COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft 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

Delegations will find attached Commission document SEC(2006) 634.

Encl.: SEC(2006) 634

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.5.2006
SEC(2006) 634

COMMISSION STAFF WORKING DOCUMENT

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

EXPLANATORY MEMORANDUM

The World Organisation for Animal Health (OIE) is an International organisation designated under the Agreement on the Application of Sanitary and Phytosanitary Measures in application of the World Trade Organisation rules as responsible for the establishment of international animal health rules for trade in animals and their products. These codes and manuals are published following proposals by the various OIE bodies and adoption at the General Session which meets annually in Paris.

The comments of the Community on preliminary texts to be submitted by the OIE for adoption and consideration in the 74th General Session to be held in May 2006 have been sent to the OIE [SEC (2006) 47 Final by letter D(2005) 522619] signed by Dr J Husu-Kallio and Dr U. Herzog CVO of Austria (Council Presidency).

The OIE Terrestrial Animal Health Standards Commission met at the OIE Headquarters in Paris in March 2006.

The OIE Biological Standards Commission met at the OIE Headquarters in Paris in January 2006.

Proposals for modifications of several OIE Code Chapters are for adoption or consideration at the next General Session to be held in Paris from 21-27 May 2006.

These reports and proposals have been circulated to member countries. In view of the status of these Health Codes, in particular in making recommendations for international trade in animals and their products, it is necessary for the Community to take a common position on this matter. In this context, the Community thanks the OIE for providing the electronic version of the Reports

The Commission therefore proposes to the Council to authorise the Commission:

- to present, as since 1995, the following written positions at Annex I to the OIE for information prior to submission of this final position at the General Session in May 2006. The cover letter to be sent with our response is attached (see document D(2006)/411181 at Annex A). The Community speaking positions to be raised during the meeting including additional written comments have been incorporated in boxes into the OIE reports together with speaking notes.

- to co-ordinate consultations with Member States in order to reach a Community position on matters raised during the General Session of the OIE. Daily co-ordination meetings will be organised on-the-spot.

ANNEX A

UNION EUROPEENNE

Bruxelles, le
D(2006) 411181 HLB

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

Dear Director General,

Please find attached, for your informal information, an annex indicating the intended position of the Community including written comments on the report of the Terrestrial Animal Health Standards Commission to be raised at the General Session in May 2006 in Paris.

Concerning the report of the Biological Standards Commission I would like to advise you that the Community agrees with the listing and updates for the new applications for OIE Reference Laboratories and Collaborating Centres etc and also with the proposed amended three chapters for the diagnostic manual for a vote during the General Session. The other manual proposals are enclosed with our comments to be examined at the next meeting of the Biological Standards Commission.

I trust you will find this useful.

Thank you for your continued cooperation

Kind regards

Dr.Jaana Husu-Kallio
Directeur Général Adjoint

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

ANNEX

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

74 SG/12/CS1 B

Original: English
March 2006

Unofficial version

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.

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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

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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

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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 speaking position:
The European Community can support this proposal but has communicated written comments on some particular issues 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.

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Community speaking 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 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 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 if not what is its status.

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 speaking position:
The Community supports this proposal but has sent in written 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 make some comments at this

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time as 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 further diseases such as Avian Influenza (in view of the importance of this disease as was done for BSE) and indeed also for Classical Swine Fever.

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.

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.

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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 speaking position:

The Community can support these proposals but would like the minor inconsistencies communicated to the OIE 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 speaking position:

Community speaking 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

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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 already communicated to the OIE. For the Surveillance Chapter 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).

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 speaking 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" countries associated to 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 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.

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In summary the Community can support the current proposal but would like to touch on two important issues within this Chapter.

Firstly based on the experience within EU linked to the implementation of the feed ban and the problems linked to cross contamination the Community would however ask that provision related to the feed ban and to expand to ruminant feed ban to a Mammalian to ruminant feed ban be reconsidered.

Secondly on gelatine: to be elaborated following CVO meeting

Coming now to the last but very important topic linked to the categorisation of countries according to their BSE risk. OIE as World Animal health Organisation 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 linked to the feed ban and the production standards for the gelatine production.

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

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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.

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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.

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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 speaking 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. It has sent in written comments to the OIE concerning these points.

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.

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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 speaking position:

The European Union 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. But recent experiences have shown that there are problems in international trade in relation to the use of vaccination against AI. - I would like to endorse what Dr Husu-Kallio has said in the opening ceremony that from this General Session a clear signal in respect of the use of vaccination against AI should be sent out! Furthermore we appreciate that highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry will be included in the OIE list and that all members will report these outbreaks starting from the end of this General Session.

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 speaking position:

The Community can support the proposals for the adoption of the proposed Annexes XVII and XVIII.

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

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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 speaking 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 speaking 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.

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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 speaking 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.

Speaking Community position (common position for Appendices 3.7.2 and 3.7.3, land and sea transport):

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The European Community can support these proposals but will communicate written comments on some particular issues. 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.

Speaking Community position (common 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 this proposal but has communicated written comments on some particular issues 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. The European Community can support these proposals but will communicate written comments on some particular issues. 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. On a more specific issue the Community believes that the inclusion of the rotating box as a recommended method for restraining animals should be re-considered. The negative welfare implications of this method have been scientifically documented and alternative

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methods of restraint are available. 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 speaking position:
The Community can support this proposal but would like the written comments already communicated to the OIE taken into account at the

Unofficial version

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 speaking position:
The Community can support this initiative as it had some serious concerns over the drafting of these Chapters.

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 speaking 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.

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

Community speaking 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. 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

(NB Go to Chapter for specific details).

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 speaking 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.

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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.

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Community speaking 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 speaking position:
The Community can only support this proposal if the points 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 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 speaking 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 speaking 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

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Commission does not intend to incorporate any such guidelines into the *Terrestrial Code*, but to use another approach to make the information available.

Community speaking 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 speaking 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 speaking 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).

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.../Appendices

Appendix I

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6-10 March 2006

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Appendix II

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 6-10 March 2006

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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

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Item 19 Other issues

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CHAPTER 1.1.1.

GENERAL DEFINITIONS

Speaking Community position:

The European Community can support this proposal but has communicated written comments on some particular issues (see below) 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 see 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*.

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 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. Community comments:
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 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 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).

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— text deleted

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

10230/06
ADD 1

LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volumes IV, V and VI

Delegations will find attached Commission document SEC(2006)634 - Volumes IV, V and VI.

Encl.: SEC(2006) 634

Appendix IV

CHAPTER 1.3.3.

~~1.~~ EVALUATION OF VETERINARY SERVICES

Community speaking 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 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 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 if not what is its status.

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.

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Appendix V

CHAPTER 1.3.4.

~~1.2.~~ GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Community speaking 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

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Performance, Vision and Strategy (PVS) *for*

VETERINARY SERVICES (VS)[1]

Community speaking position:
The Community supports this draft.

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

[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

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[1]; 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

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

[1] 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

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[1] confirmation.

1. For zoonoses[2] 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[3] the quality of its clinical diagnostic, collection and shipment of samples procedures.

2. Early detection and emergency response capability
The capability and authority of the VS to rapidly respond to unexpected disease outbreak[4] or other situations that put at immediate risk the sanitary status[5] of the animal populations covered under its mandate.

Levels of advancement:

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[1] 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.

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

[3] 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.

[4] 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.

[5] 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.

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[1] 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[2] 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.

3. The VS can or has implemented specialized quarantine programs[3] 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[4]

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[1] 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.

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

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

[4] 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.

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.

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[1]
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:

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*.

[1] 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.

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.[1]

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.

3. The VS incorporates technical innovations into selected functions and procedures, with specific resources and the collaboration or contributions of its users.[2]

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

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

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

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[1] 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[2].

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)

[1] 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.

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

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[1].

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[2] to execute specific programs under complete transparency and ensuring full independence[3].

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[4] at all levels.

1. The VS is reorganized frequently at some levels.

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

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

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

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

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

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[1].

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[2] 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.

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

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

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[1].

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[2].

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

[2] in compliance with OIE standards on independence and impartiality of VS

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[1] 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[2] and users[3].

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.

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.

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[1] Means every six months

[2] private sector includes farmers, industry, transport and distribution

[3] " users" means all beneficiaries of the VS activities

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[1].

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[2] 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[3] 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[4] 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.

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

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[1] in compliance with international procedures and practices.

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

[3] *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.

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

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[1].

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

1. Compliance with regulations[1]

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[2]

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.

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

[1] 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

[2] 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

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.[1]

4. Certification[2]

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.

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

[2] 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.

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[1] 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.

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[2].

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.

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[1] 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

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

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.

4. The VS, along with the other relevant State institutions, carries out audits of its transparency procedures[1] through an efficient national chain of command.

8. Zoning[2]

The capability and authority of the VS to establish and maintain disease free zones/ [3] or zones/ of low disease prevalence[4], 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.

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

[2] 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

[3] 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.

[4] 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

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 [1]

The capability and authority of the VS to establish and maintain disease free compartments[2] / or compartments / of low disease prevalence[3], in accordance to the criteria established by the WTO/SPS and the OIE.

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.

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

[2] 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

[3] 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.

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volumes VII and VIII

Delegations will find attached Commission document SEC(2006)634 - Volumes VII and VIII.

Encl.: SEC(2006) 634

Appendix VII

CHAPTER 1.3.5.

ZONING AND COMPARTMENTALISATION

Community speaking position:
The Community supports this proposal but has sent in written 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 make some comments at this time as 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 further disease such as Avian Influenza in view of the importance of this disease as was done for BSE and indeed for Classical Swine Fever.

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*.

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Appendix VIII

CHAPTER 2.1.1.

CRITERIA FOR LISTING DISEASES

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

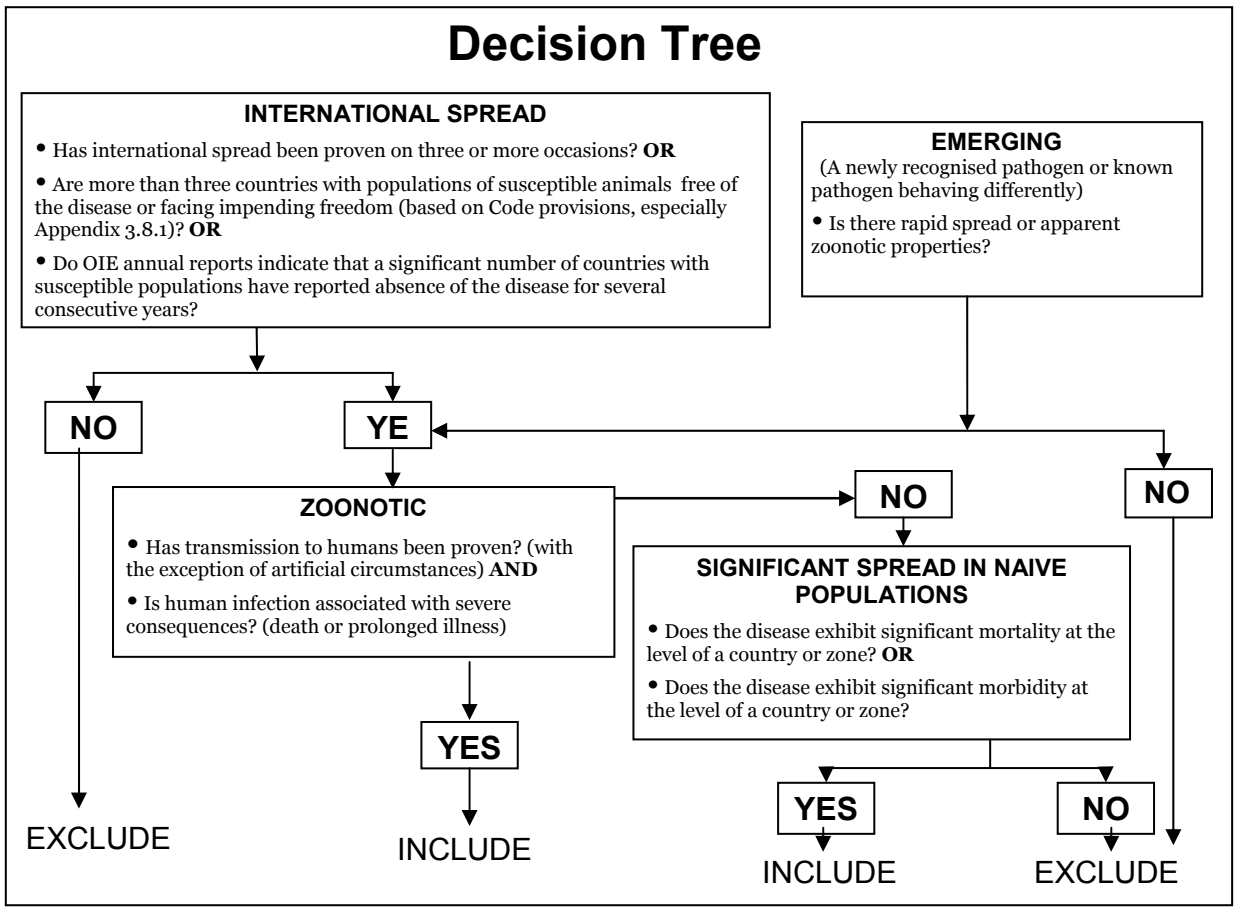
Article 2.1.1.1.

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 in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 2.7.12
- 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.

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volumes IX and X

Delegations will find attached Commission document SEC(2006)634 - Volumes IX and X.

Encl.: SEC(2006) 634

Appendix IX

CHAPTER 2.2.10.

FOOT AND MOUTH DISEASE

Community speaking position:

The Community can support this proposal but the Community would like the minor inconsistencies communicated to the OIE 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 within the proposed FMD *free zone*:

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 proposed 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* or physical or geographical barriers,

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.

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— text deleted

Appendix X

APPENDIX 3.8.7.

GUIDELINES FOR THE SURVEILLANCE OF FOOT AND MOUTH DISEASE

Community posssible speaking position [only if necessary]:
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.

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.

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;

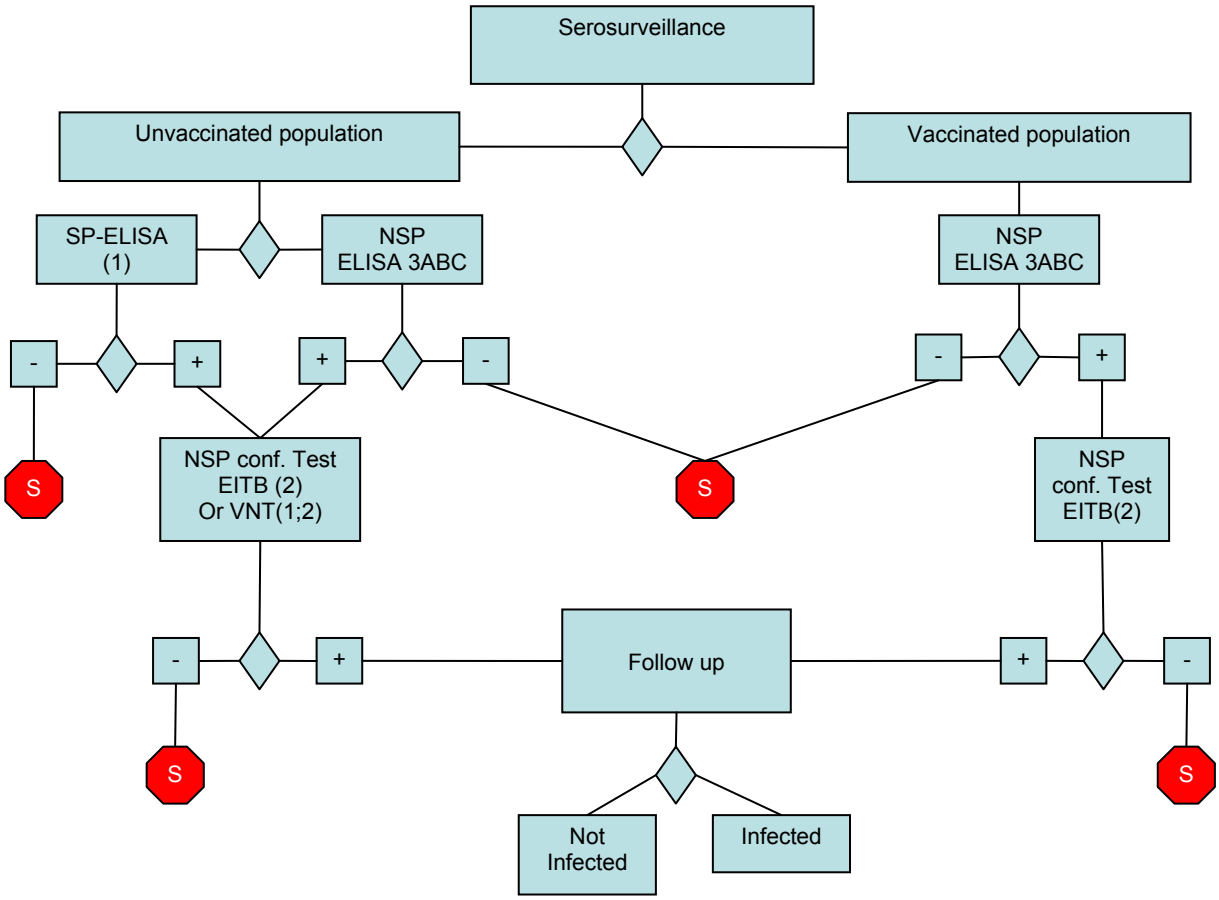
– sanitary protocol and history of the *establishments* with positive reactors;

– 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

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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ADD 3

LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volumes IX and X

Delegations will find attached Commission document SEC(2006)634 - Volumes IX and X.

Encl.: SEC(2006) 634

Appendix IX

CHAPTER 2.2.10.

FOOT AND MOUTH DISEASE

Community speaking position:

The Community can support this proposal but the Community would like the minor inconsistencies communicated to the OIE 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 within the proposed FMD *free zone*:

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 proposed 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* or physical or geographical barriers,

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.

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— text deleted

APPENDIX 3.8.7.

GUIDELINES FOR THE SURVEILLANCE OF FOOT AND MOUTH DISEASE

Community posssible speaking position [only if necessary]:
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.

1. <u>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</u>

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.

2. <u>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</u>

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;

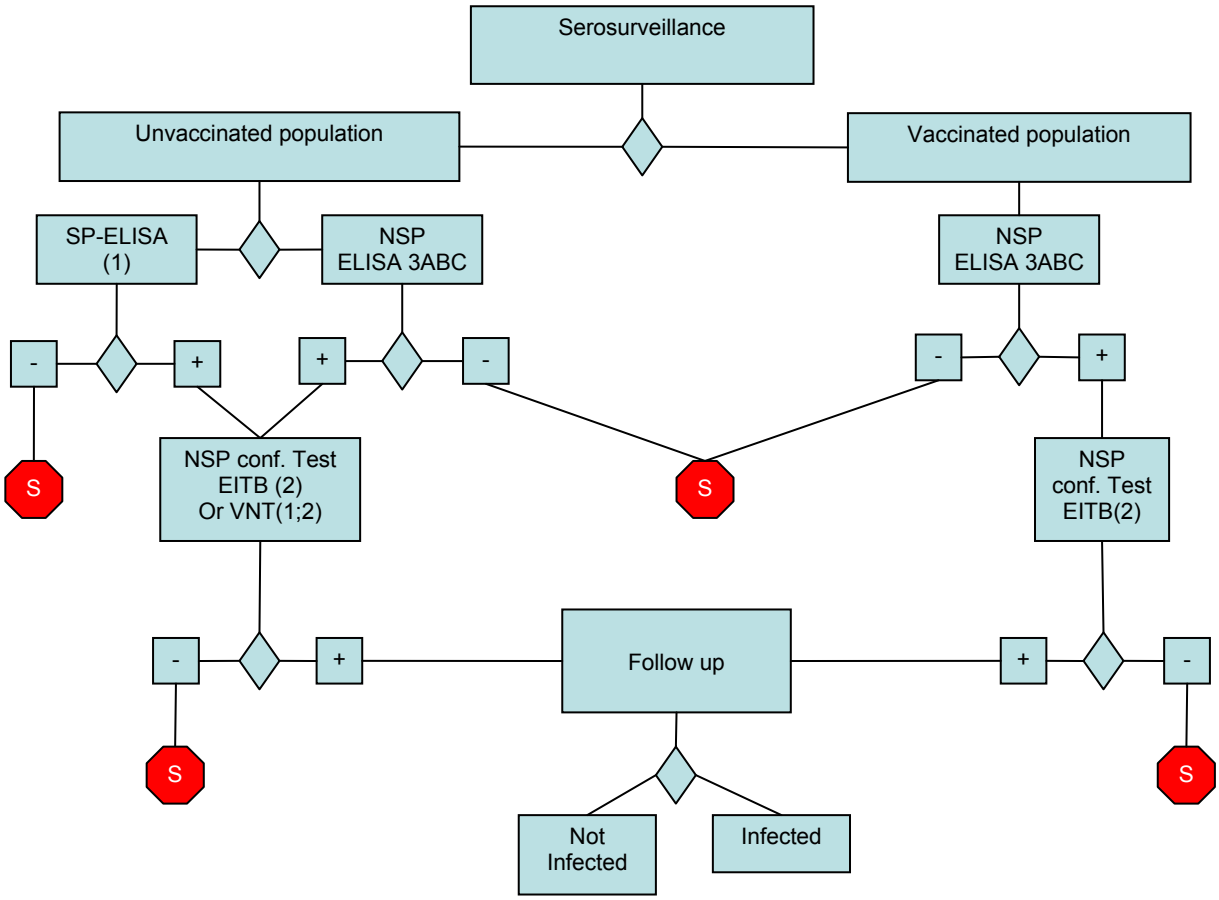
– sanitary protocol and history of the *establishments* with positive reactors;

– 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

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

10230/06
ADD 5

LIMITE

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XV

Delegations will find attached Commission document SEC(2006) 634 - Volume XV.

