for domestic horses

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were kept in an AHS free country or *zone* since birth or for at least 40 days prior to shipment;

AND

4. either:

   a) did not transit through an infected country or *zone*; or

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

Community written comments:
The Community cannot agree to 4(b).

The provided transit conditions, are not able to be policed and not compatible with the other rules on movement of equidae in and out of infected areas, notably the requirement for 40 days residence in a free country.

The Community propose to replace paragraph 4 by the following wording:

"4. were protected from attack from *Culicoides* likely to be competent AHS vectors at all times when being transported to the place of shipment,

5. did not transit through an infected country or *zone*."

Article 2.x.x.7.

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

for other equines

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

1. showed no clinical sign of AHS on the day of shipment;

2. have not been vaccinated against AHS within the last 40 days;

3. were kept in an AHS free country or *zone* since birth or for at least 40 days prior to shipment;

AND

if the animal originates from a *zone* or country adjacent to a *zone* or country considered infected with AHS:

4. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days prior to shipment; and, either:

   a) were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the AHS group, 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

   b) were subjected during that period to an agent identification test according to the *Terrestrial Manual* 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*;

Community written comments:
Paragraph 4 is in contradiction to the definition of free country in Article 2.x.x.2. (1) (a)

5. were protected from attack from *Culicoides* likely to be competent AHS vectors during transportation to and at the place of shipment.

Article 2.x.x.8.

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

for domestic horses

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

1. were kept during the seasonally free period in an AHS seasonally free *zone* for at least 40 days prior to shipment;

Community written comments:
The Community proposes to replace paragraph 1 with the following wording:

"1. were kept during the seasonally free period in an AHS seasonally free *zone* for at least 40 days prior to shipment in a pre-export quarantine station under official veterinary supervision, and have not shown clinical signs of AHS during this period."

2. have not been vaccinated against AHS within the past 40 days;

AND

3. either:

   a) did not transit through an infected country or *zone*; or

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

Community written comments:
The Community cannot agree to 3(b).

The provided transit conditions, are not able to be policed and not compatible with the other rules on movement of equidae in and out of infected areas, notably the requirement for 40 days residence in a free country.

Article 2.x.x.9.

When importing from AHS infected countries or *zones*, *Veterinary Administrations* should require:
for domestic horses
the presentation of an *international veterinary certificate* attesting that the animals:

1. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days prior to shipment; or

Community written comments:
The Community proposes to replace paragraph 1 with the following wording:

"1. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days prior to shipment in a pre-export quarantine station under official veterinary supervision, and have not shown clinical signs of AHS during this period."

2. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 28 days prior to shipment, and were subjected during that period to a serological test in accordance with the *Terrestrial Manual* to detect antibody to the AHS group, 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

Community written comments:
Double testing makes sense only when also a stable or declining titre would be accepted as indicating previously acquired immunity.
If this was considered, it would be in line with the requirement in 4, as this requirement does not exclude vaccinated animals, it only says not vaccinated during the past 40 days.

3. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 14 days prior to shipment, and were subjected during that period to an agent identification test in accordance with the *Terrestrial Manual* 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*;

AND

4. have not been vaccinated against AHS within the last 40 days;

5. were protected from attack from *Culicoides* likely to be competent AHS vectors during transportation to and at the place of shipment.

Article 2.x.x.10.

When importing from AHS free countries or *zones*, *Veterinary Administrations* should require:
for semen of domestic horses
the presentation of an *international veterinary certificate* attesting that the donor animals:

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;

2. had not been vaccinated against AHS within 40 days of the day of collection;

3. were kept in an AHS free country or *zone* for at least 40 days before commencement of, and during collection of the semen.

Article 2.x.x.11.

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

for semen of domestic horses

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;

2. were not vaccinated against AHS within 40 days of the day of collection;

3. were kept during the seasonally free period in an AHS seasonally free *zone* for at least 40 days before

commencement of, and during, collection of the semen.

Article 2.x.x.12.

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

for semen of domestic horses

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. were not vaccinated against AHS within 40 days of the day of collection;
3. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days before commencement of, and during, collection of the semen.

Article 2.x.x.13.

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

for *in vivo* derived embryos of domestic horses

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

1. the donor females:
   a) showed no clinical sign of AHS on the day of collection of the embryos and for the following 40 days;
   b) have not been vaccinated against AHS within 40 days prior to collection;
   c) were kept in an AHS free country or *zone* for at least the 40 days prior to, and at the time of, embryo collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.x.x.14.

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

for *in vivo* derived embryos of domestic horses

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

1. the donor females:
   a) showed no clinical sign of AHS on the day of collection of the embryos and for the following 40 days;
   b) have not been vaccinated against AHS within the 40 days prior to collection;
   c) were kept during the seasonally free period in an AHS seasonally free *zone* for at least the

40 days prior to, and at the time of, collection of the embryos;

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

Article 2.x.x.15.

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

for *in vivo* derived embryos of domestic horses

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

1. the donor females:

   a) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;

   b) have not been vaccinated against AHS within the 40 days prior to collection;

   c) were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days before commencement of, and during, collection of the embryos;

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

Article 2.x.x.16.

Protecting animals from *Culicoides* attack

When transporting equines through AHS infected countries or *zones*, *Veterinary Administrations* should require strategies to protect animals from attack from *Culicoides* likely to be competent AHS vectors during transport, taking 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 and 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 AHS modelling information to identify low risk ports and transport routes.

Appendix XXXII

CHAPTER 2.3.1.

BOVINE BRUCELLOSIS

Community position
The Community can only support this proposal if the written comments below are taken on board at the next OIE meeting on this subject. In particular the status "free with vaccination" and "free without vaccination" do not equate one with the other. A country free without vaccination should not import vaccinated animals. In addition the Community would like an explanation of why B. suis is included.