Encl.: SEC(2006) 634

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Community speaking 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 Community has sent in written comments in this respect.

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.

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XVI

Delegations will find attached Commission document SEC(2006) 634 - Volume XVI.

Encl.: SEC(2006) 634

Appendix XVI

CHAPTER 2.7.12.

AVIAN INFLUENZA

Community speaking 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. But recent experiences have shown that there are problems in international trade in relation to the use of vaccination against AI. - I would like to endorse what Dr Husu-Kallio has said in the opening ceremony that from this General Session a clear signal in respect of the use of vaccination against AI should be sent out!
Furthermore we appreciate that highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry will be included in the OIE list and that all members will report these outbreaks starting from the end of this General Session.

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

Appendix XVI (contd)

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.

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APPENDIX 3.8.9.

GUIDELINES FOR THE SURVEILLANCE OF AVIAN INFLUENZA

Community speaking position:
The Community can support this proposal but would still like the written comments already submitted to the OIE 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.

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.

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

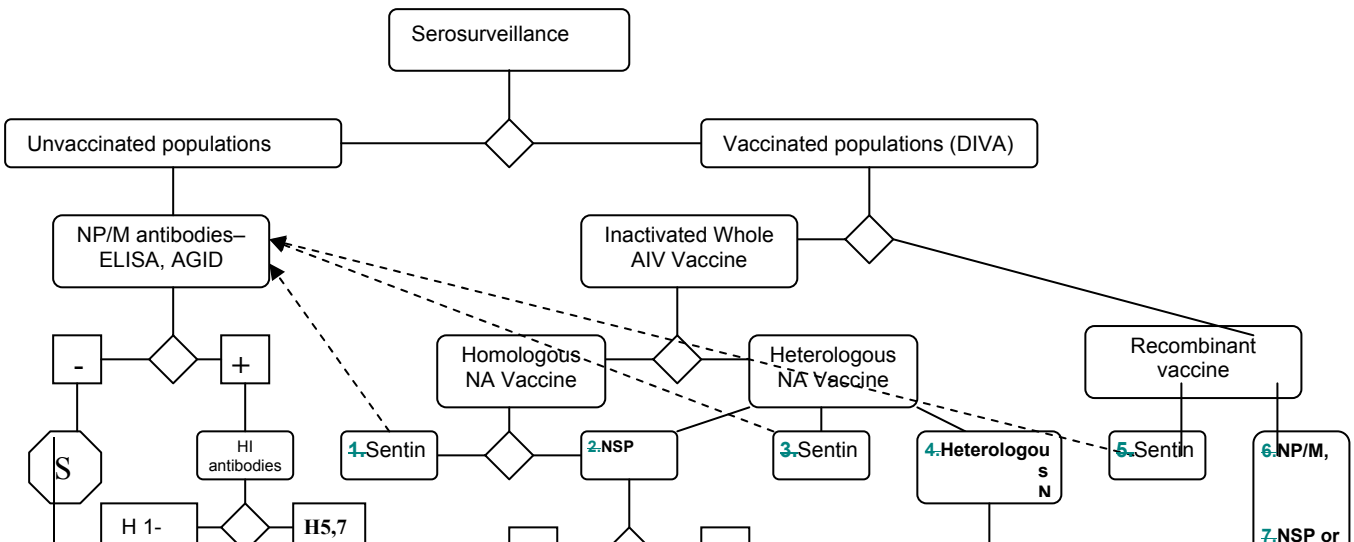
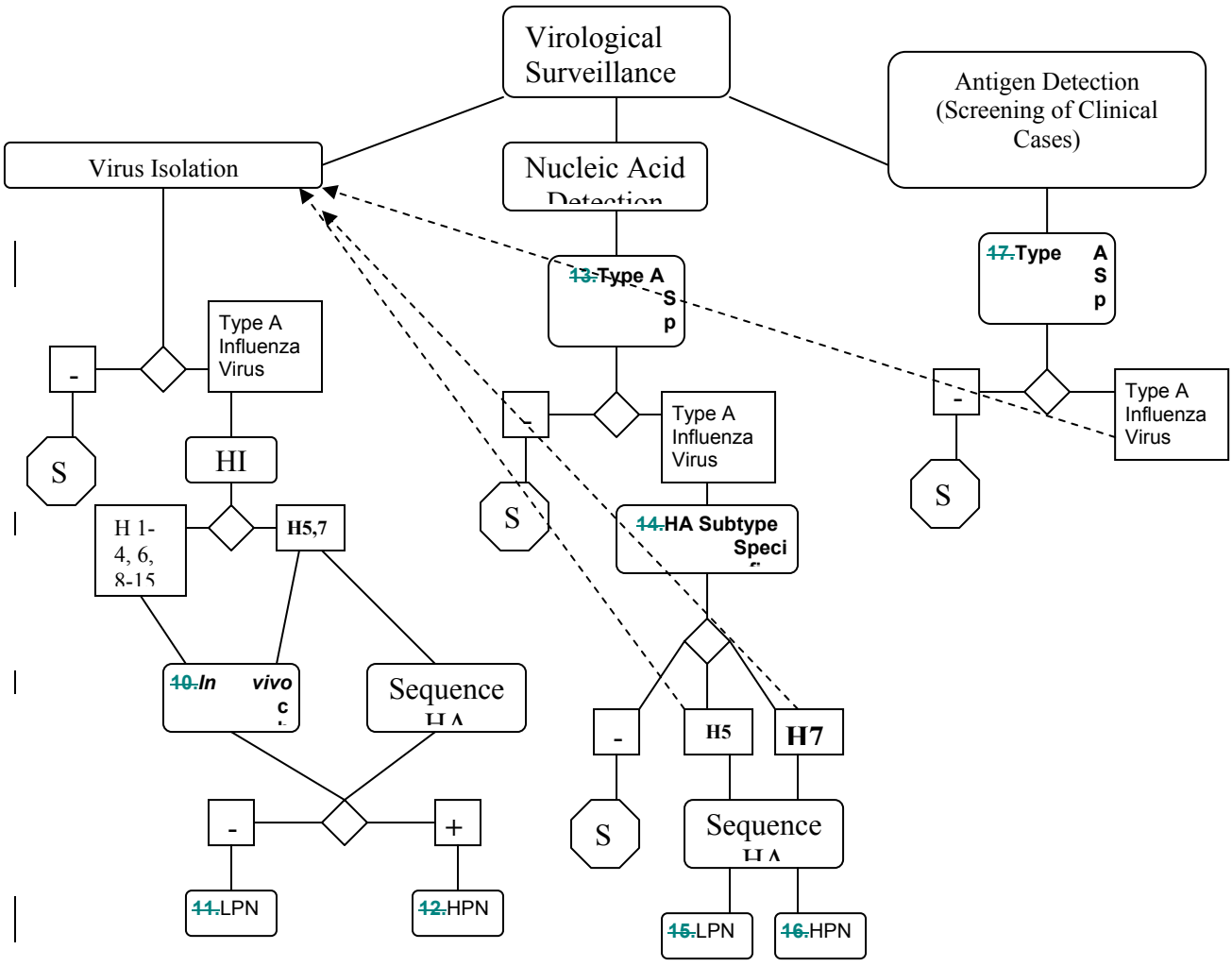


Figure 2. - Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods



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.

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XIX

Delegations will find attached Commission document SEC(2006) 634 - Volume XIX.

Encl.: SEC(2006) 634

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 written comments already submitted to the OIE 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 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) 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 veterinarian. 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.

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— text deleted

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

10230/06
ADD 8

LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXIV

Delegations will find attached Commission document SEC(2006) 634 - Volume XXIV.

Encl.: SEC(2006) 634

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 written comments already communicated to the OIE 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*

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[1] (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to 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

[1] Code of Hygienic Practice for Meat, CAC/RCP 58-2005

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.

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

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

10230/06
ADD 10

LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXVI, XXVIII, XXIX, XXXI and XXXIII (new)

Delegations will find attached Commission document SEC(2006) 634 - Volume XXVI, XXVIII, XXIX, XXXI and XXXIII (new).

Encl.: SEC(2006) 634

Appendix XXVI

CHAPTER 2.5.4.

EQUINE INFECTIOUS ANAEMIA

Community speaking position:
The Community can support this proposal but would like the written comments already communicated 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 speaking position:
The Community can support this proposal but would like the comments alraedy submitted 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.*

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— text deleted

Appendix XXVIII

CHAPTER 2.5.7.

EQUINE RHINOPNEUMONITIS

Community speaking 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 look at the comments already communicated to the OIE 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.**

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— text deleted

Appendix XXIX

CHAPTER 2.5.8.
GLANDERS

Community speaking 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.

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— text deleted

Appendix XXX

CHAPTER 2.5.10.

EQUINE VIRAL ARTERITIS

Community position:
The Community cannot support this proposal as no Community comments were taken on board.
!

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

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.

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.

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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ADD 11

LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXXII

Delegations will find attached Commission document SEC(2006) 634 - Volume XXXII.

Encl.: SEC(2006) 634

CHAPTER 2.3.1.

BOVINE BRUCELLOSIS

Community written 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.

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXXIV

Delegations will find attached Commission document SEC(2006) 634 - Volume XXXIV.

Encl.: SEC(2006) 634

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.~~

~~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.~~

~~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.

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

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXXII

Delegations will find attached Commission document SEC(2006) 634 - Volume XXXII.

Encl.: SEC(2006) 634

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 document	To update	expert
BSE risk assessment	To update	expert
Current chapter on Veterinary Services	To revise to better address the role of the Statutory Body, the early	expert

	detection of disease and greater detail on how the auditing of Veterinary Services could be implemented.	
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.

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXXV

Delegations will find attached Commission document SEC(2006) 634 - Volume XXXV.

Encl.: SEC(2006) 634

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.

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Volume XXV

Delegations will find attached Commission document SEC(2006) 634 - Volume XXV.

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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 remaining comments already communicated to the OIE 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.*

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— text deleted

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Brussels, 7 June 2006

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AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Non paper amended 11-5-2006

Delegations will find attached Commission document SEC(2006) 634 - Non paper amended 11-5-2006.

Encl.: SEC(2006) 634

Non paper amended 11-5-2006

1. Draft speaking note on the Community position related to General definitions (Chapter 1.1.1.) at Appendix III for the 74th General Session of OIE

The European Community can support this proposal but has communicated written comments on some particular issues 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. Draft speaking note on the Community position related to the Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4.) Appendices IV and V.

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 raise the broad question of Code/import requirements versus management guidelines for member countries and it is not clear how the conclusions of the experts(s) would bind the OIE (and thereby the member countries) and possibly have official capacity or status. It would

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like to know if it's the intention of the OIE to incorporate the Performance, Vision and Strategy document in the code as what exactly is the status of the PVS document if it is not incorporated in the code.

3. Draft speaking note on the Community position related to the Zoning and compartmentalisation (Chapter 1.3.5.) Appendix VII.

The Community supports this proposal but would like the comments incorporated in the draft Chapter taken into account. In addition it 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; therefore trade can take place from the rest of the country. The Community would strongly suggest that this is better clarified in the text. An example of this would be the introduction of a disease into a previously free country with measures taken to control the disease so the rest of the country is protected from the infected zone for example as has occurred with Avian Influenza.

4. Draft speaking note on the Community position related to the criteria for listing Diseases (Chapter 2.1.1.) Appendix VIII.

NONE

5. Draft speaking note on the Community position related to foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7) Appendices IX and X.

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The Community can support this amended Chapter but would like the minor inconsistencies communicated to the OIE 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.

NB Only if necessary The Community fully supports these guidelines 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. 4. Draft speaking note on the Community position related to Bluetongue (BT) (CHAPTER 2.2.13 Appendix XI and) for the 74th General Session of OIE.

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

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developed inactivated BT vaccines and of its other comments already communicated to the OIE.

For the Surveillance Chapter 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).

7. Draft speaking note on the Community position related to BSE (Chapter 2.3.13, and Appendices 3.8.4. and 3.8.5.)

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" countries associated to 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 Resolution will be adopted to categorise countries in this risk category.

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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 touch on two important issues within this Chapter.

Firstly based on the experience within EU linked to the implementation of the feed ban and the problems linked to cross contamination the Community would however ask that provision related to the feed ban and to expand to ruminant feed ban to a Mammalian to ruminant feed ban be reconsidered.

Secondly on gelatine: to be elaborated following CVO meeting

Coming now to the last but very important topic linked to the categorisation of countries according to their BSE risk. OIE as World Animal health Organisation 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.

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To conclude the Community can support the current proposal but encourages the OIE to consider the comments made linked to the feed ban and the production standards for the gelatine production.

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Point for Discussion: Article 2.3.13.14. of chapter 2.3.13. on BSE of the Terrestrial Animal health Code

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk and ~~come~~ are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

   a) skulls from cattle over 30 months of age at the time of slaughter ~~and vertebrae (except tail vertebrae)~~ have been excluded;

Community written comments*:

On 18 January 2006 the European Food Safety Authority adopted an opinion on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE risk".

Previous scientific advice recommended that for countries with a BSE risk in addition to appropriate sourcing of bones, and pending the outcome of QRA, the skull and vertebrae from bovine animals older than 12 months should not be used in the production of gelatine. In this context, the QRA of residual BSE risk in bone derived gelatine provides no support for this recommendation as the relevant exposures are regarded as very small.

Therefore the Community can support this amendment for countries with a controlled BSE risk.

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

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) ~~prolonged~~ acid or alkaline treatment,

      iv) filtration,

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

      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating);

OR

3. they originate from a country, *zone* or *compartment* posing an undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

   a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of

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slaughter have been excluded;

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

i) pressure washing (degreasing),

ii) acid demineralisation,

iii) acid or alkaline treatment,

iv) filtration,

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

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

8. Draft speaking note on the Community position related to Classical Swine Fever (CSF) (CHAPTER 2.6.7.) Appendix XV for the 74th General Session of OIE.

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. It has sent in written comments to the OIE concerning these points.

9. Draft speaking note on the Community position related to Avian Influenza (AI) (Chapter 2.7.12. and Appendices 3.8.9. and 3.6.X.) for the 74th General Session of OIE

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The European Union 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 these proposals. But recent experiences have shown that there are problems in international trade in relation to the use of vaccination against AI. - I would like to endorse what Dr Husu-Kallio has said in the opening ceremony that from this General Session a clear signal in respect of the use of vaccination against AI should be sent out!

Furthermore we appreciate that highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry will be included in the OIE list and that all members will report these outbreaks starting from the end of this General Session.

10 Draft speaking note on the Community position related to Bovine and small ruminant semen (Appendix 3.2.1)

NONE

11. Draft speaking note on the Community position (common position for Appendices 3.7.2 and 3.7.3, land and sea transport welfare code chapters):

Speaking Community position (common position for Appendices 3.7.2 and 3.7.3, land and sea transport):

The European Community can support these proposals but will communicate written comments on some particular issues. 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

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that all of its comments will be considered by the relevant OIE Working Group.

Draft speaking note on the Community position (common position for Appendices 3.7.2 and 3.7.3, Guidelines for Slaughter and for the killing of animals for disease control purposes code chapters):

Speaking Community position (common 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 will communicate written comments on some particular issues. 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. On a more specific issue the Community believes that the inclusion of the rotating box as a recommended method for restraining animals should be re-considered. The negative welfare implications of this method have been scientifically documented and alternative methods of restraint are available. The European Community hopes that all of its comments will be considered by the relevant OIE Working Group.

12. Draft Community speaking position on 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

The Community can support this proposal but would like the written comments already communicated to the OIE taken into account at the next meeting of the Code Commission to improve the text. However the

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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. Draft Community speaking position on Animal identification and traceability Appendices XXXV and XXV.

None

14. Draft Community speaking position on **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 Community can support the initiative to convene ad hoc groups of experts on equine viral arteritis and African horse sickness as it had some serious concerns over the drafting of these Chapters.

The Community can support the chapter on equine infectious anaemia, equine piroplasmosis and equine rhinopneumonitis at Appendices XXVI XXVIII and XXIX but would like the points already communicated to the OIE taken on board at the next OIE meeting on this subject.

Unofficial version

The Community cannot support the proposal for glanders at Appendix XXVII. The Community comments on this draft were not taken into account and a number of important points remain to be discussed.

(NB Go to Chapter for specific details).

15. ***Draft Community speaking position on Disposal of dead animals Appendix XXX***

NONE

Unofficial version

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - SANCO/10264/2006 Rev 2 BSE part - Volumes XIII, XIV, XXX and XXXI

Delegations will find attached Commission document SEC(2006) 634 - SANCO/10264/2006 Rev 2 BSE part - Volumes XIII, XIV, XXX and XXXI.

Encl.: SEC(2006) 634

SANCO/10264/2006 Rev 2 BSE part

Appendix XIII

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community speaking position:

The Community welcomes the work done by the Code Commission and can support this proposal but has sent some written comments to be considered or reflected on or taken on board during the next code Commission meeting in September 2006. See speaking note.

Article 2.3.13.1.

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

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:

   a) *milk* and *milk products*;

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

   c) hides and skins;

   d) gelatine and collagen prepared exclusively from hides and skins;

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

Community written comment:
Based on the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow. the Community can only support the inclusion of protein-free tallow with a maximal 0,15% insoluble impurities to the list under Article 2.3.13.1, point 1) if no SRM is used for the production of tallow and that the animals of which the raw material has been derived, have passed ante- and post mortem inspection.

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

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, ~~30 months of age or less,~~ which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which ~~were subject to~~ passed ante-mortem and post-mortem inspections ~~and were not suspect or confirmed BSE *cases*~~, and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

Community speaking position*:

The Community welcomes the decision to keep the age limit awaiting the outcome of ongoing research and pathogenesis studies before assessing the modification of the current age criteria for de-boned muscle meat of cattle as defined in Article 2.3.13.1, point g).

h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

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

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

Article 2.3.13.2.

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* ~~(which is reviewed annually)~~, based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective. Countries should review the risk assessment annually to determine whether the situation has changed.

Community written comments:
In case the situation changes over the year the member countries should review but also be obliged to provide this documentation. This should be clearly specified. The surveillance results should be part of this documentation.

The Community proposes the following:
"1. the outcome of a risk assessment, based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective. Countries should review the risk assessment annually to determine whether the situation has changed . It the latter case, countries have to provide the documentation, including the surveillance results. In that case a review of the risk assessment is needed."

Furthermore the Community recommends that the risk assessment should be carried out by an international expert panel. The European Community wants to emphasize the importance that OIE start establishing the working method for future categorisation in order to initiate the categorisation process as soon as the Code Chapter is agreed.

a) Release assessment

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

~~i) the presence or absence of animal TSE agents the BSE agent in the country, *zone* or *compartment* and, if present, evidence regarding their its prevalence based on the outcomes of surveillance;~~

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

~~iii) imported *meat-and-bone meal* or *greaves*;~~

~~iv) imported live ruminants animals;~~

~~v) imported animal feed and feed ingredients;~~

~~vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;~~

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

~~The results of any surveillance and other epidemiological investigation into the disposition of the *commodities* identified above (especially surveillance for BSE conducted on the cattle population) relevant to the above should be taken into account in carrying out the assessment.~~

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

Community written comment:
The Community cannot support the deletion of surveillance in point (i). If a risk assessment is to be based on solid data, it is natural to incorporate the surveillance data. There is no reason to omit this reference, since a BSE risk assessment should be based, at least partly, on surveillance data.

ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

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

iv) imported cattle, sheep and goats;

v) imported animal feed and feed ingredients;

vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

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

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

Community written comments:
When using the concept of zone or compartment in addition to a country, it is also important to assess the flow of animals and other potentially contaminated commodities between zones in the country, it is not totally clear if the term "imported" in a) iii), iv), v), vi) and vii) also includes trade or movements within a country from another zone. It should be clearly stated that, when performing

a risk assessment for a zone, the term import also includes movements from other zones.

b) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of ~~exposure of the BSE agent to cattle~~ cattle being exposed to the BSE agent, through a consideration of the following:

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

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

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

iv) the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance;

2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;

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

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

Community written comments:
Apart from the approval of the laboratory the test methodology should also be approved.
The Community proposes to replace "approved laboratories" by "approved laboratories and approved method" under point 4) of Article 2.3.13.2.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above)~~ demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above)~~ ~~demonstrates non-negligible~~ fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent~~, should~~ if the following conditions ~~be~~ are met:

1. a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify

the historical and existing risk factors, and the country has demonstrated that appropriate ~~generic~~ specific measures have been taken for the relevant period of time defined below to manage ~~all risks~~ each identified risk;

2. the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met;

Community written comments:
It should be specified what kind of surveillance will be required if the relevant point target has been met for countries with a negligible BSE risk.