Article 2.3.1.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with *Brucella abortus*, *B. melitensis* or *B. suis* infection in cattle (*Bos taurus*, *B. indicus* and *B. grunniens*) and buffalo (*Bubalus bubalis*).

For the purposes of this chapter, a herd means an animal (cattle or buffalo) or a group of animals (cattle or buffalo) kept on one or several holding(s) under a common biosecurity management system in such a way that it constitutes an animal sub-population with a distinct health status.

When authorising import or transit of the following *commodities*, *Veterinary Administrations* should comply with the requirements prescribed in this Chapter relevant to the status of bovine brucellosis in the *exporting country*, *zone* or *compartment*:

1) live animals;

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

3) *meat* and *meat products*;

4) *milk* and *milk products*.

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

Article 2.3.1.2.

Country or zone free from bovine brucellosis without vaccination

To qualify as free from bovine brucellosis without vaccination, a country or *zone* should satisfy the following requirements:

Community written comments:

The Community would like to point out that there appears to be no separate way of regaining status. So this means if the status is lost then the period for regaining the status is 3 three years. This seems to be excessive.

1) ~~bovine~~ brucellosis or any suspicion thereof is *notifiable* in the country;

2) the entire cattle and buffalo population of the country or zone is under *official veterinary control* ~~and it has been ascertained that the rate of brucellosis infection does not exceed 0.2% of the cattle herds in the country or zone under consideration~~;

~~3. the serological tests for bovine brucellosis are periodically conducted in each herd, with or without the ring test;~~

~~4. no animal has been vaccinated against bovine brucellosis for at least the past 3 years;~~

~~5. all reactors are slaughtered;~~

~~6. animals introduced into a free country or zone shall only come from herds officially free from bovine brucellosis or from herds free from bovine brucellosis. This condition may be waived for animals which have not been vaccinated and which, prior to entry into the herd, were isolated and were subjected to the serological tests for bovine brucellosis with negative results on two occasions, with an interval of 30 days between each test. These tests are not considered valid in female animals which have calved during the past 14 days.~~

~~In a country where all herds of cattle have qualified as officially free from bovine brucellosis and where no reactor has been found for the past 5 years, the system for further control may be decided by the country concerned.~~

3) regular and periodic testing of all cattle and buffalo herds has shown that at least 99.8% of the herds and 99.9% of the animals in the country or *zone* have been found free from bovine brucellosis for 3 consecutive years;

Community written comment:

The period of time should be 5 years not 3 years.

4) no case of abortion due to *Brucella* infection and no isolation of *Brucella* has been recorded in cattle and buffalo for at least the last 3 years;

Community written comment:

This statement of 'no case' does not fit with paragraph 3 above which refers to percentages for freedom and see also first comment for regaining status

5) no animal has been vaccinated against bovine brucellosis for at least the past 3 years. This condition may be waived for animals introduced for slaughter;

6) cattle and buffalo introduced into a country or *zone* free from brucellosis without vaccination should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

   a) a country or *zone* free from bovine brucellosis without vaccination; or

   b) a *compartment* or a herd free from bovine brucellosis with or without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment. This test is not considered valid in female animals which have calved during the past 30 days;

7) a surveillance programme based on regular and periodic serological testing of cattle and buffalo with or without milk testing should be in place in the country or *zone* to detect bovine brucellosis in accordance to Appendix 3.8.1.

Article 2.3.1.3.

~~**Herd officially free from bovine brucellosis**~~

Compartment or herd free from bovine brucellosis without vaccination

To qualify as ~~officially~~ free from bovine brucellosis without vaccination, a *compartment* or herd of cattle or buffalo ~~shall~~ should satisfy the following requirements:

~~1. it is under *official veterinary control*;~~

~~2. it contains no animal which has been vaccinated against bovine brucellosis during at least the past 3 years;~~

~~3. it only contains animals which have not showed evidence of bovine brucellosis infection during the past 6 months, all suspect cases (such as animals which have prematurely calved) having been subjected to the necessary laboratory investigations;~~

~~4. all cattle over the age of one year (except castrated males) were subjected to serological tests with negative results on two occasions, at an interval of 12 months between each test; this requirement is maintained even if the entire herd is normally tested every year or testing is conducted in conformity with other requirements established by the *Veterinary Administration* of the country concerned;~~

~~5. additions to the herd shall only come from herds officially free from bovine brucellosis. This condition may be waived for animals which have not been vaccinated, come from a herd free from bovine brucellosis, provided that negative results were shown following a buffered *Brucella* antigen test and the complement fixation test during the 30 days prior to entry into the herd. Any recently calved or calving animal should be retested after 14 days, as tests are not considered valid in female animals which have calved during the past 14 days.~~

1) brucellosis or any suspicion thereof is *notifiable* in the country;

2) the *compartment* or herd is in a country or *zone* free from bovine brucellosis without vaccination and is certified free by the *Veterinary Administration*; or

3) all cattle and buffalo in the *compartment* or in the herd:

   a) are under *official veterinary control*;

b) showed no evidence of bovine brucellosis infection for at least the past 6 months;

c) have not been vaccinated against bovine brucellosis during at least the past 3 years;

d) over 12 months of age, were subjected to a prescribed test with negative results on two occasions, at an interval of more than 6 months and less than 12 months between each test, the second test being performed not before 9 months after the slaughter of the last affected animal;

Community written comment:

The interval of time should be 3 months and not 6.

e) showed a negative result to annual testing regime using tests recommended in the *Terrestrial Manual* to ensure the continuing absence of bovine brucellosis;

4) cattle and buffalo introduced into a *compartment* or herd free from bovine brucellosis without vaccination should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

a) a country or *zone* free from bovine brucellosis without vaccination; or

b) a *compartment* or a herd free from bovine brucellosis with or without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment. This test is not considered valid in female animals which have calved during the past 30 days.