In addition there should be a more stringent surveillance programme for countries with cases reported in their past to asses the effectiveness of the measures taken in the past. Therefore the Community proposes to modify Article 2.3.13.3. point 2 as follows:

"2) EITHER

a) if there has been no indigenous case of BSE, the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met, or

b) if there has been an indigenous case of BSE, the country has demonstrated that Type A surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met

3. EITHER:

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

i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* ~~or~~ nor *greaves* derived from ruminants has ~~not~~ been fed to ruminants;

Community written comments:

Experience within the European Community pointed out the risk of cross-contamination when applying a restricted ruminant to ruminant feed ban. The Community proposes to modify Article 2.3.13.3.., point 3a) ii) as follows:

"ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years meat-and-bone meal or greaves derived from mammals has not been fed to ruminants;"

OR

b) ~~the last indigenous *case* of BSE was reported more than 7 years ago~~ if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; ~~any indigenous *case* of BSE was born more than 8 years ago~~; and

Community written comments:

The Community can support the proposed change under Article 2.3.14.3. point 3 b) . It is far more relevant to take into account the date of birth rather than the date of reporting. The Community can support the modification from " born more than 8 years " into born more than 11 years".

However in view of the long incubation period of BSE, it is not possible to precisely assess the impact of any control measure before several years. Simulation studies have been performed in France and Denmark to estimate the pattern of the BSE epidemic and indicate clear differences pending on the demography of the cattle population. This should be taken into account in future reviews.

i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* ~~and~~ nor *greaves* derived from ruminants has ~~not~~ been fed to ruminants; and

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

- ~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~
- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

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

Article 2.3.13.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent~~; should~~ if the following conditions ~~be~~ are met:

1. a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time ~~to manage all risks identified the country has not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified~~;

2. the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. ~~is in place~~ has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target~~, in accordance with Table 1,~~ is met;

Community written comments:
The level of surveillance needed after reaching the target points of type A surveillance should be specified but there is also a need for more clarity on the regime that is required after the points target of type B surveillance is met.

The Community cannot agree that a country with a controlled risk after having reached the target points for type A surveillance can implement a lower level of surveillance awaiting to fulfil the requirements for the negligible risk status. Therefore the Community proposes to impose for countries posing controlled BSE risk that a type A surveillance should be maintained at least seven years preceding the date when the country meets the criteria for a negligible risk status. This would ensure that countries with a controlled risk can only receive the negligible risk status, where no SRM removal is required, following an increased surveillance programme immediately prior to the change of risk status.

3. EITHER

a) there has been no *case* of BSE, or, ~~any~~ if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* ~~and~~ nor *greaves* derived from ruminants has ~~not~~ been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

Community written comments:

Experience within the European Community pointed out the risk of cross-contamination when applying a restricted ruminant to ruminant feed ban. The Community proposes to modify Article 2.3.13.4., point 3a) ii) as follows:

"ii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from mammals to ruminants have been in place for 8 years"

OR

b) there has been an indigenous *case* of BSE ~~reported~~, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that neither *meat-and-bone meal* ~~and~~ nor *greaves* derived from ruminants ~~have not~~ has been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

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

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

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

contaminated feed during that period, or

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

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

Article 2.3.13.5.

Undetermined BSE risk

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

Article 2.3.13.6.

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

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

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.3.

Community written comments*:

Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present in the age cohorts born before the risk management measures were taken for the appropriate period of time, assurances should be given to exclude those animals and products derived thereof from trade. In practice, those animals and products derived should be excluded from trade from countries with a negligible BSE risk status. The possibility of cases born just after the implementation of the feed ban should be considered and should not always, based on the situation and an assessment, constitute a reason to question the negligible risk status. The Community took note of the intention of the TAHSC to look into this issue in the second half of 2006.

The Community proposes the following:

"For cattle from countries with a negligible BSE risk where any indigenous case of BSE was detected, the presentation of an international veterinary certificate attesting that:

1. the country, zone or compartment complies with the conditions in Article 2.3.13.3.;

2. cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.3. point 3,b,iii);

3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been

effectively enforced or after the date of birth of the last indigenous case if born after the date of the feed ban ."

Article 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for cattle

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;

2. cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.4.;

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

Community written comments:

The current wording in point 3) referring to indigenous cases could be misinterpreted that only countries with indigenous cases should comply with point 3). In addition the possibility of cases born just after the implementation of the feed ban should be considered. The Community proposes to clarify as follows:

"3) Cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last indigenous case if born after the date of the feed ban .."

Article 2.3.13.8.

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

for cattle

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

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

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

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

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

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

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

3. cattle selected for export:

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

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

Article 2.3.13.9.

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

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.3.;

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

Community written comments*:

The Community proposes to amend Article 13, point 1) as follows:
Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present born before the risk management measures were taken, assurances should be given to exclude those animals and products derived from trade. The Community took note of the intention of the TAHSC to look into this issue in the second half of 2006.

The Community proposes:
"point 3: In countries with negligible BSE risk where there have been indigenous cases, the cattle from which the fresh meat and meat products were derived passed ante-mortem and post-mortem inspections, and were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced."

Article 2.3.13.10.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;

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

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

4. the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in points 1 and 2 of Article 2.3.13.13.,

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

   ~~all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.~~

Community written comments:

Community speaking position
The Community feels that for control reasons the harvesting of mechanically recovered meat should not only be extended to the skull or vertebral column of bovine animals of any age but should also be extended to all bovine bones.

In view of this the Community suggest replacing article 11 point 2 c with:

'4) b) mechanically separated meat from all bones from cattle of all ages,'

Article 2.3.13.11.

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

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

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

1. the cattle from which the *fresh meat* and *meat products* are derived:

   a) ~~are not suspect or confirmed BSE *cases*~~;

   b) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

   c) ~~were subjected to~~ passed ante-mortem and post-mortem inspections;

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

2. the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the tissues listed in points 1 and 3 of Article 2.3.13.13.,

b) nervous and lymphatic tissues exposed during the deboning process,

c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

~~all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.~~

Article 2.3.13.12.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Community written comments*:

Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present born before the risk management measures were taken, assurances should be given to exclude those animals from trade.

Therefore the Community proposes the following:

"In countries with a negligible BSE risk, ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products derived from cattle born before the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced should not be traded between countries."

Article 2.3.13.13.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum ~~and derived protein products~~. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Community written comments:
In their opinion of 27-28 November 2000 the Scientific Steering Committee recommend that the entire intestine of bovine animals of all ages should be removed as specified risk material whenever it is not highly unlikely that the slaughtered animals are infected. On previous occasions (the minutes of the ad hoc Group meeting in 2004) the experts did not consider that there were sufficient new data to recommend a change from its previous recommendation to remove tonsils and intestine from cattle of all ages due to the presence of lymphoid tissue throughout the intestines. The Community would like to be informed of the scientific data which supports the premise to limit the removal to the distal ileum.

2. From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., the following commodities, and any commodity

contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column ~~and derived protein products~~. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Community written comments:
In the opinions of the former Scientific Steering Committee it was considered that the intestines and tonsils of bovine animals should be considered a risk at any age and therefore be removed in all cattle. For the rest of SRM the SSC took, according to the opinion, an extremely cautious approach and although it was considered extremely unlikely to have detectable infectivity below an age of 30 months being the half of the mean incubation period in field BSE cases (60 months), the exceptional finding of BSE cases in younger animals lead to an age limit of 12 months. This age limit was considered by the SSC as a considerable reassurance of non-infectivity.

The recent conclusions from the recent EFSA opinion on SRM, published in May 2005, stated that following a cautious approach and taking into account the appearance of infectivity in central nervous system (CNS) at ¾ of the incubation period and the age of BSE cases in young animals (less than 35 months old, 0.06 % of total of BSE cases), a cut-off at 21 months would give the highest safety margin. If the rare BSE cases found in very young animals (4 cases in 40 Million tested since 2001) are not taken into account, a cut-off at 30 months would represent a "considerable but not an absolute safety margin with respect to detectable infectivity". There is no scientific basis to raise the age limit for removal of tonsils and intestines. In addition EFSA recommends further work on the epidemiological data to evaluate the likelihood of infectivity in SRM derived from young animals.

The Community reserves its position on the 30 month age limit pending the further work by the EFSA.

3. From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column ~~and derived protein products~~. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk and ~~come~~ are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

   a) skulls from cattle over 30 months of age at the time of slaughter ~~and vertebrae (except tail vertebrae)~~ have been excluded;

Community written comments*:
On 18 January 2006 the European Food Safety Authority adopted an opinion on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE risk".

Previous scientific advice recommended that for countries with a BSE risk in addition to appropriate sourcing of bones, and pending the outcome of QRA, the skull and vertebrae from bovine animals older than 12 months should not be used in the production of gelatine. In this context, the QRA of residual BSE risk in bone derived gelatine provides no support for this recommendation as the relevant exposures are regarded as very small.

Therefore the Community can support this amendment for countries with a controlled BSE risk.

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

i) pressure washing (degreasing),

ii) acid demineralisation,

iii) ~~prolonged~~ acid or alkaline treatment,

iv) filtration,

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

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating);

OR

3. they originate from a country, *zone* or *compartment* posing an undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;

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

i) pressure washing (degreasing),

ii) acid demineralisation,

iii) acid or alkaline treatment,

iv) filtration,

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

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 2.3.13.15.

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than ~~protein free tallow~~ as defined in Article 2.3.13.1.) intended

for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk, ~~it originates~~ ~~come~~ are derived from cattle which ~~been subjected to~~ have passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.13.

Article 2.3.13.16.

Veterinary Administrations of *importing countries* should require:

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

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

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. they are derived from tallow meeting the conditions referred to in Article 2.3.13.15; or

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

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APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Community written comments:

The Community can support the improvement made to the surveillance Appendix and in particular the requirement to test all clinical suspects in addition to animals of other risk groups.

At the General Session in May 2005 it was agreed that countries were allowed to use the full BSurvE model on the countries own data as an alternative to the Terrestrial Code Appendix 3.8.4. This Community would welcome some clarification.

Article 3.8.4.1.

Introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;

   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

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

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

      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

iii) the smallest number will show clinical signs.

3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

   a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

   b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle);

Community written comments:
The terminology "downer cattle" might be confused with "fallen stock". The Community proposes to clarify and to reword Article 3.8.4.1., point 4 b) as follows

"b) cattle over 30 months of age that are unable to rise or to walk without assistance (downer cattle); cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (emergency slaughter);"

The same applies for article 3.8.4.2. point 2.

   c) cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock);

   d) cattle over 36 months of age at routine slaughter.

5. A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. ~~All countries should sample at least three of the four subpopulations.~~ This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 3.8.4.2.

Description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

   Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals

displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation~~, particularly cattle over 30 months of age,~~ is the one exhibiting the highest prevalence. ~~The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.~~ The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

   These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

   These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

   Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

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

~~When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implication. Authorities must find ways to overcome these difficulties.~~

Article 3.8.4.3.

~~1)~~ **Implementation of ~~Type A~~ surveillance**

In order to implement efficiently a surveillance strategy for BSE, a country must use ~~good quality data (or reliable estimates)~~ documented records or reliable estimates of ~~concerning~~ the age distribution of ~~it's~~ the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*. ~~The application of the following~~

~~procedure will allow the detection of BSE at a prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern.~~

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A ~~country should design its~~ surveillance strategy should be designed to ensure that samples are representative of the herd of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and surveillance point values in this appendix were obtained by applying the following factors to a statistical model:

a) ~~a~~ the design prevalence for Type A or Type B surveillance ~~of one case per 100,000 of the adult cattle population~~;

b) a confidence level of 95%;

c) the pathogenesis, and pathological and clinical expression of BSE:

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between clinical pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

a) cattle population numbers stratified by age;

b) the number of cattle tested for BSE stratified by age and by subpopulation.

This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

Community written comments*:
The Community is aware and acknowledge that not the same surveillance criteria might apply to countries with or without a BSE risk.

The Community strongly support the amendment is the last phrase in Article 3.8.4.3. just above point i.e.
"All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested".
In addition, the assessment of the surveillance programme should also take into account the number of clinical suspects identified in the country during previous years. The clinical suspects should be documented.
The Community asks the TAHSC to clarify if the Community understanding is correct.

1. Type A surveillance

   The application of Type A surveillance will allow the detection of BSE around a design prevalence[1] of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. ~~Maintenance (~~Type B~~)~~ surveillance

   The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

   Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 2.3.13.3) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

   Type B surveillance may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 2.3.13.4), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

   ~~For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk', should continue at a reduced maintenance level.~~

   ~~In order to implement efficiently a maintenance surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. The application of the following procedure will allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.~~

   ~~Maintenance surveillance should focus on the higher prevalence subpopulations (especially clinical suspects). The number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, *zone* or *compartment*'s BSE status (to a maximum of 7 years).~~

[1] DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

1. Selecting the points target

The ~~desired~~ surveillance points target ~~is~~ should be selected from Table 1, which shows target points for adult cattle populations of different sizes. ~~A country's~~ The size of the adult cattle population ~~size~~ of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size. ~~The target depends on the design prevalence chosen by the country.~~

Table 1 Points targets for different adult cattle population sizes in a country, *zone* or *compartment* ~~which has not identified any BSE cases~~

Points targets for country, *zone* or *compartment* ~~with 0 cases, 95% confidence~~		
Adult cattle population size (24 months and older)	**Type A surveillance**	**Type B surveillance**
≥ 1,000,000	300,000	150,000
800,000 – 1,000,000	240,000	120,000
600,000 – 800,000	180,000	90,000
400,000 – 600,000	120,000	60,000
200,000 – 200,000	60,000	30,000
100,000 – 200,000	30,000	15,000
50,000 – 100,000	15,000	7,500

~~DP is the maximum possible prevalence or "design prevalence".~~

Community written comments:
The categories are very broad, especially for the smaller populations. This will have negative consequences for countries just above the limit for one category. For example a country with 410 000 adult cattle will be obliged to collect twice as many points as a country with 390 000 adult cattle. It would be better to split in more categories for the smaller populations.

2. Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*.

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

Community written comments:

The Community suggests the following wording in accordance with the definitions of the subpopulations as mentioned in Article 3.8.4.1. and 3.8.4.2.:

'If a country, zone or compartment determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'emergency slaughter' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

~~In addition, Countries should sample at least three of the four subpopulations.~~

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Table 2 Surveillance point values for samples collected from animals in the given subpopulation and age category

Surveillance subpopulation			
Routine slaughter[1]	**Fallen stock[2]**	**Casualty slaughter[3]**	**Clinical suspect[4]**
Age ≥ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

[1] See point 4) of Article 3.8.4.2.
[2] See point 3) of Article 3.8.4.2.
[3] See point 2) of Article 3.8.4.2.
[4] See point 1) of Article 3.8.4.2.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

Community written comments:
The Community suggests aligning the terminology in the table with the definitions under Article 3.8.4.1. and 3.8.4.2.

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APPENDIX 3.6.5

GENERAL GUIDELINES FOR THE DISPOSAL OF DEAD ANIMALS

Community speaking position:
The Community supports this proposal.

Introduction

The mass disposal of dead animals associated with an animal disease outbreak is often subject to intense public and media scrutiny thereby obligating the *Veterinary Administration* of a Member Country to not only conduct disposal operations within acceptable scientific principles to destroy the causative pathogen but also to address public and environmental concerns.

The guidelines in this Appendix are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and be attainable with the resources available. The guidelines should also be applied in conjunction with the procedures described for the humane killing of animals in Appendix 3.7.6.

Strategies for the disposal of dead animals (entire animals or parts thereof) should be prepared well in advance of any emergency. Major issues related to the disposal of dead animals include the number of animals involved, biosecurity concerns over the movement of infected or exposed animals, people and equipment, environmental concerns, and the psychological distress experienced by farmers and animal handlers.

Regulations and jurisdiction

The legislation regulating animal health and the organisation of the *Veterinary Administration* should give the *Veterinary Services* the authority and the legal powers to carry out the activities necessary for the efficient and effective disposal of dead animals. Cooperation between the *Veterinary Service* and other relevant government bodies is necessary to developing a coherent set of legal measures for the disposal of dead animals in advance of any emergency. In this context the following aspects should be regulated:

- Right of entry to an establishment for the *Veterinary Services* and associated personnel;
- Movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead animals to another location for disposal;
- The obligation on the involved farmer and animal handlers to cooperate with the *Veterinary Services*;
- Any need to transfer the ownership of animals to the *Competent Authority;*
- The determining of the method and location of disposal, and the necessary equipment and facilities, by the V*eterinary Services*, in consultation with other involved authorities including national and local governmental organisations competent for the protection of the environment,;

Should the chosen option for the disposal of dead animals be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Preparedness

The mass killing and disposal of animals in the event of a disease outbreak or disposal of animals in the event of natural disasters such as floods, usually must proceed with the minimum delay. The success is determined by the structures, policies and infrastructure established in advance:

- *Technical preparedness* – standard operating procedures (including documented decision-making processes, training of staff); a relationship with industry is essential to obtain compliance with animal health policies - farmer associations, commodity representatives, animal welfare organisations, support structures such as security services, relevant government agencies, the media and consumer representatives

- *Financial preparedness* - a compensation or insurance mechanism; access to emergency funding; access to personnel through agreements with private veterinarians;

- *Communication plan* - Information sharing with officials involved in the outbreak, affected farmers, professional organizations, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

- *Resources* –The management of resources should address such items as personnel, transport, storage facilities, equipment (such as mobile handling facilities for animals, disinfection equipment), fuel, protective and disposable material and logistical support.

- *Heavy equipment* – including trucks, tractors, bulldozers, and front-end loaders.

Critical elements

The list of critical elements, which has not the pretension to be complete, needs to be taken into account in planning and implementation.

- *Timeliness* - early detection of new infections, immediate killing of infected animals and rapid removal of the dead animals with inactivation of the pathogen are important. Spread of the pathogen from the dead animals and their surroundings should be blocked as soon and as effectively as possible.

- *Occupational health and safety* - Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposing dead animals. Special attention should be given to zoonotic aspects. Workers should be sufficiently protected against infection with protective clothing, gloves, face masks, spectacles, vaccination, anti viral medicines, regular health checks.

- *Pathogen inactivation* - the disposal procedure should be selected to result in inactivation of the pathogen.

- *Environmental concerns* - different methods of the disposal of dead animals have different effects on the environment. For instance pyre burning will produce smoke and smells; burial might lead to gas production and also a risk of contamination of air, soil, surface and sub surface water.

- *Availability of capacity* - An assessment of capacities of different methods of disposal should be made prior to any emergency. Temporary storage of dead animals in cold stores may relieve a lack of processing capacity.

- *Inadequate funding*

- *Public reaction*

- *Acceptance by farmers* - Farmers will be sensitive to the safety measures taken to prevent spread of the disease by disposal method selected and the transport of the dead animals to the disposal site. Adequate compensation of owners for the loss of animals or for burial or burning sites will improve acceptability.

- *Equipment* - Equipment used in the disposal of dead animals can transfer infection to other premises. The cleaning and disinfection of the outside surfaces of equipment such as cranes, containers and trucks, and the departure of vehicles from the farm should receive special attention. Trucks transporting dead animals should be leak proof.

- *Wildlife* - When disposing of dead animals, full attention should be given to preventing scavengers gaining access to dead animals, which might cause spread of disease.

Practical considerations

- *Selection of disposal site* – sufficient top soil to cover the site; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites.

- *Selection of contractors for transport* – availability; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.

- *Logistical preparedness for the appropriate technology* – availability of fuel (wood, old tyres); sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to minimise the spread of infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (eg vaccination) of personnel; rendering capacity at rendering plants; arms and ammunition, additional cold storage and holding facilities at rendering plants and abattoirs.

- *Procedures and policies for disposal of other possibly contaminated products* – manure, eggs; milk; non-animal products; animal feed.

- *Wildlife* –need to address risk posed; expertise availability for capture/culling of wildlife.

Recommended methods for the disposal of dead animals

The method(s) chosen should be based on local conditions and circumstances.

Some of the methods below may require on-farm pre-processing prior to transportation of dead animals to central facilities for rendering or incineration. Preprocessing could include the grinding of dead animals which can be transported in sealed containers, or be subjected to fermentation or freezing.

- *Rendering* - This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. The technology exists in dedicated facilities. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. The availability of the capacity should be determined in advance.

- *Incineration in a dedicated facility* – In such a facility, whole dead animals or parts of animals can be completely burned and reduced to ash, often in conjunction with other substances (such as municipal waste, hazardous waste or hospital waste). Effective inactivation of pathogens, including spores, occurs. Fixed facility incineration is wholly contained and has some advantages from the environmental viewpoint as the exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber.

- *Rendering and incineration* - These may be combined for improved security and to provide additional fuel for furnaces in facilities used for other purposes such as in cement kilns and electricity generation plants.

- *Air curtain incineration* – This process fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times for example in a burn-pit. The equipment can be mobile and, because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens.

- *Pyre burning* - This open system of burning dead animals is a well established procedure that can be conducted on site with no requirement for transportation of animal material. However, it takes an extended period of time and has no way of verifying pathogen inactivation, and there may be particulate dissemination from incomplete combustion. Further, because the process is open to view, there may be a lack of acceptance by the public.