Article 2.3.1.4.

Country or zone free from bovine brucellosis with vaccination

To qualify as free from bovine brucellosis with vaccination, a country or *zone* should satisfy the following requirements:

1) brucellosis or any suspicion thereof is *notifiable* in the country;

2) the entire cattle and buffalo population of the country or zone is under *official veterinary control*;

3) regular and periodic testing of all cattle and buffalo herds has shown that at least 99.8% of the herds and 99.9% of the animals in the country or *zone* have been found free from bovine brucellosis for 3 consecutive years;

4) no case of abortion due to *Brucella* infection and no isolation of *Brucella* has been recorded in cattle and buffalo for at least the past 3 years;

5) herds are subjected to either a vaccination or a non-vaccination programme;

6) cattle and buffalo introduced into a country or *zone* free from bovine brucellosis with vaccination should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

- a country or *zone* free from bovine brucellosis with or without vaccination; or

- a *compartment* or a herd free from bovine brucellosis with or without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment. This test is not considered valid in female animals which have calved during the past 30 days. This test is not required for young animals vaccinated young with the S19 vaccine according to the specific recommendations of the *Terrestrial Manual*, and subject to trade before the age of 24 months;

7) a surveillance programme based on regular and periodic serological testing of cattle and buffalo with or without milk testing should be in place in the country or zone to detect bovine brucellosis in accordance to Appendix 3.8.1.

Article 2.3.1.~~4.~~5.

~~**Herd free from bovine brucellosis**~~

~~To qualify as free from bovine brucellosis, a herd of cattle shall satisfy the following requirements:~~

~~1. it is under *official veterinary control*;~~

~~2. it is subjected to either a vaccination or a non-vaccination regime;~~

~~3. if a live vaccine is used in female cattle, vaccination must be carried out between 3 and 6 months of age, in which case these female cattle must be identified with a permanent mark;~~

~~4. all cattle over the age of one year are controlled as provided in paragraph 4) of the definition of a herd of cattle officially free from bovine brucellosis; however, cattle under 30 months of age which have been vaccinated using a live vaccine before reaching 6 months of age, may be subjected to a buffered *Brucella* antigen test with a positive result, with the complement fixation test giving a negative result;~~

~~5. all cattle introduced into the herd come from a herd officially free from bovine brucellosis or from a herd free from bovine brucellosis, or from a country or zone free from bovine brucellosis. This condition may be waived for animals which have been isolated and which, prior to entry into the herd, were subjected to the serological tests for bovine brucellosis with negative results on two occasions, with an interval of 30 days between each test. These tests are not considered valid in female animals which have calved during the past 14 days.~~

Compartment or herd free from bovine brucellosis with vaccination

To qualify as free from bovine brucellosis with vaccination, a *compartment* or herd of cattle or buffalo should satisfy the following requirements:

1) brucellosis or any suspicion thereof is *notifiable* in the country;

2) the *compartment* or herd is in a country or *zone* free from bovine brucellosis with vaccination and is certified free by the *Veterinary Administration*; or

3) all cattle and buffalo in the *compartment* or in the herd:

4) are under *official veterinary control*;

5) showed no evidence of bovine brucellosis infection for at least the past 6 months;

6) are or have been subjected to a vaccination programme. Where vaccine is used all vaccinated animals should be permanently identified as such;

7) over 12 months of age, were subjected to a prescribed test with negative results on two occasions, at an interval of more than 6 months and less than 12 months between each test, the second test being performed not before 9 months after the slaughter of the last affected animal;

Community written comment:

The interval of time should be 3 months not 6 months.

8) showed a negative result to annual testing regime using tests recommended in the *Terrestrial Manual* to ensure the continuing absence of bovine brucellosis;

9) however, in animals less than 24 months of age vaccinated as young with the S19 vaccine, according to the specific recommendations of the *Terrestrial Manual*, the tests referred in paragraphs d) and e) need not to be performed;

10) cattle and buffalo introduced into a *compartment* or herd free from brucellosis with vaccination should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

a) a country or *zone* free from bovine brucellosis with or without vaccination; or

b) a *compartment* or a herd free from bovine brucellosis with or without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment. This test is not considered valid in female animals which have calved during the past 30 days. This test is not required for young animals vaccinated young with the S19 vaccine according to the specific recommendations of the *Terrestrial Manual*, and subject to trade before the age of 24 months.

Article 2.3.1.~~5.~~6.

Veterinary Administrations of *importing countries* should require:

for cattle and buffalo for breeding or rearing ~~(except castrated males)~~

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

1) showed no clinical sign of bovine brucellosis on the day of shipment;

~~2. were kept in a herd in which no clinical sign of bovine brucellosis was officially reported during the 6 months prior to shipment;~~

~~3. were kept in a country or zone free from bovine brucellosis, or were from a herd officially free from bovine brucellosis and were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment; or~~

~~4. were kept in a herd free from bovine brucellosis and were subjected to buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to shipment;~~

~~if the cattle come from a herd other than those mentioned above:~~

~~5. were isolated prior to shipment and were subjected to a serological test for bovine brucellosis with negative results on two occasions, with an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment. These tests are not considered valid in female animals which have calved during the past 14 days.~~

2) originate from a herd free from bovine brucellosis that is in a country or *zone* free from bovine brucellosis without vaccination; or

Community written comment:

The status free with vaccination and free without vaccination do not equate one with the other. A country free without vaccination should not import a vaccinated animal. There are a number of places where this occurs in this chapter.

3) originate from a *compartment* or a herd free from bovine brucellosis without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment. This test is not considered valid in female animals which have calved during the past 30 days. This test is not required for young animals vaccinated young with the S19 vaccine according to the specific recommendations of the *Terrestrial Manual*, and subject to trade before the age of 24 months; or

4) were isolated and showed no clinical sign of bovine brucellosis for 6 months prior to shipment and were subjected to a prescribed test with negative results on two occasions, with an interval of not less than 6 months between each test. These tests are not considered valid in female animals which have calved during the past 30 days.

Article 2.3.1.~~6~~.7.

Veterinary Administrations of *importing countries* should require:

for cattle and buffalo for slaughter ~~(except castrated males)~~

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

~~1. showed no clinical sign of bovine brucellosis on the day of shipment;~~

~~2. are not being eliminated as part of an eradication programme against bovine brucellosis;~~

~~3. were kept in a country or zone free from bovine brucellosis; or~~

~~4. were kept in a herd officially free from bovine brucellosis; or~~

~~5. were kept in a herd free from bovine brucellosis; or~~

~~6. were subjected to a serological test for bovine brucellosis with negative results during the 30 days prior to shipment.~~

1) originated from a herd free from bovine brucellosis with or without vaccination;

2) were not being eliminated as part of an eradication programme against bovine brucellosis;

3) showed no clinical sign of bovine brucellosis on the day of shipment.

Article 2.3.1.~~7~~.8.

Veterinary Administrations of *importing countries* should require:

for ~~bovine~~ cattle and buffalo semen

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

~~1. when the semen is from an *artificial insemination centre*, the testing programme includes the buffered *Brucella* antigen and complement fixation tests;~~

~~2. when the semen is not from an *artificial insemination centre*, the donor animals:~~

~~a) were kept in a country or zone free from bovine brucellosis; or~~

~~b) were kept in a herd officially free from bovine brucellosis, showed no clinical sign of bovine~~

~~brucellosis on the day of collection of the semen and were subjected to a buffered *Brucella* antigen test with negative results during the 30 days prior to collection; or~~

~~c) were kept in a herd free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection and were subjected to the buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to collection; or~~

~~3. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.~~

1) the donor animals:

a) showed no clinical sign of bovine brucellosis on the day of collection of the semen;

b) were not vaccinated against brucellosis;

c) were kept in an *artificial insemination centre* free from bovine brucellosis without vaccination in a country or *zone* free from bovine brucellosis without vaccination and which only accepts animals from herds free from bovine brucellosis without vaccination in a country or *zone* free from bovine brucellosis without vaccination; or

d) were kept in an *artificial insemination centre* free from bovine brucellosis without vaccination and showed negative results to prescribed tests carried out annually; or

e) were kept in a herd or a *compartment* free from bovine brucellosis without vaccination and were subjected annually to a prescribed test with negative results on two occasions, with an interval of not less than 6 months between each test; and

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. (3.2.1.7. to 3.2.1.10.).

Article 2.3.1.~~8.~~9.

Veterinary Administrations of *importing countries* should require:

~~for *in vivo* derived bovine embryos~~ for embryos/ova of cattle

the presentation of an *international veterinary certificate* attesting that the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., 3.3.2. or 3.3.3., as relevant.

Article 2.3.1.~~9.~~10.

Veterinary Administrations of *importing countries* should require:

~~for *in vitro* produced bovine embryos/oocytes the presentation of an *international veterinary certificate* attesting that:~~

~~1. the donor females: a) were kept in a country or zone free from bovine brucellosis; or b) were kept in a herd officially free from bovine brucellosis and were subjected to tests as prescribed in Appendix 3.1.1.;~~

~~2. the oocytes were fertilised with semen meeting the conditions referred to in Appendix 3.2.1.;~~

~~3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.~~

for *fresh meat* and *meat products* of cattle

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which have been subjected to ante-mortem and post-mortem veterinary inspections as described in the Codex Alimentarius Code of Practice for Meat Hygiene.

Article 2.3.1.11.

Veterinary Administrations of *importing countries* should require:

for *milk* and *milk products*

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

1) has been derived from animals in a herd free from bovine brucellosis with; or

2) was subjected to pasteurisation or a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

- - - - - - - - - - - - - - -
— text deleted

Appendix XXXIII (NEW)

CHAPTER 2.5.5.

EQUINE INFLUENZA

Community position:
The Community can support this proposal.

Article 2.5.5.1.

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an infection of domestic horses which shall include donkeys and mules.

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of infection with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of horses from horses of a different equine influenza health status, with the purpose of preventing the transmission of infection'.

For the purposes of the *Terrestrial Code*, the *infective period* for equine influenza is 21 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. For the purposes of this chapter, a primary vaccination course for an inactivated vaccine comprises two vaccine doses given at an interval specified by the manufacturer; in the case of a live vaccine, one dose constitutes the primary course. Subsequent doses are classified as booster doses.

Article 2.5.5.2.

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for EI occurrence and their historic perspective;

2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, laboratory investigations;

3. appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in horses; this may be achieved through an EI surveillance programme.

Article 2.5.5.3.

Equine influenza free country, zone or compartment

A country or *zone* or *compartment* may be considered free from EI provided it shows evidence of an effective surveillance programme, planned and implemented according to the general principles in Appendix 3.8.1. The surveillance may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

For a country, *zone* or *compartment* in which vaccination is not practised or is practised at a moderate to low level, the absence of clinical equine influenza in the country, *zone* or *compartment* for the past 12 months should be demonstrated.

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised at a high level, should also demonstrate that EIV has not been circulating in the domestic horse population during the past 12 months, through surveillance at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%. The level of population immunity required to prevent transmission will depend on the size, composition and density of the susceptible population, but the aim should be to vaccinate at least 80% of the susceptible population. Based on the epidemiology of EI in the country, *zone* or *compartment*, a decision may be reached to vaccinate only certain subsets of the total susceptible horse population.