- *Composting* - Composting is a natural ~~biological~~ decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients. However some viruses and spore forming bacteria, such as *Bacillus anthracis*, and other pathogens such as *Mycobacterium tuberculosis* may survive.

- *Trench burial* - In this method, whole dead animals are buried and covered by soil. Burial is an established procedure which may be conducted on site. It may not inactivate all pathogens. In some circumstances, dead animals may be disposed of by *mounding* whereby they are covered by a layer of soil above ground.

- *Biogas production* - This is a closed system of anaerobic fermentation which would require for the disposal of dead animals or their parts prior mechanical and thermal treatment of the input material (such as the liquid product of rendering plants). This process may not inactivate all pathogens.

- *Alkaline hydrolysis* – This method uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150^{o}C) to accelerate the process. The only solid byproducts are the mineral constituents of bones and teeth. This residue (2% of the original weight of the animal) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel.

- *Bio-refining* - this is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurised vessel. The waste material is treated at 180^{o}C at 12 bar pressure for 40 minutes, heated by the indirect application of steam kj, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. The process inactivates all microbiological agents.

- *Dead animal disposal at sea* - International Conventions define the conditions to be met for the disposal of dead animals at sea.

Guidelines for decision-making for the disposal of dead animals

Strategies for dead animal disposal require preparation well in advance of an emergency in order to maximize the efficiency of the response. Major issues related to dead animal disposal can include the number of animals involved, bio-security concerns over movement of infected and exposed animals, people and equipment, environmental concerns, and the extreme psychological distress and anxiety experienced by producers and emergency workers.

The disposal of large numbers of dead animals will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the

environment, local economies, producers, and the livestock industry. Decision makers need to understand the economic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of dead animal disposal technologies and must reflect a balance between the scientific, economic, and social issues at stake. Timely slaughter, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question:

Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety; community concerns; international acceptance; transport availability; industry standards; cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.

Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, must total 100.

Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor, (eg 1 = the worst possible fit, and 10 = the best fit).

Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg V = F x U)

Step 5 -By adding the Balanced Values to a sum for each disposal option, it is possible to compare the suitability of disposal options by numerically ranking the sums of the Balanced Values for each disposal option. The largest sum would suggest that disposal option as the best balanced choice.

An example of the use of this process follows in Table 1. In this example rendering achieved the highest sum and would be considered as the best balanced choice and the most suitable disposal option for the factors considered.

Appendix XXX (contd)

Table 1: **Decision Making Process**

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial		Commercial Landfill	
	Weight	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Factors															
Operator Safety	20	7	140	4	80	8	160	3	60	7	140	8			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	8	120	5	75	4	60	4			
Impact on Environment	10	10	100	8	80	3	30	10	100	3	30	3			
Reaction of the Public	10	10	100	7	70	1	10	9	90	3	30	4			
Transport Availability	5	1	5	1	5	8	40	5	25	3	15	8			
Acceptable to Industry	5	7	35	7	35	7	35	7	35	6	30	7			
Cost	5	4	20	1	5	6	30	9	45	8	40	9			
Risk to Wildlife	5	10	50	10	50	5	25	4	20	5	25	5			
Capacity to Meet Requirements	5	5	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	650	sum	535	sum	595	sum	515	sum		sum	

Unofficial version

APPENDIX 3.8.5.

FACTORS TO CONSIDER IN CONDUCTING THE BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT RECOMMENDED IN CHAPTER 2.3.13.

Community written comments:
The Community supports this proposal but would like the written comments below taken on board in the next working group meeting.

Unofficial version

Article 3.8.5.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country, *zone* or *compartment* is to conduct a risk assessment (reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence, their historical perspective and the risk management measures which have been adopted to prevent cattle from becoming infected:

1) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present:

a) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

b) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

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

d) imported cattle, sheep and goats;

e) imported animal feed and feed ingredients;

f) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

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

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

2) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, through a consideration of the following, to assess the likelihood of exposure of cattle to the BSE agent:

a) the epidemiological situation concerning BSE in the country or *zone*;

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

c) the origin and use of bovine, caprine or ovine carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

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

e) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance.

The following guidelines are intended to assist *Veterinary Services* in conducting such a risk assessment.

Article 3.8.5.1.(bis)

The presence or absence of the BSE agent in the indigenous ruminant population

Assumptions:

- While cattle pose the only demonstrated risk, and must be regarded as the best "indicator species" for the presence of BSE in a country, BSE has recently been demonstrated in a goat and there is potential for it to also be present in sheep.

- If a surveillance programme for BSE in cattle, as described in Appendix 3.8.4. is in place for an appropriate length of time and has failed to detect cases, it can be assumed that the disease is unlikely to be present in small ruminants.

- The BSE status of a country may change as more data become available; this may result from a change in status of any risk factor such as, for example, the detection of clinical disease, following active surveillance, or assessment of geographical BSE risk;

Question to be answered: Is a BSE surveillance programme as described in Appendix 3.8.4. in place? If so, for what period of time? Has BSE been identified in the country?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of BSE. The greater the surveillance effort, the greater the power of the information. Adequately targeted surveillance for BSE, such as described in Appendix 3.8.4., provides more powerful information than generic animal disease surveillance. Failure of an appropriate surveillance programme as described in Appendix 3.8.4., conducted for a period of 7 years (Article 2.3.13.3.) to detect a case of BSE indicates that either the agent was not released into the country, *zone* or *compartment*, or cattle were not exposed to the agent, or the production system was sufficiently stable to prevent the agents amplifying and recycling.

Evidence required: Documentation on awareness and surveillance programmes for BSE, their legal basis, scale, duration, and data generated.

Article 3.8.5.1. (tris)

The potential for the release of the BSE agent through meat-and-bone meal or greaves of local origin, or livestock feedstuffs potentially contaminated with them

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Unofficial version

Assumption: That *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal* or *greaves* of local origin been used in livestock feedstuffs in the past? If so, where from which species and in what quantities? If so, what level of risk does this present?

Community written comments:
If meat-and-bone meal or greaves of local origin have been used in livestock feedstuffs in the past it is also interesting to know to which species, not only from which species. It is also interesting to know whether meat-and-bone meal of local origin have been used in feedstuffs for other animals and in that case if there have been any possible cross-contamination to livestock feedstuffs.

Rationale: Knowledge of the origin of *meat-and-bone meal* or *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent.

Evidence required:

- Documentation to support claims that *meat-and-bone meal* or *greaves* of local origin have not been used in livestock feedstuffs, OR

Community written comments:
Following the comment made under " question to be answered", the Community proposes to include:

"Documentation concerning prevention and control of potential cross-contamination."

- Where *meat-and-bone meal* or *greaves* of local origin have been used in livestock feedstuffs, documentation on annual volume.
- Documentation describing the composition (tissues used and species and class of stock) of the *meat-and-bone meal* or *greaves* of local origin.
- Documentation supporting why the rendering processes used to produce *meat-and-bone meal* or *greaves* of local origin would have inactivated, or significantly reduced the titre of the BSE agent, should it be present.
- Documentation describing the fate of locally-produced *meat-and-bone meal* and *greaves*.

Article 3.8.5.2.

The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves or livestock feedstuffs potentially contaminated with them

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal* or *greaves*, or feedstuffs containing either, been imported in the past? If so, when and where from and in what quantities? If so, what level of risk does the importation present?

Community written comments:
Regarding the destination of imported meat-and-bone meal, greaves or feedstuffs. It should be considered if imported meat-and-bone meal and greaves been used in

Unofficial version

livestock feedstuffs or other feedstuffs including the possible cross-contamination of livestock feedstuffs.

Rationale: Knowledge of the origin of *meat-and-bone meal* or *greaves*, or feedstuffs containing either, is necessary to assess the risk of release of BSE agent.

Evidence required:

- Documentation to support claims that *meat-and-bone meal* or *greaves*, or feedstuffs containing either, have not been imported, OR
- Where *meat-and-bone meal* or *greaves,* or feedstuffs containing them, have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on dates of imports and annual volume, by country of origin, of *meat-and-bone meal* or *greaves,* or feedstuffs containing them, imported in the past.

Community written comments:
Following the comment made under " question to be answered", the Community proposes to include:

"- documentation describing the destination/use of imported meat-and-bone meal, greaves and feedstuffs.
- Documentation regarding to which species imported meat-and-bone meal, greaves or feedstuffs have been fed.
- Documentation concerning prevention and control of potential cross-contamination.."

- Documentation describing the composition (tissues used and species and class of stock) of the imported *meat-and-bone meal* or *greaves,* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal* or *greaves,* or feedstuffs containing them, would have inactivated, or significantly reduced the titre of the BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal*, *greaves* and feedstuffs.

Article 3.8.5.3.

The potential for the release of the BSE agent through the importation of bovine, caprine and ovine animals

Assumptions:

- Countries which have imported cattle from countries infected with BSE are more likely to experience BSE.
- Countries which have imported caprine and ovine animals from countries infected with BSE may be more likely to experience BSE, although this risk is largely hypothetical.

Community written comments:
In assessing this potential risk of imports of caprine and ovine animals from countries infected with BSE, the surveillance efforts of the country of origin should be taken into account in the evaluation.

- Animals imported for breeding may pose a greater risk than animals imported for slaughter because they are typically kept to a greater age than animals imported for slaughter.

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- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: Have bovine, caprine or ovine animals been imported at any time since 1980? If so, what level of risk does the importation present?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;

- the *exporting country*'s policies with respect to the feeding to livestock of rations containing protein of animal origin;

- how imported ruminants were disposed of at the end of their productive life and whether their tissues could have been rendered into *meat and bone meal* or *greaves*;

- species of ruminant animals imported;

- factors such as production type (e.g. dairy versus meat breeds), geographic location and the potential influence of culturally unique husbandry practices which may give rise to differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

- age at slaughter or death;

- fate (rendered, incinerated, buried) and, if tested for BSE, the results.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of birth, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

Community written comments:

Regarding the country of origin of imports the BSE status of the exporting country should be included in this documentation.

- Documentation describing numbers, origins and species imported.
- Documentation describing the fate of imported animals, including their age at slaughter or death and, if tested for BSE, the results.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.4.

The potential for the release of the BSE agent through the importation of products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13.

Assumptions:

- Current scientific evidence strongly indicates that semen, embryos, muscle meat, gelatine, blood and blood products, protein-free tallow, hides and skins, and milk play no role in the transmission of BSE.

Unofficial version

- Countries which have imported products of bovine, caprine or ovine origin containing or contaminated with tissues listed in Article 2.3.13.13. from countries with BSE are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: What products of bovine, caprine and ovine origin potentially containing or contaminated with tissues listed in Article 2.3.13.13. have been imported in the past? What level of risk does the importation present?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.13);
- dates and annual volumes of imports;
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- temperature, time and pressure parameters of processes used in the manufacture of the products;
- the *exporting country*'s policies with respect to the feeding to livestock of rations containing protein of animal origin;
- whether products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. may have been diverted from intended use and been rendered into *meat-and-bone meal* or *greaves*.

Evidence required:

- Documentation on the country of origin of imports of products potentially containing or contaminated with tissues listed in Article 2.3.13.13. This should identify the country of birth of bovine, caprine and ovine animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.5.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine, caprine or ovine origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of bovine, caprine and ovine origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

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Question to be answered: Has *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin ever been fed to ruminants? If so, what level of risk does the practice present?

Rationale: If cattle have never been fed products potentially containing *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Evidence required: Documentation on feeding practices and feed bans, and measures to prevent cross-contamination of animal feed.

Community written comments:
It should also be assessed if there have been any possible cross-contamination to livestock feedstuffs. Therefore the Community proposes to add:

"and measures to prevent cross-contamination of animal feed and control of these measures. "

Article 3.8.5.6.

The potential for the release of the BSE agent through the importation of products of ruminant origin intended for *in vivo* use in cattle

Assumptions:

- TSEs have been demonstrated to be transmissible between animals iatrogenically, through the use of tissues containing potentially high levels of infectivity in the manufacture of vaccines in particular. Although such records relate specifically to the use in small ruminants of vaccines derived from brain or mammary tissue, the use of bovine brain for such purposes must also logically present a risk.

- International guidelines for the production of veterinary biological medicinal products recognise these risks, and aim to mitigate them by safe sourcing (as in Article 2.3.13.13) coupled, where necessary, by safe production methods.

Questions to be answered:

- Have veterinary biological medicinal products ever been imported from countries at risk of BSE?

- Would such products be manufactured by companies that guarantee compliance with international guidelines on the manufacture of veterinary medicinal products?

- Are individuals permitted to produce veterinary biological medicinal products that are not subject to national regulation, such as for use only within the herd or flock of origin, and is there potential for source materials to be derived from other countries?

Rationale:

- Scrapie has been demonstrated to be transmissible through the administration of vaccines against louping ill and against *Mycoplasma agalactiae*, which have been produced from ovine brain tissue and mammary tissue respectively. Parenteral inoculation of products containing such tissues, or organs such as the pituitary gland, is an effective means of transmitting infection. Similar risks could arise with regard to bovine derived vaccines which involved brain, spinal cord or pituitary gland.

Evidence required:

- Documentary evidence of national controls over the manufacture, importation and use of veterinary medicines.

- Specific documentation on products that contain, or have used bovine, ovine or caprine brain tissue as a substrate in manufacture.

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Article 3.8.5.7.

The fate of tissues listed in Article 2.3.13.13, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- BSE has a long incubation period and insidious onset of signs, so cases may escape detection.
- Except for cases in the late *incubation period*, pre-clinical BSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- BSE may manifest in chronic disease or recumbency, and may be presented as fallen stock.
- Tissues listed in Article 2.3.13.13 (including tissues most likely to contain high titres of BSE infectivity) may be present in materials condemned as unfit for human consumption and may be rendered.
- BSE agent survival in rendering is affected by the method of processing. Rendering processes are described in Appendix 3.6.3.

Question to be answered: How has material containing tissues listed in Article 2.3.13.13 been processed in the past?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 3.8.5.8.

The overall risk of BSE in the cattle population of a country, *zone* or *compartment* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the risk assessment to conclude that the cattle population of a country, *zone* or *compartment* poses a negligible BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.

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COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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ADD 16

LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - SANCO/102464 Rev 1 WELFARE part - Volumes XX, XXI, XXII and XXIII

Delegations will find attached Commission document SEC(2006) 634 - SANCO/102464 Rev 1 WELFARE part - Volumes XX, XXI, XXII and XXIII.

Encl.: SEC(2006) 634

SANCO/102464 Rev 1 WELFARE part

APPENDIX 3.7.2.

Speaking Community position:

The European Community can support this proposal but will communicate written comments on some particular issues (see below).

However certain OIE amendments initially proposed in September are not submitted here and the Community would like to confirm that it maintains its comments previously communicated to the OIE on 15 February 2006 on the parts of the text not discussed today (Ref. D(2005) 522619). The European Community hopes that all those comments will be later considered by the relevant OIE Working Group.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY SEA

Preamble: These guidelines apply to the following live domesticated animals: cattle, buffalo, deer, camelids, sheep, goats, pigs and equines. They may also be applicable to other domesticated animals.

Written Community comments:
The text on animal behaviour in the guidelines for the slaughter of animals for human consumption should also be inserted into the land and sea transport guidelines.

Justification: Such guidance and information would also be useful to handlers involved in the transport of animals, not just their slaughter.

Article 1

The amount of time animals spend on a journey should be kept to the minimum.

Written Community comments:
The word "bis" should be deleted from the next article heading.

Justification: The word is not necessary.

Article 3.7.2.1. bis

Responsibilities

Once the decision to transport the animals by sea has been made, the welfare of the animals during their journey ~~transport~~ is the paramount consideration and is the joint responsibility of all people involved with the individual responsibilities of those persons being described in more detail in this Article. These guidelines may also be applied to the transport of animals by water within a country.

The management of animals at post-discharge facilities is outside the scope of this Appendix.

The roles of each of those responsible are defined below:

Written Community position

The responsibilities of those various persons involved in the transport chain are presented in a confusing and overlapping manner. To facilitate the correct interpretation and application of these animal welfare guidelines, which is paramount, these responsibilities should be defined and described in a much clearer way, e.g. in tabular fashion describing clearly "who is responsible for what" during transport. Definitions or clearer descriptions are needed for some of the agents described, such as manager of facilities.

Justification

Reading the current text it is very difficult to grasp the interlinked and overlapping responsibilities described, and it is even difficult to understand who is being referred to in some cases e.g. manager of facilities, senior animal handler…..

1. Exporters, owners of animals and managers of facilities are jointly responsible for the general health of the animals and their fitness for the journey, and for their overall welfare during the journey, regardless of whether duties are subcontracted to other parties during transport.

2. The exporter has overall responsibility for the organisation, carrying out and completion of the journey, regardless of whether duties are subcontracted to other parties during transport. The exporter is also responsible for ensuring that equipment and medication are provided as appropriate for the species and journey, and for the presence during the journey of at least one *animal handler*[1] competent for the species being transported. The exporter is also responsible for ensuring compliance of the animals with any required veterinary certification and, in the case of animals for export, any other requirements of the *importing* and *exporting countries*.

3. Business or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with masters of vessels and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals, and for emergencies.

4. Animal handlers are responsible for the humane handling and care of animals, especially during loading and unloading. To carry out these responsibilities, they should have the authority to take prompt action.

[1] ~~An *animal handler* is 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.~~

5. The exporter, the shipping company and the master of the vessel are jointly responsible for planning the journey to ensure the care of the animals, including:

   a) choosing appropriate vessels and ensuring that ~~competent~~ *animal handlers* are available to care ~~for loading and caring~~ for the animals ~~throughout the journey~~;

   b) developing and keeping up to date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;

   c) correct loading of the ship, regular inspections during the journey and for appropriate responses to problems arising;

   d) disposal of carcasses according to international law.

6. To carry out these responsibilities, the people involved should be competent regarding transport regulations, equipment usage, and the humane handling and ~~the~~ care of animals.

7. Managers of facilities during loading of the animals are responsible for:

   a) providing suitable premises for loading the animals;

   b) providing ~~competent~~ *animal handlers* to load the animals ~~in a manner that causes~~ with minimum stress and the avoidance of injury;

   c) providing appropriate facilities for emergencies;

   d) providing facilities and veterinarians or ~~competent~~ *animal handlers* capable of killing animals humanely when required.

8. Managers of facilities at the end of the journey are responsible for:

   a) providing suitable facilities for unloading the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit;

   b) providing ~~competent~~ *animal handlers* to unload the animals with minimum stress and injury;

   c) minimising the opportunities for disease transmission while the animals are in the facilities;

   d) providing appropriate facilities for emergencies;

   e) providing facilities and veterinarians or ~~competent~~ *animal handlers* capable of killing animals humanely when required.

9. The responsibilities of the *Competent Authority* of the *exporting country* include:

   a) establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;

Written Community comments:

Under point (b) the apparent obligation for a Competent Authority to approve all facilities, containers and vessels should be re-considered.

Justification: This would imply a very high administrative burden and would be very difficult to achieve in the case of all transport of animals by sea.

b) approving facilities, containers, vehicles/vessels for the holding and transport of animals;

c) setting competence standards for *animal handlers* and managers;

d) ensuring that the vessel transporting animals meets the required standards, including those of the *importing country*;

e) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;

Written community comments:

Under point (f) the apparent obligation for a Competent Authority to monitor animal health and welfare during the journey should be re-considered.

Justification: It may be impossible under practical conditions for a competent authority to monitor the health and welfare of all animals transported by sea.

f) monitoring and evaluating health and welfare performance, including the use of any veterinary medications.

10. The responsibilities of the *Competent Authority* of the *importing country* include:

a) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;

Written community comments:

Under point (b) the apparent obligation for a Competent Authority to approve all facilities, containers and vessels should be re-considered.

Justification: This would imply a very high administrative burden and would be very difficult to achieve in the case of all transports of animals by sea.

b) approving facilities, containers and vehicles for the unloading, holding and transport of animals;

c) setting competence standards for *animal handlers* and managers;

d) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;

e) ensuring that the *exporting country* is aware of the required standards for the vessel transporting the animals;

Written community comments:

Under point (f) the apparent obligation for a Competent Authority to monitor animal health and welfare during the journey should be re-considered.

Justification: It may be impossible under practical conditions for a competent authority to monitor the health and welfare of all animals transported by sea.

f) monitoring and evaluating health and welfare performance, including the use of any veterinary medications.

Written Community position

The last sentence of point 11 should be changed as follows: "The veterinarian should meet with the Master or Chief Officer of the vessel and the animal handler on a daily basis".

Justification

The current wording implies meeting the Master and the Chief Officer of the vessel on a daily basis and this has no additional value. The term "senior animal handler" has not been defined and so "animal handler" is a more appropriate term.

11. When travelling on vessels with the animals, veterinarians are responsible for the humane handling and treatment of the animals during the journey. To carry out these responsibilities, they should have the authority to act and report independently. The veterinarian should meet with the Master, Chief Officer and the senior *animal handler* on a daily basis.

12. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the journey.

Article 3.7.2.2.

Competence

1. All people ~~handling animals or who are otherwise~~ responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.2.1. Competence in areas other than animal welfare would need to be addressed separately. Competence may be gained through formal training and/or practical experience.

2. ~~This~~ The competence of *animal handlers* should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by ~~a~~ the *Competent Authority*. The certificate should be in one of the OIE official languages if the international transport of animals is involved.