If an outbreak of clinical equine influenza occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical case, providing that surveillance for evidence of infection has been carried out during that 12-month period at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%.

Article 2.5.5.4.

Country, zone or compartment of undetermined equine influenza status

A country, *zone* or *compartment* may be considered of undetermined status when it does not meet the conditions for free status.

Article 2.5.5.5.

Regardless of the EI status of the *exporting country*, *zone* or *compartment*, the *Veterinary Administration* of a country, *zone* or *compartment* should authorise without restriction on account of EI the importation into their *territory* of the following *commodities*:

a) semen;

b) *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.5.5.6.

When importing horses for immediate slaughter, the *Veterinary Administration* of an EI free country, *zone* or *compartment* should require:

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; or

2) came from a country, *zone* or *compartment* of undetermined EI status and had been subjected to pre-export isolation for 21 days, and showed no clinical sign of EI during isolation nor on the day of shipment.

Article 2.5.5.7.

When importing horses for immediate slaughter, the *Veterinary Administration* of a country, *zone* or *compartment* of undetermined EI status should require:

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; or

2) came from a country, *zone* or *compartment* of undetermined EI status and showed no clinical sign of EI on the day of shipment.

Article 2.5.5.8.

When importing horses for unrestricted movement, the *Veterinary Administration* of an EI free country, *zone* or *compartment* should require:

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days;

OR

2) came from a country, *zone* or *compartment* of undetermined EI status, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3) were vaccinated between 14 and 90 days before shipment either with a primary course or a booster.

Article 2.5.5.9.

When importing horses for unrestricted movement, the *Veterinary Administration* of a country, *zone* or *compartment* of undetermined EI status should require:

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2) came from a country, *zone* or *compartment* of undetermined EI status and showed no clinical sign of EI on the day of shipment; and

3) were vaccinated between 14 and 180 days before shipment either with a primary course or a booster.

Article 2.5.5.10.

When importing horses which will be kept in isolation, the *Veterinary Administration* of an EI free country, *zone* or *compartment* should require:

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2) showed no clinical sign of EI in any premises in which the horses had been resident for the 30 days prior to shipment nor on the day of shipment; and

3) were vaccinated between 14 and 180 days before shipment either with a primary course or a booster;

4) (where applicable) had been kept in isolation except during competition.

Article 2.5.5.11.

When importing horses which will be kept in isolation, the *Veterinary Administration* of a country, *zone* or *compartment* of undetermined EI status should require:

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2) showed no clinical sign of EI in any premises in which the horses had been resident for the 30 days prior to shipment nor on the day of shipment; and

3) were vaccinated between 14 and 180 days before shipment either with a primary course or a booster;

4) (where applicable) had been kept in isolation except during competition.

Article 2.5.5.12.

When importing *fresh* horse *meat*, the *Veterinary Administration* of a country, *zone* or *compartment* should require:

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

1) came from an EI free country, *zone* or *compartment* in which the horses from which the meat was derived had been resident for at least 21 days; or

2) came from horses which had been subjected to ante-mortem and post-mortem inspections as described in the Codex Alimentarius Code of Practice for Meat Hygiene.

Appendix XXXII

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Community position:
The Community fully supports the future work programme of the OIE as laid down below however there appears to a be a section on risk mitigating factors and inactivation of pathogens missing. This was included in the 5 year work programme and a commitment to this has been given on a number of occasions. The Community insists that the OIE re-examine the formalisation of numbering of outbreaks (annual serial numbers) and dates (initial detection, suspicion and confirmation etc.) in member countries. It believes members need further guidance on this and it would facilitate the following of reported outbreaks, give a reference point to laboratory typing of different types and sub-types and improve consistency of reporting.
In addition guidelines for disease control should be produced and this would also be useful in consideration of BVD. The Community would be pleased to help in this work.

Topic	**Action**	**How to be managed**
Traceability	*Ad hoc* Group to develop specific Chapter on animal identification and traceability	Animal Production Food Safety Working Group (APFS WG).
Consolidation of *Terrestrial* and *Aquatic Codes*	To work with the Aquatic Commission to maximise harmonisation of present Codes, with an ultimate goal of a single Code in three parts: horizontal chapters, terrestrial animal disease chapters and aquatic animal disease chapters.	The Secretariat will continue to harmonise horizontal chapters, and work towards their consolidation. Each Commission to invite other Commission President to its meetings.
Good farming practices	To coordinate with the FAO's work to publish a single guideline on good farming practices for the guidance of Member Countries and the public.	APFS WG
Control of hazards of animal health and public health importance through ante- and post-mortem meat inspection	To develop Code guidelines	APFS WG
Anthrax	To develop an appendix on the inactivation of the bacillary and spore forms of *Bacillus anthracis.*	Secretariat
BSE – safety of gelatine and tallow	To update 'safe commodities' article	*ad hoc* Group
BSE supporting	To update	expert

document		
BSE risk assessment	To update	expert
Current chapter on Veterinary Services	To revise to better address the role of the Statutory Body, the early detection of disease and greater detail on how the auditing of Veterinary Services could be implemented.	expert
Other *Terrestrial Code* texts in need of revision	To update chapter on equine influenza	Reference Laboratory
	To update chapter on brucellosis	SCAD then APFS WG
	To update chapter on Newcastle disease	SCAD
	To update chapter on African swine fever	SCAD
***Terrestrial Code* texts identified as priorities by APFS WG**	Salmonellosis	SCAD
	Cysticercosis	SCAD
Harmonisation of international health certificates	To finalise with view of replacing existing Code certificates **Community Comment:** **The Community suggests to add "with co-ordination of Codex Alimentarius"**	APFS WG
Dead animal disposal	To finalise Code appendix	SCAD
Animal welfare – companion animals and laboratory animals	To draft new chapters	AW WG
Alternative approaches to providing OIE advice*	To develop alternative mechanism for providing guidance to Member Countries on managing certain animal health and welfare issues outside the Code framework *	TCC, AW WG and APFS WG
Surveillance for vectors	To develop guidelines for the surveillance of vectors capable of transmitting animal diseases	SCAD
***Community written comments:** **The Community is in favour of the development by the OIE of specific guidance for the control of specific diseases not included in the code providing they do not impinge on trade.**		

Appendix XXXIV

CHAPTER 1.4.5.

INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENS

Community position:

The Community supports this proposal.

Article 1.4.5.1.

Object

To prevent the introduction and spread of animal diseases caused by pathogens.

Article 1.4.5.2.

Introduction

1. The consequences of the introduction into a country of an infectious disease or an animal pathogen or new strain of animal pathogen from which it is currently free, are potentially very serious. This is because animal health, human health, the agricultural economy and trade may all be adversely affected to a greater or a lesser degree. Countries will already have in place a range of measures, such as requirements for pre-import testing and quarantine, to prevent such introductions through the importation of live animals or their products.

2. However, there is also the risk that disease may occur as a result of the accidental release of animal pathogens from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied either at national borders by prohibiting or controlling the importation of specified pathogens or their carriers ~~(see Article 1.4.5.7.)~~ or within national boundaries by specifying the conditions under which laboratories must handle them. In practice, a combination of external and internal controls is likely to be applied depending on the risk to animal health posed by the pathogen in question.

Article 1.4.5.3.

Classification of pathogens

Pathogens should be categorised according to the risk they pose to both human and animal health. They are grouped into four risk categories. Detailed information is provided in the *Terrestrial Manual.*

~~Article 1.4.5.3.~~

~~**Purpose**~~

1) ~~To provide guidance on the laboratory containment of animal pathogens according to the risk they pose to animal health and the agricultural economy of a country, particularly when the disease they cause is not enzootic.~~

2) ~~To provide guidance on the import conditions applicable to animal pathogens.~~

Appendix XXXIV (contd)

~~3) Where animal pathogens also pose a risk to human health, guidance on their laboratory containment should be sought from the *Terrestrial Manual* and other relevant published documents.]~~

Article 1.4.5.4.

Importation of animal pathogens

1. The importation of any animal pathogen, *pathological material* or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of hazardous substances. The import licence for risk groups 2, 3 or 4 should only be granted to a laboratory that is licensed to handle the particular pathogen as in Article 1.4.5.5.

2. When considering applications to import *pathological material* from other countries, the authorities should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various diseases and the animal health situation of the country of origin. It may be advisable to require that material is pre-treated before import to minimise the risk of inadvertent introduction of a pathogen.

~~Article 1.4.5.4.~~

~~**Classification of animal pathogens**~~

~~1) Animal pathogens should be categorised on the risk they pose to animal health, should they be introduced into a country or accidentally released from a laboratory. In categorising pathogens into four groups according to containment requirements, the following factors should be taken into account: the organism's pathogenicity, the biohazard it presents, its ability to spread, the economic aspects and the availability of prophylactic and therapeutic treatments.~~

~~2) Some pathogens need to be transmitted by specific vectors or require intermediate hosts to complete their life cycles before they can infect animals and cause disease. In countries where such vectors or intermediate hosts do not occur, or where climatic or environmental factors mitigate against their survival, the pathogen poses a lower risk to animal health than in countries where such vectors or intermediate hosts occur naturally or could survive.~~

~~3) When categorising animal pathogens into specific groups, the following criteria should be taken into account:~~

~~a) Group 1 animal pathogens~~

~~Disease producing organisms which are enzootic but not subject to official control.~~

~~b) Group 2 animal pathogens~~

~~Disease producing organisms which are either exotic or enzootic but subject to official control and which have a low risk of spread from the laboratory.~~

~~i) They do not depend on vectors or intermediate hosts for transmission.~~

~~ii)~~ ~~There is a very limited or no transmission between different animal species.~~

iii) Geographical spread if released from the laboratory is limited.

iv) Direct animal to animal transmission is relatively limited.

v) The need to confine diseased or infected non-diseased animals is minimal.

vi) The disease is of limited economic and/or clinical significance.

c) Group 3 animal pathogens

i) Disease-producing organisms which are either exotic or enzootic but subject to official control and which have a moderate risk of spread from the laboratory.

ii) They may depend on vectors or intermediate hosts for transmission.

iii) Transmission between different animal species may readily occur.

iv) Geographical spread if released from the laboratory is moderate.

v) Direct animal to animal transmission occurs relatively easily.

vi) The statutory confinement of diseased, infected and in-contact animals is necessary.

vii) The disease is of severe economic and/or clinical significance.

viii) Prophylactic and/or therapeutic treatments are not readily available or of limited benefit.

d) Group 4 animal pathogens

Disease-producing organisms which are either exotic or enzootic but subject to official control and which have a high risk of spread from the laboratory.

i) They may depend on vectors or intermediate hosts for transmission.

ii) Transmission between different animal species may occur very readily.

iii) Geographical spread if released from the laboratory is widespread.

iv) Direct animal to animal transmission occurs very easily.

v) The statutory confinement of diseased, infected and in-contact animals is necessary.