3. The assessment of competence ~~for~~ of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

   a) responsibilities for animals during the journey;

   b) sources of advice and assistance;

   c) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;

   d) assessment of fitness to travel;

   e) relevant authorities and applicable transport regulations, and associated documentation requirements;

   f) general disease prevention procedures, including cleaning and disinfection;

g) appropriate methods of animal handling during transport and associated activities such as assembling, loading, and unloading;

h) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies;

i) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection;

j) ~~appropriate record keeping and~~ maintaining a journey log and other records.

4. Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a journey, including appropriate space allowances, and feed, water and ventilation requirements;

b) relevant authorities and applicable transport regulations, and associated documentation requirements;

c) appropriate methods of animal handling during transport and associated activities such as cleaning and *disinfection*, assembling, loading, and unloading;

d) species-specific aspects of animal handling and care, including appropriate equipment and medication;

e) sources of advice and assistance;

f) appropriate record keeping ~~and journey log~~;

g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

Article 3.7.2.3.

Planning the journey

1. General considerations

a) Adequate planning is a key factor affecting the welfare of animals during a journey.

b) Before the journey starts, plans should be made in relation to:

i) preparation of animals for the journey;

ii) type of transport vessel required;

iii) route, taking into account distance, expected weather and sea conditions;

iv) nature and duration of journey;

v) daily care and management of the animals by providing the appropriate number of *animal handlers*;

vi) avoiding the mixing of animals from different sources in a single pen group;

vii) provision of appropriate equipment and medication for the numbers and species carried;

viii) emergency response procedures.

2. Preparation of animals for the journey

a) When animals are to be provided with a novel diet ~~e.g. for dry food, and~~ or unfamiliar methods of supplying of feed ~~and~~ or water, they should be preconditioned ~~may be required~~.

b) There should be planning for water and feed availability during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.

c) Extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.

e) Behaviour-modifying or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian. Treated animals should be placed in a dedicated area.

~~d) Where there is a potential for spread of infectious disease, and when requested by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.~~

~~h) There should be an emergency management plan that identifies the important adverse events that may be encountered during the journey, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.~~

3. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, journey planning should take into account the following:

a) when possible and agreed by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;

b) medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian;

c) mixing of animals from different sources in a single consignment should be minimized.

4. Vessel and container design and maintenance

a) Vessels used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non-slip flooring. The avoidance of injury to *animal handler*s while carrying out their responsibilities should be emphasised.

b) Vessels should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.

c) Vessels and their fittings should be maintained in good mechanical and structural condition.

d) Vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported. The ventilation system should be ~~capable of operating~~ effective when the vessel is stationary ~~and the air flow should be adjustable~~. An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown.

Written Community position
The need for lighting to facilitate inspection of the animals needs to be mentioned. The following wording is proposed: "Vessels should be properly illuminated to allow animals to be observed and inspected."

Justification
It is a basic requirement to have sufficient light to carry out proper inspections of the animals.

e) The feeding and watering system should be designed to permit adequate access to feed and water appropriate to the species, size and weight of the animals, and to minimise soiling of pens.

f) Vessels should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, or their feed or water.

g) Loading and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water

h) Where appropriate, suitable bedding, such as straw or sawdust, should be added to vessel floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard or rough flooring surfaces and adverse weather conditions.

i) The above principles apply also to containers used for the transport of animals.

5. Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers

a) Road vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.

b) Road vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

c) Vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary vehicle/container on enclosed decks.

d) Due to the risk of limited airflow on certain vessels' decks, a road vehicle or container may require a forced ventilation system of greater capacity than that provided by natural ventilation.

Written Community position

The list of factors described under point 6 to determine the maximum duration of a journey is incomplete and should be placed "under study" pending further analysis and preparation of a more complete list of determining factors. The first sentence should be rephrased as follows: "The maximum duration of a journey should be determined in relation to the overall welfare of the animal taking into account factors such as::"

An additional point should be added:

i) vehicle type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver".

Justification

When determining the duration of a journey a risk-based approach should be taken which balances the risks of welfare costs to the benefit of each risk factor. The list of factors proposed is incomplete and further evaluation is necessary to more accurately address this point. The proposed text is scientifically incomplete and should be placed "under study" pending further careful analysis by the OIE's ad hoc expert groups.

6) Nature and duration of the journey

The maximum duration of a journey should be determined according to factors such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the animals' previous transport experience;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

g) space allowance and vessel design;

h) weather conditions.

7. Space allowance

a) The number of animals which should be transported on a vessel and their allocation to different pens on the vessel should be determined before loading.

b) The amount of space required, including headroom, depends on the species of animal and should allow the necessary thermoregulation. Each animal should be able to assume its natural position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vessel. When animals lie down, there should be enough space for every animal to adopt a ~~comfortable,~~ normal lying posture.

Written Community position

In the first sentence of the next bullet point the words "in Appendix XXX, or, in their absence" should be deleted.

Justification

Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

c) Calculations for the space allowance for each animal should be carried out, using the figures given in ~~these guidelines~~ Appendix XXX or, in their absence, in a relevant national or international document. The size of pens will affect the number of animals in each.

d) The same principles apply when animals are transported in containers.

8. Ability to observe animals ~~en route~~ during the journey

a) Animals should be positioned to enable ~~them~~ each animal to be observed regularly and clearly by the *animal handler* or other responsible person, during the journey to ensure their safety and good welfare.

~~b) To allow an adequate inspection of animals en route, it should be possible for each animal to be clearly observed by the *animal handler* or other responsible person.~~

9. Emergency response procedures

~~Appropriate contingency plans to address emergencies should be prepared in advance.~~

There should be an emergency management plan that identifies the important adverse events that may be encountered during the journey, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Article 3.7.2.4.

Documentation

1. Animals should not be loaded until the documentation required to that point is complete.
2. The documentation accompanying the consignment should include:

Written Community comments:
The word "including" should be changed to "and".

Justification: The emergency plan is an important issue and does not comprise part of the journey travel plan, which is implied by the current wording "including".

a) journey travel plan (including an emergency management plan);

b) time, date and place of loading;

c) the journey log – a daily record of inspection and important events which includes records of morbidity and mortality and actions taken, climatic conditions, food and water consumed, medication provided, mechanical defects;

d) expected time, date and place of arrival and unloading;

e) veterinary certification, when required;

f) animal identification to allow traceback of individual animals to the premises of departure, and, where possible, to the premises of origin;

Written Community comments:
In the next bullet point the cross-reference should be amended to "Article 3.7.2.5.3 e)".

Justification: To facilitate proper interpretation and application the text and any cross-references used should be as clear and precise as possible.

Written Community comments:
The words "Animals considered at risk" should be changed to "Animals considered at particular risk of suffering poor welfare during transport".

Justification: It is important in such international guidelines that scientific terms are used in as clear, correct and comprehensible a manner as possible.

g) details of any animals considered 'at risk' (Article 3.7.2.5);

h) number of *animal handler*s on board, and their competencies;

i) stocking density estimate for each load in the consignment.

3. When veterinary certification ~~should~~ is required to accompany consignments of animals ~~and,~~ it should address:

a) when required, ~~cleaning and~~ details of *disinfection* carried out ~~of the vessel~~;

b) fitness of the animals to travel;

c) animal identification (description, number, etc.) ;

d) health status including any tests, treatments and vaccinations carried out~~, if required~~.

Article 3.7.2.5.

Pre-journey period

1. General considerations

a) Before each journey, vessels should be thoroughly cleaned and, if necessary, treated for animal and public health purposes, using chemicals approved by the *Competent Authority*. When cleaning is necessary during a journey, this should be carried out with the minimum of stress to the animals.

b) In some circumstances, animals may require pre-journey assembly. In these circumstances, the following points should be considered:

i) Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the journey, a short period of feed deprivation prior to loading is desirable.

~~ii) When animals will be provided with a novel diet or method of water provision during or after transport, an adequate period of pre-exposure is necessary. Preconditioning to the feed to be used on the vessel may be necessary in such cases.~~

iii) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.

c) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a veterinarian.

d) Pre-journey assembly /holding areas should be designed to:

i) securely contain the animals;

ii) maintain an environment safe from hazards, including predators and disease;

iii) protect animals from exposure to adverse weather conditions; ~~and~~

iv) allow for maintenance of social groups; and

v) allow for rest, watering and feeding.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:

a) animals of different species should not be mixed unless they are judged to be compatible;

b) animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.2.10.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;

c) young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot;

d) animals with horns or antlers should not be mixed with animals lacking horns or antlers, unless judged to be compatible;

e) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

3. Fitness to travel

a) Animals should be inspected by a veterinarian or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a veterinarian. Animals found unfit to travel ~~before travel and those found unfit to travel by farm staff, an *animal handler* or a veterinarian,~~ should not be loaded onto a vessel.

b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.

c) Animals that are unfit to travel include:

i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided ~~and~~ or bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

vi) females travelling without young which have given birth within the previous 48 hours;

vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

Written Community comments:
The words "at risk" should be changed to "at particular risk of suffering poor welfare during transport".

Justification: More clear and precise wordings should be used where possible to facilitate correct interpretation of the intended meaning. In such internationally agreed guidelines it is important that scientific terms such as "risk" are used in as clear, correct and precise a manner as possible.

e) Animals at risk, and requiring better conditions and additional attention during transport include:

i) very large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals subject to motion sickness;

v) animals which have had little contact with humans;

vi) females in the last third of pregnancy or in heavy lactation.

f) Hair or wool length ~~needs consideration~~ should be considered in relation to the weather conditions expected during transport.

Article 3.7.2.6.

Loading

1. ~~Experienced~~ Competent supervision

   a) Loading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

Written Community comments:
The words "loading should be supervised by the Competent Authority" need to be carefully considered.

Justification: These guidelines may be applicable not just to the international transport of animals but also within national boundaries and journeys of short duration. It is questionable whether all Competent Authorities have the requisite resources to supervise the commencement of all such journeys.

   b) Loading should be supervised by the *Competent Authority* and ~~managed~~ conducted by ~~an~~ *animal handler*(s). Animal handlers should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

   ~~c) Ventilation during loading and the journey should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.~~

2. Facilities

   a) The facilities for loading including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.

   b) Ventilation during loading and the journey should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.

   c) ~~All~~ Loading facilities should be properly illuminated to allow the animals to be easily inspected by the *animal handler*(s), and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter lighting light levels inside *vehicles / containers*, in order to minimise baulking. Dim lighting light levels may be advantageous for the catching of some animals. Artificial lightening may be required.

3. Goads and other aids

   The following principles should apply:

Written Community comments:
The following sentence should be added to point a: "Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving".

Justification: This is in line with basic practice that goods should not be used on animals who are unable to move. a) ~~Goads (aids for encouraging animals to move) should not be used on~~ Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.

b) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals ~~but without physical contact with them~~.

c) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.

~~c) Unsuitable goads such as large wooden sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts should not be used to strike animals.~~

d) The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. ~~If~~ Such use ~~is necessary, it~~ should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

e) Shouting or yelling at animals or making loud noises eg through the cracking of whips to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.

f) The use of well trained dogs to help with the *loading* of some species may be acceptable.

g) Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the lifting of animals by body parts such as their tail, head, horns, ears, limbs, wool or hair should not be permitted. The throwing or dropping of animals should not be permitted.

Article 3.7.2.7.

Travel

1. General considerations

a) Animal handler(s) should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked again within ~~24~~ 12 hours.

Written Community position

The words "If necessary and where possible" should be added to the start of the next bullet point.

Justification

In many cases stocking density will not need to be changed during the journey. If it is necessary to make changes to the stocking density during the journey, this implies that additional free space should be held in reserve if the

aforementioned stocking density changes are necessary. For these reasons the current wording should be changed.

b) Adjustments should be made to the stocking density ~~within 48 hours of departure and~~ as appropriate during the journey.

c) Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.

d) Adequate access to suitable feed and water should be ensured for all animals in each pen.

Community position

The text "Sick and injured" should be changed to "Sick or injured".

Justification

The current wording is illogical. An animal may be sick without necessarily being injured.

This should also be changed again in points 2a-b and elsewhere in the text whenever this wording is used.

2. Sick and injured animals

Written Community position

1. The words: "if possible" should be deleted.

Justification

There should be a possibility to separate these sick or injured animals to avoid further seriously compromising their welfare.

2. The text "Sick and injured" should be changed to "Sick or injured".

Justification

The current wording is illogical. An animal may be sick without necessarily being injured.

a) Sick and ~~or~~ injured animals should be segregated~~/isolated~~ if possible.

Community position

The text "Sick and injured" should be changed to "Sick or injured".

Justification

The current wording is illogical. An animal may be sick without necessarily being injured.

b) Sick ~~or~~ and injured animals should be appropriately treated ~~promptly and~~ or humanely killed, in accordance with a predetermined emergency response plan (Article 3.7.2.3). ~~and~~ Veterinary advice should be sought if necessary. All drugs and products should be used in accordance with the manufacturer's or veterinarian's recommendations.

c) A record of treatments carried out and their outcomes should be kept.

d) When euthanasia is necessary, the person responsible for the animals must ensure that it is carried out humanely, ~~and results in immediate death. When necessary.~~ Assistance should be sought from a veterinarian or other person(s) competent in euthanasia procedures. Recommendations for specific species are described in Appendix 3.7.6. on humane killing of animals for disease control purposes.

~~3.~~ ~~Cleaning and disinfection~~

~~a) Vessels and containers used to carry the animals should be cleaned before re use through the physical removal of manure and bedding by scraping, washing and flushing vessels and containers with water. This should be followed by *disinfection* when there are concerns about disease transmission.~~

~~b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.~~

~~c) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum stress to the animals.~~

Article 3.7.2.8.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 3.7.2.6. apply equally to unloading, but consideration should be given to the likelihood that the animals will be fatigued.

b) Unloading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

c) A livestock vessel should have priority attention when arriving in port and have priority access to a berth with suitable unloading facilities. As soon as possible after the ship's arrival at the port and acceptance of the consignment by the *Competent Authority*, animals should be unloaded into appropriate facilities.

d) The accompanying veterinary certificate and other documents should meet the requirements of the *importing country*. Veterinary inspections should be completed as quickly as possible.

e) Unloading should be supervised by the *Competent Authority* and ~~managed~~ conducted by an ~~competent~~ *animal handler*(s). The *animal handler*s should ensure that animals are unloaded as soon as possible after arrival but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

2. Facilities

a) The facilities for unloading including the collecting area at the wharf, races and unloading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.

b) All unloading facilities should ~~be properly illuminated~~ have sufficient lighting to allow the animals to be easily inspected by the *animal handler*(s), and to allow the animals' ease of movement at all times.

c) ~~In case of emergencies,~~ There should be facilities ~~should~~ to provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

3. Sick and injured animals

a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Appendix 3.7.6.). When necessary, veterinary advice should be sought in the care and treatment of these animals.

b) In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanased aboard the vessel.

c) If unloading is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane unloading of such animals. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities and treatments should be provided for sick or injured animals.

4. Cleaning and disinfection

a) Vessels and containers used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding, by scraping, washing and flushing vessels and containers with water until visibly clean. This should be followed by disinfection when there are concerns about disease transmission.

b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

c) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the animals.

Article 3.7.2.9.

Actions in the event of a refusal to allow the importation of a shipment

1. The welfare of the animals should be the first consideration in the event of a refusal to import.

2. When ~~a shipment has~~ animals have been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the unloading of animals from a vessel and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:

a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;
b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health

status with regard to the *importing country*'s concerns, and the necessary facilities and approvals to expedite the required diagnostic testing;

c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and welfare situation;

d) if the matter cannot be promptly resolved, the *Competent Authority* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that the animals are required to remain on the *vessel*, the priorities should be:

a) the *Competent Authority* of the *importing country* should allow reprovision of the vessel with water and feed as necessary;

b) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;

c) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the *importing country*'s concerns, and the necessary facilities and approvals to expedite the required diagnostic testing;

d) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and ~~welfare situation~~ other aspects of the welfare of the animals, and the necessary actions to deal with any issues which arise;

e) if the matter cannot be urgently resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

Article 3.7.2.10.

Written Community comments:

This text should be replicated at the end of Annex 3.7.1.

Justification: This text contains useful descriptions of issues of general interest and information, not specifically related to the transport of animals by sea. As such it could be useful to bring it to the attention of persons reading the other OIE animal welfare guidelines. Only presenting this text in the sea transport guidelines means that persons only reading the other animal welfare guidelines will be unaware of these important descriptions of species-specific issues.

Species specific issues

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Sheep are sociable animals with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to

rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

Pigs have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of loading resulting in good or bad experiences. Good training should result in easier loading, but some horses can prove difficult, especially if they are inexperienced or have associated loading with poor transport conditions. In these circumstances, two experienced handlers can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Camelids in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

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— text deleted

Appendix XXI

APPENDIX 3.7.3.

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY LAND

Speaking Community position:

The European Community can support this proposal but will communicate written comments on some particular issues (see below).

However certain OIE amendments initially proposed in September are not submitted here and the Community would like to confirm that it maintains its comments previously communicated to the OIE on 15 February 2006 on the parts of the text not discussed today (Ref. D(2005) 522619). The European Community hopes that all those comments will be later considered by the relevant OIE Working Group.

Article 1

The amount of time animals spend on a journey should be kept to the minimum.

Written Community comments:
The word "bis" should be deleted from the next article heading.

Justification: The word is not necessary.

Article 3.7.3.1. bis

Responsibilities

Once the decision to transport the animals has been made, the welfare of the animals during their journey ~~transport~~ is the paramount consideration and is the joint responsibility of all people involved with the individual responsibilities of those persons being described in more detail in this Article.

The roles of each of those responsible are defined below:

1. The owners and managers of the animals are responsible for the general health of the animals and their fitness for the journey, and for their overall welfare during the journey~~, regardless of whether duties are subcontracted to other parties during transport.~~ They are also responsible for ensuring

compliance with any required veterinary or other certification, and for the presence during the journey of at least one *animal handler*[2] competent for the species being transported, with the authority to take prompt action. They are also responsible for ensuring that equipment and veterinary assistance are provided as appropriate for the species and journey. These responsibility should apply regardless of whether duties are subcontracted to other parties during transport.

2. Business agents or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with market owners and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals, including for any stops at resting points during the journey and for emergencies.

3. Animal handlers are responsible for the humane handling and care of the animals, especially during loading and unloading, and for maintaining a journey log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.

4. Transport companies, vehicle owners and drivers are responsible for planning the journey to ensure the care of the animals:

Written Community position
An extra bullet point should be added with the following text: "Transport companies are also responsible for the welfare of the animals during the actual transport".

Justification
Transport companies have very important responsibilities concerning the transport of animals by land. Practical experience has shown the considerable animal welfare gains that can be achieved where transport companies promote a positive approach to ensuring the welfare of animals transported.

a) transport companies and vehicle owners are responsible for choosing appropriate vehicles and ensuring that properly trained staff are available for loading and caring for animals;

b) transport companies and vehicle owners are responsible for developing and keeping up to date contingency plans to address emergencies and minimise stress during transport;

Written Community position

In the next bullet point the words "and vehicle owners" should be deleted.

Justification

Vehicle owners are usually natural persons or commercial haulage agencies not directly involved in planning and carrying out the transport.

Written Community position

The word "itinerary" should be added after "journey duration".

[2] ~~An *animal handler* is 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.~~

Justification

It is important that the description of the minimum requirements of the journey plan should be widened to include an itinerary, which is important for the driver to complete the journey in an efficient manner with appropriate animal welfare safeguards.

c) transport companies and vehicle owners are responsible for producing a journey plan which includes a loading plan, journey duration and location of resting places;

d) drivers are responsible for loading only those animals which are fit to travel, for their correct loading into the vehicle and their inspection during the journey, and for appropriate responses to problems arising. If its fitness to travel is in doubt, the animal should be examined by a veterinarian in accordance with point 5 a) of Article 3.7.3.5.

Written Community position

"Managers of facilities" should be defined.

Justification

In order to ensure that these guidelines can be applied it is important that they are drafted in as clear and precise a manner as possible, especially with regard to the responsibilities of those involved in the animal transport chain.

Written Community position

The first phrase of 5 should be replaced by "Drivers should only load and unload animals in places:".

Justification

Drivers are a key actor in the animal transport chain and have important responsibilities in ensuring that the welfare of transported animals is properly safeguarded.

5. Managers of facilities at the start and at the end of the journey and at resting points are responsible for:

a) providing suitable premises for loading, unloading and securely holding the animals, with water and feed when required, until further transport, sale or other use (including rearing or slaughter);

Written Community position

Point (b) should be replaced with the following text

"- providing appropriate personnel to hold and care for the animals in a manner that causes minimum stress and injury

- providing appropriate personnel including animal handlers to load unload, hold and care for animals in the facility in a manner that causes minimum stress and injury".

Justification

The responsibility of managers of facilities should be changed, because loading, unloading and driving are the responsibility of animal handlers and/or drivers rather than the manager of the facilities. Also cooperation between the animal handler (driver) and personnel of the facility during loading and unloading should take place.

b) providing ~~competent~~ *animal handler*s to load, unload, drive and hold animals in a manner that causes minimum stress and injury;

c) minimising the opportunities for disease transmission;

d) providing appropriate facilities, with water and feed when required;

e) providing appropriate facilities for emergencies;

f) providing facilities for washing and disinfecting vehicles after unloading;

g) providing facilities and competent staff to allow the humane killing of animals when required;

h) ensuring proper rest times and minimal delay during stops.