~~vi) The statutory control of animal movements over a wide area is necessary.~~

~~vii) The disease is of extremely severe economic and/or clinical significance.~~

~~viii) No satisfactory prophylactic and/or therapeutic treatments are available.~~

Appendix XXXIV (contd)

~~Article 1.4.5.5.~~

~~**Containment levels**~~

~~1) The principal purpose of containment is to prevent the escape of the pathogen from the laboratory into the national animal population. Some animal pathogens can infect man. In these instances the risk to human health may demand additional containment than would otherwise be considered necessary from purely animal health considerations.~~

~~2) The level of physical containment and biosecurity procedures and practices should be related to the group into which the pathogen has been placed, and the detailed requirements should be appropriate to the type of organism (i.e. bacterium, virus, fungus or parasite). The lowest containment level will be required for pathogens in group 1 and the highest level for those in group 4. Guidance on the containment requirements for groups 2, 3 and 4 is provided in Table 1.~~

~~3) Arthropods may be pathogens or vectors for pathogens. If they are a vector for a pathogen being used in the laboratory, the appropriate containment level for the pathogen will be necessary in addition to the containment facilities for the arthropod.~~

~~Article 1.4.5.6.~~

~~**Possession and handling of animal pathogens]**~~

Article 1.4.5.5.

Laboratory containment of animal pathogens

1. Guidance on the laboratory containment of animal pathogens and on the import conditions applicable to animal pathogens is found in the Chapter I.1.6. of the *Terrestrial Manual*. Additional guidance on human safety is also found in this chapter.

2. A laboratory should be allowed to possess and handle animal pathogens in group 3 or 4 only if it can satisfy the relevant authority that it can provide containment facilities appropriate to the group. However, depending on the particular circumstances of an individual country, the authority might decide that the possession and handling of certain pathogens in group 2 should also be controlled. The authority should first inspect the facilities to ensure they are adequate and then issue a licence specifying all relevant conditions. There should also be a requirement for appropriate records to be kept and for the authority to be notified if it is suspected that a material being handled contains a pathogen not covered by the licence. The authority should visit the laboratory periodically to ensure compliance with the licence conditions. It is important that authority staff carrying out the visit should not have any contact with species susceptible to the pathogens being handled at the laboratory for a specified period after visiting the laboratory. The length of this period will depend on the pathogen.

3. Licences should specify:

   a) how the pathogen is to be transported and the disposal of the packaging;

   b) the name of the person responsible for the work;

c) whether the pathogen may be used *in vivo* (and if so whether in laboratory animals or other animals) and/or only *in vitro*;

d) how the pathogen and any experimental animals should be disposed of when the work is completed;

e) limitations on contact by laboratory staff with species susceptible to the pathogens being used;

f) conditions for the transfer of pathogens to other laboratories;

g) specific conditions relating to the appropriate containment level and biosecurity procedures and practices.

Appendix XXXIV (contd)

Table 1. Guidance on the laboratory requirements for the different containment groups

-	CONTAINMENT GROUP		
REQUIREMENTS OF THE LABORATORY	**2**	**3**	**4**
A)Laboratory siting and structure	-	-	-
1.Not next to known fire hazard	Yes	Yes	Yes
2.Workplace separated from other activities	Yes	Yes	Yes
3.Personnel access limited	Yes	Yes	Yes
4.Protected against entry/exit of rodents and insects	Yes	Yes	Yes
5.Liquid effluent must be sterilised	-	Yes and monitored	Yes and monitored
6.Isolated by airlock. Continuous internal airflow	-	Yes	Yes
7.Input and extract air to be filtered using HEPA or equivalent	-	Single on extract	Single for input, double for extract
8.Mechanical air supply system with fail-safe system	-	Yes	Yes
9.Laboratory sealable to permit fumigation	-	Yes	Yes
10.Incinerator for disposal of carcasses and waste	Available	Yes	Yes on site
B)Laboratory facilities			
11.Class 1/2/3 exhaust protective cabinet available	Yes	Yes	Yes
12.Direct access to autoclave	Yes	Yes with double doors	Yes with double doors
13.Specified pathogens stored in laboratory	Yes	Yes	Yes
14.Double ended dunk tank required	-	Preferable	Yes
15.Protective clothing not worn outside laboratory	Yes	Yes	Yes
16.Showering required before exiting laboratory	-	-	Yes
17.Safety Officer responsible for containment	Yes	Yes	Yes
18.Staff receive special training in the requirements needed	Yes	Yes	Yes
C)Laboratory discipline	-	-	-
19.Warning notices for containment area	Yes	Yes	Yes
20.Laboratory must be lockable	Yes	Yes	Yes
21.Authorised entry of personnel	Yes	Yes	Yes
22.On entering all clothing removed and clean clothes put on	-	Yes	Yes
23.On exiting all laboratory clothes removed, individual must wash and transfer to clean side	-	Yes	-
24.Individual must shower prior to transfer to clean side	-	-	Yes
25.All accidents reported	Yes	Yes	Yes
D)Handling of specimens	-	-	-
26.Packaging requirements to be advised prior to submission	Yes	Yes	Yes
27.Incoming packages opened by trained staff	Yes	Yes	Yes
28.Movement of pathogens from an approved laboratory to another requires a licence	Yes	Yes	Yes
29.Standard Operating Procedures covering all areas must be available	Yes	Yes	Yes

- - - - - - - - - - - - - - - — text deleted

Appendix XXXV

GUIDELINES FOR ANIMAL IDENTIFICATION AND TRACEABILITY

PRELIMINARY DOCUMENT

Community position:

The Community supports this proposal.

System for identification and traceability of live animals – main points

The purpose of these guidelines for animal identification and traceability is to provide an instrument for OIE Member Countries to improve animal health and public health as well as to ensure better management of health crises at national and international levels.

Animal traceability requires an efficient animal identification system in order to ensure a continuum in the food production chain.

Several steps need to be taken before implementation can commence.

This system can be used to assist in meeting other objectives such as: quality assurance programmes, certified products, organic farming, ownership.

The development and implementation of the system should be done in consultation with representatives of the applicable animal and industry sectors.

The scope of these guidelines is to present the main points that constitute a system for identification and traceability of live animals as well as the outcomes required.