Written Community position

The words: "Competent authorities should give animal consignments priority at frontiers in order to allow them to pass without unnecessary delay" should be added as an extra point.

Justification

The responsibilities of the Competent Authorities should include giving priority to animal consignments at frontiers in order to allow them to pass without undue delay. This should be recognised in the text.

6. The responsibilities of *Competent Authorities* include:

a) establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;

b) ~~approving~~ setting standards for facilities, containers and vehicles for the transport of animals;

Written Community position

For consistency, the word "manager" in c) and d) should be changed to "managers of facilities".

Justification

Care is needed to ensure the clear and consistent use of terminology throughout the text.

c) setting standards for the competence of drivers, *animal handlers* and managers;

d) ensuring appropriate awareness and training of drivers, *animal handlers* and managers;

e) implementation of the standards, including through accreditation of / interaction with other organisations;

f) monitoring and evaluating the effectiveness of standards of health and other aspects of welfare;

g) monitoring and evaluating the use of veterinary medications.

h) expediting the passage of animal consignments at frontiers.

7. All individuals, including veterinarians, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.

8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the journey.

Article 3.7.3.2.

Competence

1. All people ~~handling animals, or who are otherwise~~ responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.3.1. Competence may be gained through formal training and/or practical experience. Competence in areas other than animal welfare would need to be addressed separately.

2. The competence of *animal handlers* should be demonstrated through a current certificate from the *Competent Authority* or an independent body, accredited by the *Competent Authority*. The certificate should be in one of the OIE official languages if the international transport of animals is involved.

3. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

a) planning a journey, including appropriate space allowance, and feed, water and ventilation requirements;

Written Community position

The words: "including loading and unloading" should not be deleted.

Justification

Loading and unloading are often the most stressful events during the journey. In addition such operations represent serious risks for the welfare of the animals (e.g. risks of injury) and allow an important opportunity for the handler to assess if the animals are fit for transport.

b) responsibilities for animals during the *journey*~~, including loading and unloading~~;

c) sources of advice and assistance;

d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;

e) assessment of fitness to travel;

f) relevant authorities and applicable transport regulations, and associated documentation requirements;

g) general disease prevention procedures, including cleaning and disinfection;

h) appropriate methods of driving;

i) methods of inspecting animals, managing situations frequently encountered during *transport* such as adverse weather conditions, and dealing with emergencies;

j) species-specific and age-specific aspects of animal handling and care, including feeding, watering and inspection;

k) maintaining a journey log and other records.

Article 3.7.3.3.

Planning the journey

Written Community position
The following points should be added under 1b:
"xi) Weather forecasting (e.g. conditions being too hot or cold to travel during certain periods of the day)
xii) Transfer time when changing mode of transport
xiii) Waiting time at frontiers and inspection points"

Justification
Planning should also incorporate forecasting of expected weather conditions and expected transfer time when changing mode of transport (e.g. from vehicle to aeroplane or to roll-on roll-off vessel). Expected waiting time at frontiers/ inspection points should also be taken into account. These could have an impact on the welfare of the animals. Therefore it is important to include the afore-mentioned 3 additional bullet points.

1. General considerations

a) Adequate planning is a key factor affecting the welfare of animals during a journey.

b) Before the journey starts, plans should be made in relation to:

i) preparation of animals for the journey;

ii) choice of road or rail;

iii) nature and duration of the journey;

iv) vehicle / container design and maintenance, including roll-on roll-off vessels;

v) required documentation;

vi) space allowance;

vii) rest, water and feed;

viii) observation of animals en route;

ix) control of disease; and

x) emergency response procedures.

c) Regulations concerning drivers (for example, maximum driving periods) should be harmonised with maximum transport journey intervals appropriate for the species.

2. Preparation of animals for the journey

Written Community position

The last part of the last sentence can be changed as follow: "……..of feed deprivation, for example 10-12 hours for pigs prior to loading may be desirable".

Justification

To avoid different interpretations of the last sentence "a short period" should be more clearly defined or otherwise the whole sentence should be deleted. According to the Report of the Scientific Committee on Animal Health and Animal welfare adopted on 11 March 2002, 10 to 12 hours fasting is recommended.

a) When animals are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the journey, a short period of feed deprivation prior to loading may be desirable.

b) ~~Animals should be exposed to appropriate contact with humans and handling conditions (including methods of restraint) prior to transport to reduce their fearfulness and improve their approachability (see Article 3.7.3.5.).~~ ~~Since~~ Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. People handling animals should handle and load animals in a manner that reduces their fearfulness and improves their approachability.

c) Behaviour-modifying compounds (such as tranquillisers) should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

Written Community position

The list of factors described under point 6 to determine the maximum duration of a journey is incomplete and should be placed "under study" pending further analysis and preparation of a more complete list of determining factors. The first sentence should be rephrased as follows: "The maximum duration of a journey should be determined in relation to the overall welfare of the animal taking into account factors such as:"

An additional point should be added:

"i) vehicle type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver".

Justification

When determining the duration of a journey a risk-based approach should be taken which balances the risks of welfare costs to the benefit of each risk factor. The list of factors proposed is incomplete and further evaluation is necessary to more accurately address this point. The proposed text is scientifically incomplete and should be placed "under study" pending further analysis by the OIE's ad hoc expert groups.

3. Nature and duration of the journey

The maximum duration of a journey should be determined according to factors such as:

a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);

b) the animals' previous transport experience;

c) the likely onset of fatigue;

d) the need for special attention;

e) the need for feed and water;

f) the increased susceptibility to injury and disease;

g) space allowance, vehicle design, road conditions and driving quality;

h) weather conditions.

4. Vehicle and container design and maintenance

a) Vehicles and containers used for the transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.

b) Vehicles and containers should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.

c) In order to minimise the likelihood of the spread of ~~pathogenic agents~~ infectious disease during transport, vehicles and containers should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a journey.

d) Vehicles and containers should be maintained in good mechanical and structural condition.

Written Community position

The last part of the last sentence should not be deleted

Justification

The temperature can change during the journey. Therefore the airflow should be adjustable.

e) Vehicles and containers should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be ~~capable of operating~~ effective when the vehicle is stationary ~~and the air flow should be adjustable~~.

f) Vehicles should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water.

g) When vehicles are carried on board ferries, facilities for adequately securing them should be available.

h) If feeding or watering while the vehicle is moving is required, adequate facilities on the vehicle should be available.

i) When appropriate, suitable bedding should be added to vehicle floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

a) Vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.

b) Vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

c) Roll-on/roll-off vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary vehicle/container on enclosed decks.

6. Space allowance

a) The number of animals which should be transported on a vehicle or in a container and their allocation to ~~different~~ compartments should be determined before ~~the vehicle or container is loaded~~ loading.

b) The space required on a vehicle or in a container depends upon whether or not the animals need to lie down (for example, pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the vehicle is driven with too much lateral movement or sudden braking.

c) When animals lie down, they should all be able to adopt a ~~comfortable,~~ normal lying posture which allows necessary thermoregulation.

Written Community position

"(Article XXX)" should be deleted.

Justification

Article XXX does not exist and referring to non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported (Article XXX).

Written Community position

The words "and there should be sufficient headroom to allow adequate airflow over the animals" should be added to the end of the next bullet point.

Justification

If the space is not sufficient this can limit the airflow, with potentially serious welfare consequences.

e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vehicle.

Written Community position

In the first sentence of the next bullet point the words "in Appendix XXX, or, in their absence" should be deleted.

Justification

Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

f) Calculations ~~according to~~ for the space allowance ~~permitted~~ for each animal should be carried out using the figures given in Appendix XXX or, in their absence, in a relevant national or international document. ~~The size of already established groups will affect the number and size of the pens, and the distribution of animals in pens on the vehicle~~. The number and size of pens on the vehicle should be varied to where possible accommodate already established groups of animals while avoiding group sizes which are too large.

g) Other factors which may influence space allowance include:

i) vehicle / container design;

ii) length of journey;

iii) need to provide feed and water on the vehicle;

iv) quality of roads;

v) expected weather conditions.

7. Rest, water and feed

a) There should be planning for the availability of suitable water and feed ~~during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, climatic conditions, etc~~ as appropriate and needed for the species, age, and condition of the animals, as well as the duration of the journey, climatic conditions, etc.

b) ~~Animals should be rested~~ There should be planning for the resting of animals at resting points at appropriate intervals during the journey. The type of transport, the age and species of the animals being transported, and climatic conditions should determine the frequency of rest stops and whether the animals ~~are~~ should be unloaded. There should be planning for water and feed availability during rest stops.

8. Ability to observe animals ~~en route in relation to~~ during the journey ~~duration~~

a) Animals should be positioned to enable each animal to be observed regularly during the journey to ensure their safety and good welfare.

Written Community position

"If" should be changed to "However" and this point (b) combined with bullet point (a).

Justification

This change is necessary for linguistic reasons and to improve readability and clarity, which are very important if the guidelines are to be correctly interpreted, understood and ultimately applied by the OIE's member countries.

Written Community position

"(i.e. less than 1.3 m)" should be deleted.

Justification

The basis for deciding on an absolute figure of 1.3 m is not clear, would an alternative figure of 1.2 or 1.4 m be acceptable under some circumstances ? Therefore this provision should be deleted.

b) If the animals are in crates or on multi-tiered vehicles which do not allow free access for observation, for example where the roof of the tier is too low (i.e. less than 1.3 m), animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter journey duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

As animal transport is often a significant factor in the spread of infectious diseases, journey planning should take the following into account:

a) mixing of animals from different sources in a single consignment should be minimised;

b) contact at resting points between animals from different sources should be avoided;

c) when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;

d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *importing country* and should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian ~~and agreed by the *Veterinary Authority* of the *importing country*~~.

10. Emergency response procedures

~~Appropriate contingency plans to address emergencies should be prepared in advance.~~

There should be an emergency management plan that identifies the important adverse events that may be encountered during the journey, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be

undertaken and the responsibilities of all parties involved, including communications and record keeping.

11. Other considerations

a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate vehicle design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 3.7.3.4.

Documentation

1. Animals should not be loaded until the ~~required~~ documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

Written Community comments:
In the next bullet point the word "including" should be changed to "and".

Justification: An emergency plan is not necessarily part of the journey travel plan, which is the meaning implied by the current wording of the text.

a) journey travel plan (including an emergency management plan);

b) date, time, and place of loading and unloading;

c) veterinary certification, when required;

d) driver's competencies;

e) identities of the animals transported to allow traceback of individual animals to the premises of departure and, where possible, to the premises of origin;

Written Community comments:
In point f) the words "Animals considered at risk" should be changed to "Animals considered at particular risk of suffering poor welfare during transport".

Justification: It is important in such international guidelines that scientific terms are used in as clear, correct and comprehensible a manner as possible.

f) details of any animals considered 'at risk' (Article 3.7.3.5.);

g) documentation of the period of rest, and access to feed and water, prior to the journey;

h) stocking density estimate for each load in the consignment;

i) the journey log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

3. When veterinary certification is required to accompany consignments of animals, it should ~~include~~ address:

   a) fitness of animals to travel;

   b) ~~appropriate~~ animal identification (description, number, etc.);

   c) health status including any tests, treatments and vaccinations ~~status~~ carried out;

   d) when required, details of *disinfection* carried out.

   At the time of certification, the veterinarian should notify the *animal handler* of any factors affecting the animals' fitness to travel for a particular journey.

Article 3.7.3.5.

Pre-journey period

1. General considerations

   a) Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

   b) Pre-journey assembly/holding areas should be designed to:

      i) securely hold the animals;

      ii) maintain a safe environment from hazards, including predators and disease;

      iii) protect animals from exposure to severe weather conditions;

      iv) allow for maintenance of social groups, and

      v) allow for rest, and appropriate water and feed.

   c) Consideration should be given to an animal's previous transport experience, training and conditioning if known as these may reduce fear and stress in animals.

   d) Feed and water should be provided pre-journey if the journey duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 3.7.3.10.

   e) When animals ~~will~~ are to be provided with a novel diet or method of feed or water provision during ~~or after transport,~~ an adequate period of adaptation should be planned. ~~pre-exposure is necessary~~.

   f) Before each journey, vehicles and containers should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a journey, this should be carried out with the minimum of stress to the animals.

   g) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined ~~inspected~~ by a veterinarian.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:

a) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together;

b) animals of the same species ~~should not~~ can be mixed ~~if~~ unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.3.10.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;

c) young or small animals should be separated from older or larger animals, with the exception ~~that dam and offspring should be transported together~~ of nursing mothers with young at foot;

d) animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible;

e) animals of different species should not be mixed unless they are judged to be compatible.

~~3. Shelter in the assembly/holding area~~

~~Assembly/holding areas should be designed to:~~

~~a) securely hold the animals;~~

~~b) maintain a safe environment from hazards, including predators and disease;~~

~~c) protect animals from exposure to severe weather conditions;~~

~~d) allow for maintenance of social groups, and~~

~~e) allow for rest, and appropriate water and feed.~~

~~4. Effect of travel experience, long and short term~~

~~a) Consideration should be given to an animal's previous transport experience, training and conditioning as these may reduce fear and stress in animals. Animals that are carefully and regularly transported may show less adverse responses to transport.~~

~~b) Exposure to familiar personnel should reduce the fearfulness of animals and improve their approachability during transport procedures.~~

5. Fitness to travel

a) Each animal should be inspected by a veterinarian or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a veterinarian. Animals found unfit to travel should not be loaded onto a vehicle, except for transport to receive veterinary treatment.

Written Community comments:
The next bullet point should be clarified.

Justification: Sharing the responsibilities between different agents "e.g. the owner or agent" is likely to give rise to confusion and ineffective handling of animal welfare problems when they arise.

b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.

c) Animals that are unfit to travel include:

i) those that are sick, injured, weak, disabled or fatigued;

ii) those that are unable to stand unaided and bear weight on each leg;

iii) those that are blind in both eyes;

iv) those that cannot be moved without causing them additional suffering;

v) newborn with an unhealed navel;

vi) ~~pregnant animals which are likely to give birth during the journey~~ pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading;

vii) females travelling without young which have given birth within the previous 48 hours;

viii) those whose body condition would result in poor welfare because of the expected climatic conditions.

d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

Written Community comments:

In point e) the words "Animals at risk" should be changed to "Animals at particular risk of suffering poor welfare during transport and which require special conditions…..".

Justification: It is important in such international guidelines that scientific terms are used in as clear, correct and comprehensible a manner as possible.

e) Animals 'at risk' which require special conditions (such as in the design of facilities and vehicles, and the length of the journey) and additional attention during transport, may include:

i) large or obese individuals;

ii) very young or old animals;

iii) excitable or aggressive animals;

iv) animals which have had little contact with humans;

v) animal subject to motion sickness;

vi) females in late pregnancy or heavy lactation, dam and offspring;

vii) ~~those~~ animals with a history of exposure to stressors or pathogenic agents prior to transport.

6. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight *zones*, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 3.7.3.10.

Article 3.7.3.6.

Loading

1. ~~Experienced~~ Competent supervision

   a) ~~Since loading has been shown to be the procedure most likely to be the cause of poor welfare in transported animals, the methods to be used should be carefully planned~~. Loading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.

Written Community comments:
The next bullet point should be clarified.

Justification: Stating that "loading should be supervised and/or conducted by animal handlers" is confusing and gives rise to the question of who will actually conduct and supervise the loading. To ensure proper application of the guidelines such responsibilities need to be clearly and carefully described.

   b) Loading should be supervised and/or conducted by *animal handlers*. These *animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

   c) When containers are loaded onto a vehicle, this should be carried out in such a way to avoid poor animal welfare.

2. Facilities

   a) The facilities for loading including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.

   b) Loading facilities should be properly illuminated to allow the animals to be observed by the *animal handler*(s), and to allow the animals' ease of movement at all times. Facilities should provide uniform ~~lighting~~ light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter ~~lighting~~ light levels inside vehicles / containers, in order to minimise baulking. Dim ~~lighting~~ light levels may be advantageous for the catching of poultry and some other animals. Artificial lightening may be required.

   c) Ventilation during loading and the journey should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.

3. Goads and other aids

   The following principles should apply:

Written Community comments:

The following sentence should be added to point a: "Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving".

Justification: This is in line with basic practice that goads should not be used on animals who are unable to move.

a) Animals which have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.

b) Useful and permitted aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals ~~but without physical contact with them~~.

c) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.

d) The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. Such use should be limited to battery-powered goads on the hindquarters of adult pigs and cattle, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on other animals.

e) The use of well trained dogs to help with the loading of some species may be acceptable.

f) The throwing or dropping of animals, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small animals is permissible.

g) Shouting or yelling at animals or making loud noises e.g. through the cracking of whips to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.

Article 3.7.3.7.

Travel

1. General considerations

Written Community comments:

The words "especially at rest or re-fuelling stops when the vehicle is stationary" should be added to the end of the next bullet point.

Justification: Drivers or conveyors of animals should be encouraged to take any available opportunity when the vehicle is stationary for a period of time in order to examine the animals.

a) Drivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip.

b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

2. Methods of restraining or containing animals

a) Methods of restraining animals should be appropriate to the species and age of animals involved and the training of the individual animal.

b) Recommendations for specific species are described in detail in Article 3.7.3.10.

3. Regulating the environment within vehicles or containers

Written Community comments:
The last sentence of the next bullet point should be deleted.

Justification: Appendix XXX does not exist and referring to such non-existent text in international guidelines to be adopted by 167 OIE member countries is inappropriate, unhelpful and confusing to the reader.

a) Animals should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the animals' environment within vehicles or containers will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented. Specific temperature and humidity parameters are described in detail in Appendix XXX.

b) The animals' environment in hot weather can be regulated by the flow of air produced by the movement of the vehicle. In warm and hot weather, the duration of journey stops should be minimised and vehicles should be parked under shade, with ~~maximal~~ adequate and appropriate ventilation.

c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

4. Sick, injured and dead animals

a) A driver or *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan.

b) If possible, sick or injured animals should be segregated.

c) Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the journey.

d) In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the waste products of the transported animals, and other farm animals should be minimised.

e) During the journey, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

f) When euthanasia is necessary, the driver or *animal handler* should ensure that it is carried out as quickly as possible and ~~humanely, and results in immediate death. When necessary,~~ assistance should be sought from a veterinarian or other person(s) competent in humane euthanasia procedures. Recommendations for specific species are described in Appendix 3.7.6. on humane killing of animals for disease control purposes.

5. Water and feed requirements

a) If journey duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals (appropriate for their species and age) carried in the vehicle should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.

b) Recommendations for specific species are described in detail in Article 3.7.3.10.

6. Rest periods and conditions including hygiene

a) Animals that are being transported should be rested at appropriate intervals during the journey and offered feed and water, either on the vehicle or, if necessary, unloaded into suitable facilities.

b) Suitable facilities should be used en route, when resting requires the unloading of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

7. In-transit observations

Written Community comments:
In the next point "With a maximum interval of 5 hours" should be deleted.
Justification: No clear basis is given for the figure of "with a maximum interval of 5 hours" and someone could equally propose a figure of 3-4-6-7 hours. In such internationally agreed guidelines it is important that recommendations should have a clear and objective scientific basis, rather than discretionary subjective figures being used.

a) Animals being transported by road should be observed soon after a journey is commenced and whenever the driver has a rest stop (with a maximum interval of 5 hours). After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.

Written Community comments:
In the next point "5 hours since" should be deleted.
Justification: No clear basis is given for the figure of "5 hours" and someone could equally propose figures of 3-4-6-7 hours. In such internationally agreed guidelines it is important that recommendations should have a clear and objective scientific basis, rather than discretionary subjective figures being used.

b) Animals being transported by rail should be observed at each scheduled stop nearest to 5 hours since the last observation. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.

c) During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 3.7.3.8.

Unloading and post-journey handling

1. General considerations

a) The required facilities and the principles of animal handling detailed in Article 3.7.3.6. apply equally to unloading, but consideration should be given to the likelihood that the animals will be fatigued.

b) Unloading should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the vehicle into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force.

c) Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

d) For details regarding the unloading of animals at a slaughterhouse, see Appendix 3.7.5. on slaughter of animals for human consumption.

Written Community comments:
In the next heading the word "and" should be changed to "or".

Justification: A sick animal is not necessarily injured.

2. Sick and injured animals

a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Appendix 3.7.6. on humane killing of animals for disease control purposes). When necessary, veterinary advice should be sought in the care and treatment of these animals. In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanased aboard the vehicle.

b) At the destination, the *animal handler* during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a suitable person.

c) There should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities should be available for sick or injured animals.

d) Feed, if appropriate, and water should be available for each sick or injured animal.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:

a) increased contact among animals, including those from different sources and with different disease histories;

b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;

c) exposure of animals to pathogens which may contaminate vehicles, resting points, markets, etc.

4. Cleaning and disinfection

a) Vehicles, crates, containers, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing vehicles and containers with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.

~~b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.~~

~~c) When disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.~~

b) Manure, litter, bedding and the bodies of any animals which die during the journey should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

c) Establishments like livestock markets, slaughterhouses, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of vehicles.

d) Where *disinfestation* is necessary, it should be carried out with the minimum stress to the animals.

Article 3.7.3.9.

Actions in the event of a refusal to allow the completion of the journey

1. The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the journey.

2. When the animals have been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the unloading of animals from a vehicle and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:

   a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;

   b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a veterinarian, where possible an OIE veterinarian(s) appointed by the Director General, to assess the animals' health status with regard to the *importing country*'s concerns, and the necessary facilities and approvals to expedite the required diagnostic testing;

   c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals;

   d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that a *Competent Authority* requires the animals to remain on the vehicle, the priorities should be:

Written Community comments:
In the next point "reprovisionsing" should be replaced by "reprovisioning".
Justification: Linguistic spelling correction.

   a) the *Competent Authority* should allow reprovisionsing of the vehicle with water and feed as necessary;

b) the *Competent Authority* should provide urgently in writing the reasons for the refusal;

c) in the event of a refusal for animal health reasons, the *Competent Authority* should provide urgent access to an independent veterinarian(s) to assess the animals' health status, and the necessary facilities and approvals to expedite the required diagnostic testing;

d) the *Competent Authority* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals, and the necessary actions to deal with any animal issues which arise.

4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Article 3.7.3.10.

Species specific issues

(To be developed)

Written Community comments: **The text on species specific issues included in the sea transport guidelines should be replicated here.**
Justification: This text contains useful descriptions of issues of general interest and information, not specifically related to the transport of animals by sea. As such it could be useful to bring it to the attention of persons reading the other OIE animal welfare guidelines. Only presenting this text in the sea transport guidelines means that persons only reading the other animal welfare guidelines will be unaware of these important descriptions of species-specific issues.

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

APPENDIX 3.7.5.

Written Community position:

The modification of the title is not in line with the definition of slaughter of Chapter 1.1.1 where "*slaughter*" is defined as "*any procedure causes the death of an animal by bleeding*". Bleeding may be in particular applied for killing animals for disease control purposes and not necessarily for human consumption.

However the Community would support this change provided that its proposed definition for slaughter as "*any procedure which causes the death of an animal intended for human consumption*" would be accepted.

GUIDELINES FOR THE SLAUGHTER OF ANIMALS ~~FOR HUMAN CONSUMPTION~~

Article 3.7.5.1.

General principles

1. Object

These guidelines address the need to ensure the welfare of food animals during pre-slaughter and slaughter processes, until they are dead.

Written Community position

Camelids should be added to the list of species established in the first sentence "These guidelines apply to the slaughter in slaughterhouses of the following ~~those~~ domestic animals ~~commonly slaughtered in slaughterhouses, that is~~: cattle, buffalo, sheep, goats, camelids, deer, horses, pigs, ratites and poultry."

These guidelines apply to the slaughter in slaughterhouses of the following ~~those~~ domestic animals ~~commonly slaughtered in slaughterhouses, that is~~: cattle, buffalo, sheep, goats, deer, horses, pigs, ratites and poultry. Other animals, wherever they have been reared, and all animals slaughtered outside slaughterhouses should be managed to ensure that their transport, lairaging, restraint and slaughter is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

2. Personnel

Persons engaged in the unloading, moving, lairaging, care, restraining, stunning, slaughter and bleeding of animals play an important role in the welfare of those animals. For this reason, there

should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the guidelines outlined in the present Appendix and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the slaughterhouse and the Veterinary Services should ensure that slaughterhouse staff are competent and carry out their tasks in accordance with the principles of animal welfare.

The management of the slaughterhouse and the *Veterinary Services* should ensure that slaughterhouse staff carry out their tasks in accordance with the principles of animal welfare.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

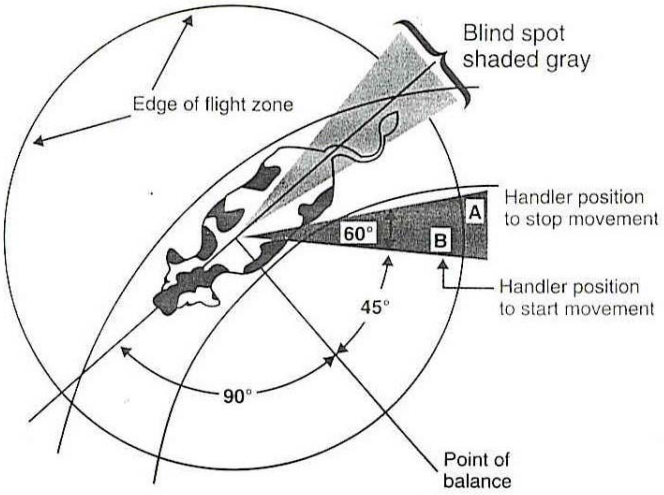
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to be hostile to each other in a group situation should not be mixed at slaughterhouses.

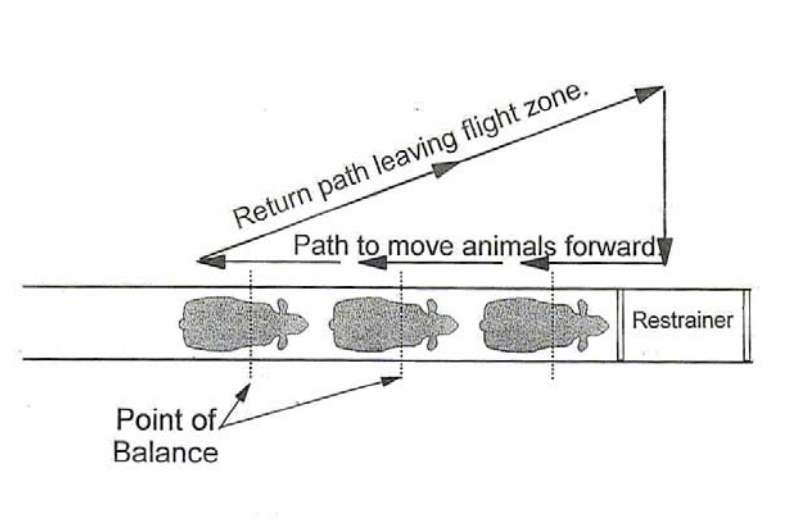
The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if an *animal handler* approaches closer than a certain distance. This critical distance, which defines the flight *zone*, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans i.e. tame have ~~no~~ a small flight *zone*, whereas those kept in free range or extensive systems may have flight *zones* which may vary from one metre to many metres. Animal handlers should avoid sudden penetration of the flight *zone* which may cause a panic reaction which could lead to aggression or attempted escape.

An example of a flight zone (cattle)


Blind spot
shaded gray
Edge of flight zone
Handler position
to stop movement
A
60°
B
Handler position
to start movement
45°
90°
Point of
balance

Handler movement pattern to move cattle forward



Animal handlers should use the point of balance at an animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of slaughterhouses. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

4. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors - move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;

c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;

d) chains or other loose objects hanging in chutes or on fences - remove them;

e) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

f) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

g) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;

h) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.5.2.

Moving and handling animals

1. General considerations

Animals should be transported to slaughter in a way that minimises adverse animal health and welfare outcomes, and the transport should be conducted in accordance with the OIE guidelines for the transportation of animals (Chapters 3.7.2 and 3.7.3).

The following principles should apply to unloading animals, moving them into lairage pens, out of the lairage pens and up to the slaughter point:

a) The conditions of the animals should be assessed upon their arrival for any animal welfare and health problems.

b) Injured or sick animals, requiring immediate slaughter, should be killed humanely, preferably at the site where they are found in accordance with the OIE guidelines for the killing of animals for disease control purposes (Chapter 3.7.6).

c) The use of force on animals that have little or no room to move should not occur.

Written Community position:

Add "*Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. They should not be used repeatedly on the same animal which may be unable to move due to other factors*".

Justification

These OIE guidelines should take into account existing good practices applied in the industry.

d) The use of instruments which administer electric shocks (e.g. goads and prods) and their power output should be restricted to that necessary to assist movement of an ~~the~~ animal~~s~~ and only when an animal has a clear path ahead to move. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets, nor on animals that have little or no room to move.

e) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric

instrument and the percentage of animals slipping or falling at a point in the slaughterhouse; the slaughterhouse should be investigated for faults in flooring, raceway design, lighting or handling, and these should be rectified to enable free movement of the animals without the need to use such instruments.

~~Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments and to measure the percentage of animals moved with an electric instrument. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 75% or more of the animals without the use of electric instruments.~~

Written Community position:

Add "*but without physical contact with them*" at the end of the following paragraph.

Justification

This was included in the original wording and we would prefer to keep it. Animals can be moved very effectively by trained personnel without the need to resort to striking animals with such "aids".

f) ~~Useful and permitted aids for moving animals include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.~~ Aids for moving animals such as panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles should be used in a manner sufficient to encourage and direct movement of the animals.

g) Shouting or yelling at animals or making loud noises e.g. through the cracking of whips to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.

h) Implements which cause pain and suffering such as large sticks, sticks with sharp ends, metal piping, fencing wire or heavy leather belts should not be used to move animals.

i) Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feet, neck, ears or tails causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.

j) Conscious animals should not be thrown or dragged.

k) Animals should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of animals slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handler*s, it should be possible to move 99% of animals without their falling.

l) ~~Animal handlers should not force an animal to walk over the top of other animals.~~ Animals for slaughter should not be forced to walk over the top of other animals.

m) Animals should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handler*s resort to violent acts to move animals, such as crushing or breaking animals' tails, grasping animals' eyes or pulling them by their ears. Animal handlers should never apply an injurious object or irritant substance to animals and especially not to

sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of animals, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small animals is permissible.

2. Provisions relevant to animals delivered in containers

Written Community position:

Add at the end of the paragraph (a):

"*In any case they should be moved and stored in an upright position as indicated by specific marks.*"

Justification

When transporting animals in containers it is very important for their welfare that they are kept upright and not mishandled. This is in line with basic good practices applied in the transport sector.

a) Containers in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should ~~be loaded and unloaded horizontally and mechanically~~ be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation.

b) Animals delivered in containers with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, animals should be unloaded from the containers individually.

c) Animals which have been transported in containers should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of slaughter should have drinking water available to them from appropriate facilities at all times. Delivery of poultry for slaughter should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

3. Provisions relevant to restraining and containing animals

Written Community position:

The following provisions should be added:

"a) *Appropriate restraint shall be applied to the animals before they are stunned or immediately killed. In particular individual restraint is necessary in the case of captive-bolt is used or when electrodes are placed on the animals. In addition restraint shall be applied to animals that are bled without stunning.*

b) The method of restraint should be adapted to the size and species of animals concerned as well as to the stunning/killing method to be used.

***c) The method of restraint should be designed and operated in order to optimise the application of the stunning/killing method.*"**

Justification

To ensure that animals are effectively stunned and to ensure their welfare the importance of appropriate restraint cannot be underestimated. See EFSA report http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

a) Provisions relevant to restraining animals for stunning or slaughter without stunning, to help maintain animal welfare, include:

   i) provision of a non-slip floor;

   ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;

   iii) equipment engineered to reduce noise of air hissing and clanging metal;

   iv) absence of sharp edges in restraining equipment that would harm animals;

   v) avoidance of jerking or sudden movement of restraining device.

b) Methods of restraint causing avoidable suffering, such as the following, should not be used in conscious animals because they cause severe pain and stress:

   i) suspending or hoisting animals (other than poultry) by the feet or legs;

   ii) indiscriminate and inappropriate use of stunning equipment;

   iii) mechanical clamping of an animal's legs or feet (other than shackles used in poultry and ostriches) as the sole method of restraint;

   iv) breaking legs, cutting leg tendons or blinding animals in order to immobilise them;

   v) severing the spinal cord, for example using a puntilla or dagger, to immobilise animals using electric currents to immobilise animals, except for proper stunning.

Article 3.7.5.3.

Lairage design and construction

1. General considerations

The lairage should be designed and constructed to hold an appropriate number of animals in relation to the throughput rate of the slaughterhouse without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the lairage areas should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight *zone*.

The following guidelines may help to achieve this.

2. Design of lairages

a) The lairage should be designed to allow a one-way flow of animals from unloading to the point of slaughter, with a minimum number of abrupt corners to negotiate.

b) In red meat slaughterhouses, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.

c) Each animal should have room to stand up and lie down and, when confined in a pen, to turn around. The lairage should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.

d) Holding pens should be designed ~~rectangular rather than square,~~ to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.

e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress ~~especially when the animals are lying down, standing up, drinking and feeding~~ to the animals and should also allow the animals to stand, lie down and access any food or water that may need to be provided.

f) Passageways and races should be either straight or ~~slightly~~ consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.

g) Animal handlers should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.

h) There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of stunning or slaughter, to ensure a steady supply of animals for stunning or slaughter and to avoid having *animal handler*s trying to rush animals from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that animals cannot be trapped or trampled.

i) Ramps or lifts should be used for loading and unloading of animals where there is a difference in height or a gap between the floor of the *vehicle* and the unloading area. Unloading ramps should be designed and constructed so as to permit animals to be unloaded from vehicles on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent animals escaping or falling. They ~~ramp~~ should be well drained, ~~non-slippery~~ with secure footholds and adjustable to facilitate easy movement of animals without causing distress or injury.

3. Construction of lairages

a) Lairages should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.

b) Floors should be well drained and not slippery; they should not cause injury to the animals' feet. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.

c) Lairages should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) Lairages should be ~~well ventilated, and the air flow should be arranged so that odours and draughts do not adversely affect the health and welfare of the anima1s~~ adequately ventilated to ensure that waste gases, e.g. ammonia do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of animals the lairage will be expected to hold.

e) Care should be taken to protect the animals from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noise to the areas where animals are held and slaughtered.

f) Where animals are kept in outdoor lairages without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 3.7.5.4.

Care of animals in lairages

Animals in lairages should be cared for in accordance with the following guidelines:

1. As far as possible, established groups of animals should be kept together. Each animal should have enough space to stand up, lie down and turn around. Animals hostile to each other should be separated.

2. Where tethers, ties or individual stalls are used, they should allow animals to stand up and lie down without causing injury or distress.

3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the animals, and sufficient bedding should be used so that animals do not become soiled with manure.

4. Animals should be kept securely in the lairage, and care should be taken to prevent them from escaping and from predators.

5. Suitable drinking water should be available to the animals on their arrival and at all times to animals in lairages unless they are to be slaughtered without delay.

6. If animals are not to be slaughtered as soon as possible, suitable feed should be available to the animals on arrival and at intervals appropriate to the species. Unweaned animals should be slaughtered as soon as possible.

7. In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of animals to thermoregulate (especially poultry) should be considered in any decision to use water sprays. The risk of animals being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8. The lairage area should be well lit in order to enable the animals to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all animals. Subdued lighting, and for example, blue light may be useful in poultry lairages in helping to calm birds.

9. The condition and state of health of the animals in a lairage should be inspected at least every morning and evening by a veterinarian or, under the latter's responsibility, by another competent person. Animals which are sick, weak, injured or showing visible signs of distress should be separated, and treated or humanely killed immediately.

10. Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.

11. ~~Pregnant~~ Animals ~~giving~~ which have given birth during the journey or in the lairage should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for its welfare and the welfare of the newborn. Under normal circumstances, animals which are expected to give birth during a journey should not be transported.

12. Animals with horns, antlers or tusks capable of injuring other animals, if aggressive, should be penned separately.

Recommendations for specific species are described in detail in Articles 3.7.5.5. to 3.7.5.8.

Article 3.7.5.5.
(under study)

Written Community comments:
1) The introductory sentence should be replaced by the following text:

"Pregnant animals that are likely to give birth should not be transported or slaughtered under normal circumstances. In any case, the welfare of foetuses during slaughter needs to be safeguarded."

2) There is no consistency between the time limit set out in paragraphs 1 and 3 (5 or 15-20 minutes).

This article needs to be kept under study and latest scientific information from Prof. David Mellor et al. carefully analysed. See for example:

D.J Mellor and N.G. Gregory (2003)
Responsiveness, behavioural arousal and awareness in fetal and newborn lambs: experimental, practical and therapeutic implications. New Zealand Veterinary Journal 51 (1) 2-13
David J Mellor, Tamara J Diesch, Alistair J Gunn, Laura Bennet (2005)
The importance of 'awareness' for understanding foetal pain. Brain Research Reviews 47 (3) 455-471
Justification: Latest scientific evidence needs to be analysed, and pending that this article 3.7.5.5 should be retained "under study". It should be emphasised that under normal circumstances animals in an advanced state of pregnancy should neither be transported nor slaughtered in slaughterhouses.

Management of foetuses during slaughter of pregnant animals

The welfare of foetuses during slaughter of pregnant animals needs to be safeguarded.

1. Foetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

2. If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

~~3.~~ When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.

4. If there is any doubt about consciousness, the foetus should be killed with a captive bolt or a blow to the head with a suitable blunt instrument.

The above guidelines do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at evisceration of the dam, should not be attempted during normal commercial slaughter as it may lead to serious welfare complications in the newborn animal. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Article 3.7.5.6.

Summary of acceptable handling and restraining methods and the associated animal welfare issues

Written Community comments:
1. The use of rotating box (i.e. restraining by inversion for cattle) should not be recommended. Therefore the two rows referring to restraining by inversion should be deleted in the table.
Justification: The rotating box represents serious animal welfare concerns while alternative methods are available which provide better welfare conditions without additional costs. See p. 25 EFSA – AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare on a request from the Commission related to welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html
2. The word "acceptable" should be deleted from the table's heading
Justification: Acceptable implies a value judgement or subjective analysis. In any given situation a variety of handling and restraining methods may be available and the best animal welfare outcome needs to be considered on a case-by-case basis. Therefore a given method may be "acceptable" under certain circumstances and "unacceptable" under a different set of conditions.

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent *animal handler*s in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	~~Shooting distance, calibre and~~ Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent *animal handler*s in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent *animal handler*s	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent *animal handler*s	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head-only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent *animal handler*s, prompt stunning or slaughter	Cattle

	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent *animal handler*	Breeding pigs (boars and sows)

Summary of acceptable handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining methods	Upright restraint	Beak holding	Captive bolt Electrical-head-only	Stress of capture	Sufficient competent *animal handler*s	Ostriches
		Head restraint in electrical stunning box	Electrical-head-only	Stress of capture and positioning	Competent *animal handler*	Ostriches
	Holding body upright-manual	Manual restraint	Captive bolt Electrical-head-only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/slaughter	Competent *animal handler*s	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/cradle/crush	Slaughter without stunning	Stress of restraint	Competent *animal handler*s	Sheep, goats, calves, camelids, cattle
	Upright restraint	Mechanical straddle (static)	Slaughter without stunning	Loading of animal and overriding	Competent *animal handler*s	Cattle, sheep, goats, pigs

	mechanical		Electrical methods Captive bolt			
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent *animal handler*s	Ostriches

Summary of acceptable handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical- upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent *animal handler*s, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent *animal handler*s; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt	Inversion stress	Competent *animal handler*s; proper design and operation of	Poultry

			Slaughter without stunning		equipment	
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent *animal handler*s; proper equipment design and operation	Ostriches

Summary of acceptable handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta. Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent *animal handler*s	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent *animal handler*s	Cattle, camelids
		Tying of 3 or 4	Mechanical	Stress of resisting restraint;	Competent *animal*	Sheep, goats,

		legs	stunning methods Slaughter without stunning	prolonged restraint, animal temperament; bruising Keep restraint as short as possible	*handler*s	small camelids, pigs

Article 3.7.5.7.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for stunning and the maintenance of the equipment are the responsibility of the management of the slaughterhouse, and should be checked regularly by a Competent Authority.

Persons carrying out stunning should be properly trained and competent, and should ensure that:

a) the animal is adequately restrained;

b) animals in restraint are stunned as soon as possible;

c) the equipment used for stunning is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal;

d) the instrument is applied correctly;

e) stunned animals are bled out (slaughtered) as soon as possible;

f) animals should not stunned when slaughter is likely to be delayed;

g) backup stunning devices are available for immediate use if the primary method of stunning fails.

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

Written Community comments:
A frontal view and lateral view of the correct stunning position should be displayed for all species mentioned here.

Justification: This would provide more comprehensive and clear information to operators on the recommended locations for appropriate stunning.

Pictures are in particular available from organisations such as the Humane Slaughter Association or in the EFSA Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html

Written Community comments:
It should be mentioned that in adult cattle for example the optimal shooting position for mechanical stunning methods is often up to 2cm paramedian from the midline.

Justification

This has been shown by scientific papers (e.g. Ilgert 1985, Kaegi 1988) and long-standing practical experience in the field. A reason for such paramedian placement is that in the actual midline the bone thickness of the sinus frontalis is several cms thick, which leads to a reduced speed of the captive bolt and thus less effective stunning.

Ilgert, H. (1985). Effizienz der Bolzenschssbetaubung beim Rind mit Berucksichtigung der Einschussstelle und der Eindringtiefe des Bolzens unter Praxisbedingungen. Vet.med.Diss. Freie Universitat Berlin.

Kaegi, B. (1988) Untersuchungen zur Bolzenschussbetaubung beim Rind. Vet.med.Diss. Universitat Zurich

Written Community comments:
For sheep the optimal stunning position should be clarified by adding the words "with the shot aiming at the angle of the jaw".