Strategy

1. **Preliminary studies**

   a. **Assess the current situation, including farming structure.** The Veterinary Administration, in collaboration with stakeholders, should assess the requirements and scope of the animal identification system and animal traceability. The current situation should be evaluated. To this end, an assessment should be carried out taking in consideration factors such as:

      - Animal populations, species
      - Farming and industry structures and production
      - Animal health
      - Public health
      - Trade issues
      - Zoning and compartmentalisation
      - Animal movement patterns (including transhumance)

- Information management
- Availability of resources
- Social and cultural aspects.

b. **Objectives.** Following the outcomes of this assessment, the objectives of animal identification system and animal traceability should be determined. These may include the improvement of:

- animal health (control of disease, disease surveillance, early disease detection and response, vaccination programmes)
- public health (control of food safety incidents, disease surveillance, control of zoonotic diseases)
- trade (reliable inspection and certification)
- animal genetic
- crisis/incident management.

c. **Scope.** According to the chosen objectives, the scope has to define the targeted species/population within a country, zone, compartment or a particular programme.

d. **Costs and benefits.** The costs and benefits need to be analytically assessed taking into account the objectives and the scope.

2. **Strategic plan.** Before implementing an animal identification and traceability system, a **strategic** plan should be developed in order to define/elaborate/determine the following elements:

a. objectives and outcomes

b. scope

c. sustainability of the system

d. human and financial resources

e. logistics

f. means of identification and technology to be used

g. pilot projects

h. communication plan (including education)

i. timetable

j. responsibility and obligation of the different parties

i. competent authority

ii. other relevant sector(s)/stakeholders

iii. management and governance

k. legal framework

l. standards, manuals of procedures

m. monitoring and evaluation.

Implementation

3. **Action plan:** The action plan must describe the roles, responsibilities and linkages between each stakeholder group and other public or private sector involved. The legal framework will establish these responsibilities.

   The action plan must specify the timetable for implementation including the milestones and performance indicators, the human and financial resources needed to achieve these milestones and monitoring, enforcement and verification arrangements.

   As part of the action plan, there needs to be a communication and a training plan.

   Depending on the elements of the system, investment may be needed in a database or linked complementary databases, communication links between participants and the database/s, equipment and materials for identification, for a system using electronic technology readers and telecommunications, and standardised documents for participant use.

   The Veterinary Administration is responsible for ensuring the integrity of the animal identification system, including verification of official identification materials and equipment to guarantee that these items comply with technical requirements and the supervision of their distribution. The Veterinary Administration is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the animal identification system.

4. **Communication**: As part of the communication plan, the objectives, costs and benefits, responsibilities, correct identification and movement recording techniques and possible sanctions need to be communicated to industry participants and stakeholders. Communication strategies need to be targeted to the audience taking into account elements such as: the level of literacy (include technology literacy) and spoken languages. Training programmes should complement communication strategies, and focus on practical demonstrations where possible.

5. **Registration of establishments/owners:** Establishments where animals are kept should be identified and registered, including at least their physical location and species. If the registration of establishments is not applicable, the recording of the animal owner and the owner's place of residence is desirable. Depending on the objectives and outcomes of the system, the types of establishments that may need to be registered include holdings, assembly centres, saleyards, abattoirs, knackeries, rendering plants, animal incinerators, agricultural fair grounds, transhumance, etc.

6. **Means of animal identification:** The means of physical animal identification must be chosen following consideration of elements such as: the costs, human resources, species, age of the animals to be identified, animal welfare, cultural aspects, technology compatibility and relevant standards, farming practices, animal population, climatic conditions, retention and readability of the identification method given the objectives of animal identification and animal traceability. Where group identification without a physical identification is adequate, documentation must be created specifying at least the number of animals in the group, the species, the date of identification, the owner and/or establishment and this documentation would constitute a unique group identifier. Where all animals in the group are physically identified with a group identifier, documentation must also specify the unique group identifier.

7. **Movement recording:** The registration of movements is necessary for animal traceability. When an animal leaves an establishment, this constitutes a movement and should be registered.

Movement records and associated documentation must specify, at least the species, the unique identifier or unique group identifier, the date of the movement, the establishment from which the animal or group of animals was dispatched, the destination establishment, and transit points in between. When establishments are not registered as part of the animal identification system, ownership and location changes constitute a movement record. Movement recording may also include registration of establishment of birth and slaughter or death, and means of transportation and the vehicle/transportation identifier.

8. **Information storage and recovery:** The methods used for collecting, compiling, storing and retrieving information as part of the animal identification system needs to be considered in the context of the objectives and outcomes of the system. The registration components of the animal identification system must be compatible and able to be linked to allow timely and reliable traceability and for other purposes. The animal identification system must minimise the duplication of information collection to reduce the burden, and to maximise the acceptance and the efficiency of the system. The duration of the storage of information should be compatible with the objectives and expected outcomes of the system.

9. **Database:** The databases should operate in order to meet the objectives of the system. The Competent Authority and Veterinary Administration must have unrestricted access to the databases as appropriate to meet the objectives of the system. The databases that are part of the animal identification system should be integrated with other complementary database such as those for epidemiology, laboratory, quality assurance programmes, certification, transportation, etc.

10. **Documentation:** Documentation, including electronic documentation, should be linked to animal identification as part of the animal identification system. Situations where documentation is needed must be specified and the information required and formats that are acceptable in each circumstance must be standardised.

11. laboratories (link with epidemiological information);

12. abattoir, rendering points, markets;

13. training;

14. awareness;

15. information on slaughter date, birth date, reproduction;

16. means of identifications (safeguarding lifetime animal identification: permanent, tamper proof).

Monitoring and verification

17. verification and auditing

18. sanctions

19. means of identifications (safeguarding lifetime animal identification: permanent, tamper proof)

20. timely notifications (minimum time for identification)

21. timely notification for movement

22. importation of animals.