Justification

See EFSA Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html

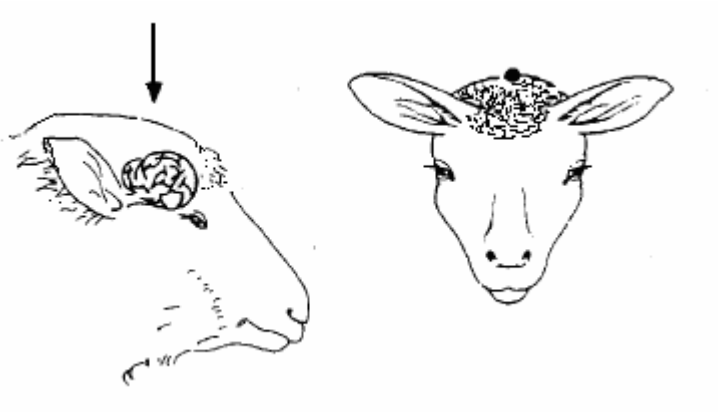
Cattle

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Pigs

The optimum position for pigs is on the midline just above ~~the~~ eyes level, with ~~and directing~~ the shot directed down the line of the spinal cord.

Sheep

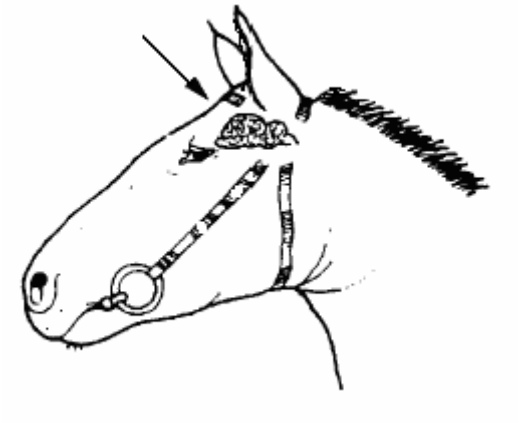


The optimum position for hornless sheep and goats is on the midline ~~just above the eye level, and directing the shot down the line of the spinal cord~~.

Goats

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Horses



~~Place the muzzle~~ The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct stunning using a mechanical instrument are as follows:

a) the animal collapses immediately and does not attempt to stand up;

b) the body and muscles of the animal become tonic (rigid) immediately after the shot;

c) normal rhythmic breathing stops; and

d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

3. Electrical stunning

a) General considerations

An electrical device should be applied to the animal in accordance with the following guidelines.

Written Community comments:
1. In the third sentence of the following paragraph, "effectively stunned" should replace "stunned".

Justification: It is important to underline, when two-cycle stun/kill methods apply with e.g. cardiac fibrillation, that the second phase of the electrical application should only take place after having ascertained that the animals is already effectively stunned.

2. The sentence "they should be placed so that they span the brain" should be further expanded, clarified and accompanied by an illustration to show proper placement.

Justification: It is important that the guidelines demonstrate clearly the proper placement of electrodes

3. A further sentence should be added stating "The electrical parameters should be set so as to ensure effective stunning, given that immediate human

intervention to correct any deficiencies may be curtailed by the design and operation of the equipment".

Justification: It is important that the guidelines take account of the practical use and design of such stunning systems and the opportunities or restrictions for operator intervention (due to health and safety considerations or logistical-layout restrictions etc.).

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with ~~to~~ manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a stunning method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Electrical stunning equipment should not be applied on animals as a means of guidance, movement, restraint or immobilisation, and shall not deliver any shock to the animal before the actual stunning or killing.

Electrical stunning apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The apparatus should incorporate a device which monitors and displays stunning current delivered to the animals.

Written Community comments:
Add a sentence above "In all cases electrodes should be applied rapidly and firmly and appropriate pressure maintained to facilitate proper contact and effective stunning".

Justification: Correct operator technique in applying the electrodes is very important to achieve effective stunning.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective stunning.

Written Community comments:
In the next paragraph "indicate" should be replaced by "indicated".

Justification: Grammatical correction.

The stunning apparatus required for electrical stunning should be provided with adequate power to achieve continuously the minimum current level recommended for stunning as indicate in the table below:

Written Community comments:
1) The table below should specify that the minimum current levels apply for head-only stunning. Therefore the table heading "Minimum current levels" should be replaced by "Minimum current levels for head-only stunning".

2) For the purpose of this table "calves" and "lambs" should be defined more specifically as the application of insufficient current may affect the welfare of the animals.

The table should be amended as follows:

"calves" should be replaced by "bovine of less than six months of age"

It should be re-considered whether a minimum current of 1.5 amps is sufficient under practical conditions to stun cattle aged over 6 months of age. Certain experts have suggested a minimum current of 2.5 amps to stun such animals.

Justification: See EFSA report for more detailed scientific basis

http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

See article Gregory N.G., M.H. Anil, I.L. McKinstry and C.C. Daly (1996). Prevalence and duration of insensibility following electrical stunning in calves. New Zealand Veterinary Journel, 44: S. 1-3.

Nevertheless it should be noted that under current practical conditions many slaughterhouses are not currently complying with the specifications set out in this Article of the OIE guidelines.

Species	Minimum current levels
Cattle	1.5 amps
Calves	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

Written Community comments:
The following paragraph should be replaced by the following text:

"In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for ~~between one and~~ three seconds and in accordance with the manufacturer's instructions."

Justification: See EFSA report for more detailed scientific basis

http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

This has also been shown in papers by Lambooij et al (1996,1997). A period of stunning of less than 3 seconds is insufficient to ensure proper and sufficient insensibility of animals under practical conditions and with sub-optimal stunning there is a risk of animals regaining consciousness during the bleeding-out period before death has intervened.

Lambooij B., S.M. Merkus, N. van Voorst u., C. Pieterse (1996). Wirkung der elektrischen Niederspannung und Hochfrequenzbetaubung auf den BewuBtseinsverlust von Schlachtschweinen. Fleischwirtschaft 76, S. 1026-1028

Lambooij B., S.M. Merkus, N. van Voorst u., C. Pieterse (1997). Effect of low voltage with high frequency electrical stunning on unconsciousness in slaughter pigs. Fleischwirtschaft International 2, S. 13-14

Nevertheless it should be noted that under current practical conditions many slaughterhouses are not currently complying with the specifications set out in this Article of the OIE guidelines.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions.

b) Electrical stunning of birds using a waterbath

Written Community comments:
The following text should be added here: "There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks."

Justification: See EFSA report for more detailed scientific basis

http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks.

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the water it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

Species	Current (milliamperes per bird)
Broilers	120
Layers (spent hens)	120
Turkeys	150
Ducks and Geese	130

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Written Community comments:
As mentioned in the previous paragraph, waterbath stunners may also use higher frequencies than 50 Hz. Therefore recommendations for those cases should also be provided. The EFSA opinion on the subject (Opinion of the Scientific Panel on Animal Health and Welfare on welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29) recommends particular figures (see p. 19). Based on this information, the following table should be added here:

Frequency (Hz)	Chickens	Turkeys
< 200 Hz	**100 mA**	**250 mA**
From 200 to 400 Hz	**150 mA**	**400 mA**
From 400 to 1500 Hz	**200 mA**	**400 mA**

Justification: See EFSA report for more detailed scientific basis

http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

Nevertheless it should be noted that under current practical conditions many slaughterhouses are not currently complying with the specifications set out in this Article of the OIE guidelines.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of stunning and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of unstunned birds, reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

4. Gas stunning (under study)

Written Community comments:
This section should be retained "under study" until further information is to hand.

Justification: New scientific data are continuing to emerge on this issue (e.g. from researchers based in Roslin-Silsoe institutes in UK, Swedish data etc.). Some of these papers are still "in press" and full publication details will be provided to the OIE once available. Examples of such studies already available and which could be usefully reviewed include:

"A Study of 2 Pig Abattoirs with Regard to CO_2 Concentration, CO_2 Exposure Time, Stun Group Size, Stun to Stick Interval, and Stun Effect, Sophie Atkinson, Swedish University of Agricultural Sciences Skara 2003"

"An investigative study of 2 pig abattoirs in Sweden with regard to CO2 concentration, CO2 exposure time, stun group size, stun to stick interval and stun effect." Bo Algers and Sophie Atkinson, Swedish University of Agricultural Sciences. Presented at ISAH (International Society for Animal Hygiene) congress October 2004.

Therefore it would be premature to finalise these provisions on CO2 concentrations etc. pending the careful analysis of such new scientific data.

It should be noted that under current practical conditions many slaughterhouses are not currently complying with the specifications set out in this Article of the OIE guidelines.

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for stunning should be preferably 90% by volume but in any case no less than 80% by volume. After entering the stunning chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until death occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the animals. The animal density within the chamber should be such to avoid stacking animals on top of each others.

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and, if possible, each other.

Written Community comments:
The next sentence should be re-considered.

Justification:

In many cases it is neither possible or practical to inspect CO2 chambers while in use. Possible occupational safety risks to personnel of such practices also need to be considered.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the animals in emergency cases.

Written Community comments:
The following text should be added here:

"Emergency stunning equipment should be available at the point of exit from the stunning chamber and used on any pigs that do not appear to be dead or completely stunned."

Justification:

The availability of emergency stunning equipment is a basic pre-requisite, in line with procedures of good practice etc. See EFSA report for more detailed scientific basis

http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

The chamber shall be equipped to continuously measure and display register at the point of stunning the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentrations of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or

Community comment:
Delete "to" at the beginning of the next sentence.

Justification: Grammatical correction, not included in (a) and is thus inconsistent in style.

ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before death supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas stunning is to avoid the pain and suffering associated with shackling conscious poultry under water bath stunning and killing systems. Therefore, gas stunning should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to poultry.

Gas stunning of poultry in their transport containers will eliminate the need for live bird handling at the processing plant and all the problems associated with the electrical stunning. Gas stunning of poultry on a conveyor eliminates the problems associated with the electrical water bath stunning.

Live poultry should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

Written Community comments:
The following text should be added here:

"The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all animals are properly stunned without unnecessary suffering and gas concentration should be established so as to avoid convulsions (wing flapping)."

Justification : See EFSA report for more detailed scientific basis

http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

i) Gas mixtures used for stunning poultry include:

Community comment:

"a" should precede each paragraph.

Justification; Linguistic correction, see previous bullet points for consistency of style etc.

- minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or

- minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or

- minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or

- minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.

ii) Requirements for effective use are as follows:

– compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock. Under no circumstances, should solid gases with freezing temperatures enter the chamber;

– gas mixtures should be humidified;

Written Community comments:
The next indent should be replaced by the following text:

" – appropriate gas concentrations of oxygen and, if necessary, carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues."

Justification: It is appropriate to measure both gas concentrations.

See EFSA report for more detailed scientific basishttp://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

– appropriate gas concentrations should be monitored and displayed continuously at the level of the birds inside the chamber.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

5. Bleeding

Written Community comments:
The following text should be amended as follows: "From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the stunning method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the slaughterhouse operator should set up a maximum stun-stick interval that ensures that no animals recover consciousness during bleeding. In any case the following time limits should be applied:"

Justification: The stun-to-stick interval depends on the parameters used for the stunning method, the species concerned and the bleeding method used (full cut or chest stick when possible). Stun-to-stick interval is more clearly understood than "Maximum delay for bleeding to be started".

See EFSA report for more detailed scientific basishttp://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf

Nevertheless it should be noted that under current practical conditions many slaughterhouses are not currently complying with the specifications set out in this Article of the OIE guidelines.

From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay and in any case within the following time limits:

Stunning method	**Maximum delay for bleeding to be started**
Electrical methods and non penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

Written Community comments:
Replace "from the point of animal welfare" by "from the point of view of animal welfare".

Justification: Linguistic correction, consistency of style etc.

All animals should be bled by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the stunning method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of animal welfare.

It should be possible for staff to observe, inspect and access the animals throughout the bleeding period. Any animal showing signs of recovering consciousness should be restunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

Written Community comments: **1. The row on captive bolt non-penetrating should be replaced as follows:**					
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	**This method should only be used when alternative methods are not available for cattle and sheep.** Presently available devices are not recommended for young bulls and animals with thick skull
Justification: According to the EFSA opinion (Opinion of the Scientific Panel on Animal Health and Welfare on welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29) the use of non-penetrating captive bolt is unreliable and should not be used for cattle (p. 9). In addition there is no available investigation for its use on adult sheep (p. 10) that would prove that it is suitable for them. **2. Delete "acceptable" from the table heading.** **Justification: Acceptable implies a value judgement or subjective analysis. In any given situation a variety of handling and restraining methods may be available and the best animal welfare outcome needs to be considered on a case-by-case basis. Therefore a given method may be "acceptable" under certain circumstances and "unacceptable" under a different set of conditions.** **3. Reconsider the inclusion of free bullet as a "stunning method".** **Justification: Free bullet if correctly applied will often kill the animal.** **4. To ensure consistency in the OIE's approach to these issues please consider other parts of the OIE code dealing with related issues, e.g. the implications that stunning-killing methods applied may have on food safety, BSE control-testing etc** **Justification: Consider EFSA and Scientific Steering Committee opinions on the risk of dissemination of brain material using penetrating stunning methods for example.**					

Summary of acceptable stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	~~Accuracy; head shots only correct ballistics~~,	Cattle, calves, buffalo, deer,	Personnel safety

			Operator competence, achieving outright kill with first shot	horses, pigs (boars and sows)	
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	Presently available devices are not recommended for young bulls and animals with thick skull
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent *animal handler*s; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used. ~~Where cardiac arrest occurs, the carcass may not be suitable for Halal~~

Summary of acceptable stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Electrical	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	~~Where cardiac arrest occurs, the carcass may not be suitable for Halal~~
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	~~Where cardiac arrest occurs, the carcass may not be suitable for Halal~~
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2 concentrations, respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	~~Gaseous methods may not be suitable for Halal~~
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	~~Gaseous methods may not be suitable for Halal~~

Written Community comments:
1) The row "bleeding out by severance of blood vessels in the neck without stunning" should be moved to the end of the table as it does not represent the most reliable and optimal method of slaughter in terms of ensuring the welfare of the animals.

2) In addition, particular attention should be drawn to the competence of the personnel and the quality of the restraint. As the animal remains conscious for a certain period of time, no further procedure should be carried out before the bleeding out is completed (see Article on bleeding provides for at least 30 s). In particular the practice to remove hypothetical blood clots just after the bleeding should be discouraged as it increases the suffering of the animals without providing a better bleeding.

Therefore this row should be moved to the end of the list and be replaced as follows:

Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries.	**Operator competencies** A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	**No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals) The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.**

3) In addition the row on "free bullet" listed within the stunning methods should be also listed here as free bullet often provides an instant killing.

4) the wording "ineffective stunning" in the column "AW concerns/implications" should be deleted as it applies to all slaughter methods.

Justification: See EFSA report

5. Delete “acceptable” from the table heading.
Justification : Acceptable implies a value judgement or subjective analysis. In any given situation a variety of handling and restraining methods may be available and the best animal welfare outcome needs to be considered on a case-by-case basis. Therefore a given method may be “acceptable” under certain circumstances and “unacceptable” under a different set of conditions.

Summary of acceptable slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries.	A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	~~This method is applicable to Halal and Kosher slaughter for relevant species~~
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats,	
	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab	Ineffective stunning;	Prompt and accurate cutting	Camelids, sheep,	

	alone	failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning		goats, poultry, ratites	

Summary of acceptable slaughter methods and the associated animal welfare issues (contd)

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; Inadequate size of stick wound; Inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
Bleeding with prior stunning	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	

		consciousness following reversible stunning systems			
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 3.7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

Written Community comments:

In paragragh 1 below the word "puntilla" should not be deleted but explained with a more precise description such as for example "puntilla (i.e. severing the spinal cord)".

Justification: Puntillas have been used in certain situations and their use should be explained rather than ignored.

1. The restraining methods which work through immobilisation by injury such as ~~'puntilla',~~ breaking legs and 'leg tendon cutting', cause severe pain and stress in animals. Those methods are not acceptable in any species.
2. The use of the electrical stunning method with a single application leg to leg is ineffective and unacceptable in any species, as it is likely to be painful. The animal welfare concerns are:

   a) accidental pre-stun electric shocks;

   b) inadequate current and voltage;

c) wrong electrode positioning;

d) recovery of consciousness.

3. The slaughter method of brain stem severance by piercing through the eye socket or skull bone without prior stunning, is not acceptable in any species.

Speaking Community comment

The Community understands that due to the large number of comments received by the OIE, the Code Commission did not have the time to consider all of them, in particular as regards the most technical ones. However the Community would like to insist on the need to delete the rotating box (restraining by inversion of cattle) as a recommended method for restraining animals. The negative welfare implications of putting cattle upside down have been scientifically documented and alternative methods are today available providing better welfare conditions without additional costs.

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— text deleted

Speaking Community position:

The European Community can support this proposal but will communicate written comments on some particular issues (see below).

However certain OIE amendments initially proposed in September are not submitted here and the Community would like to confirm that it maintains its comments previously communicated to the OIE on 15 February 2006 on the parts of the text not discussed today (Ref. D(2005) 522619). The European Community hopes that all those comments will be later considered by the relevant OIE Working Group.

APPENDIX 3.7.6.

GUIDELINES FOR THE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 3.7.6.1.

General principles

~~This Appendix is~~ These guidelines are based on the premise that a decision to kill the animals has been made, and address the need to ensure the welfare of the animals until they are dead.

Written Community comments:
The following paragraph could be completed as follows:

"*Such a certificate should be delivered if the applicant has demonstrated sufficient knowledge, with due regard to the tasks, methods, equipments and species concerned by the applicant responsibilities as laid down in these guidelines.*"

Justification: The introduction of a certificate of competence is welcomed but it should explicitly refer to the knowledge of these guidelines.

1. 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*.~~

2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects.

3. Following the decision to kill the animals, killing should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.

4. The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.

5. Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements; when restraint is required, killing should follow with minimal delay.

6. When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.

7. For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.

8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.

9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.

10. ~~To the extent possible to minimise public distress, killing of animals and carcass disposal should be carried out away from public view.~~

~~11.~~ These general principles should also apply when animals need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 3.7.6.2.

Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel ~~trained~~ competent in the humane killing of animals is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the animal welfare issues that may result from animal movement controls.

The operational activities should be led by an official veterinarian who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved has the required competencies.

The official veterinarian should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The official veterinarian should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE animal welfare and animal health guidelines.

A specialist team, led by a team leader answerable to the *official veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a veterinarian or have access to veterinary advice at all times.

In considering the animal welfare issues associated with killing animals, the key personnel, their responsibilities and competencies required are described in Article 3.7.6.3.

Article 3.7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader

   a) Responsibilities

      i) plan overall operations on an affected premises;

      ii) determine and address requirements for animal welfare, operator safety and biosecurity;

      iii) organise, brief and manage team of people to facilitate humane killing of the relevant animals on the premises in accordance with national regulations and these guidelines;

      iv) determine logistics required;

      v) monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met;

      vi) report upwards on progress and problems;

      vii) provide a written report at the conclusion of the killing, describing the practices adopted and their effect on the animal welfare, operator safety and biosecurity outcomes.

   b) Competencies

      i) appreciation of normal animal husbandry practices;

      ii) appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the killing process;

      iii) skills to manage all activities on premises and deliver outcomes on time;

      iv) awareness of psychological effects on farmer, team members and general public;

      v) effective communication skills;

      vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

i) determine and implement the most appropriate killing method to ensure that animals are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for animal welfare, including the order of killing;

iii) ensure that confirmation of animals deaths is carried out by competent persons at appropriate times after the killing procedure;

iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;

v) continuously monitor animal welfare and biosecurity procedures;

vi) in cooperation with the leader, prepare a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare.

b) Competencies

i) ability to assess animal welfare, especially the effectiveness of stunning and killing, and to correct any deficiencies;

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design and construct temporary animal handling facilities, when required;

iii) move and restrain animals;

iv) continuously monitor animal welfare and biosecurity procedures.

b) Competencies

Written Community comments:
The following text should be added:

"v*) above-mentioned competencies should be demonstrated through a certificate of competence as referred to in Article 3.7.6.1.*"

Justification: In the interests of consistency, reference to the certificate of competence mentioned in Article 3. 7. 6. 1. (paragraph 1) should be included here.

i) ~~An experience of~~ Animal handling in emergency situations and in close confinement is required;

ii) an appreciation of biosecurity and containment principles.

4. ~~Slaughterers~~ Animal killing personnel

a) Responsibilities

Humane killing of the animals through effective stunning and killing should be ensured.

b) Competencies

i) when required by regulations, licensed to use necessary equipment ~~or licensed to be slaughterers~~;

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

iv) competent to assess effective stunning and killing.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure killing operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her animals and their environment.

Article 3.7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane killing of animals. The team leader should develop a plan for humanely killing animals on the premises which should include consideration of:

Written Community comments:
Two important considerations should be added to the list below:

"- The plan should minimise the negative welfare impacts of the killing by taking into account the different phases of the procedures to be applied for killing (choice of the killing sites, killing methods, etc.) and the measures restricting the movements of the animals.

- Competences and skills of the personnel handling and killing animals"

Justification: This is in line with basic good practices. For a scientific basis see EFSA report.

1. minimising handling and movement of animals;

2. killing the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for killing; when the killing is conducted at an abattoir, the guidelines in the Chapter on slaughter of animal for human consumption should be followed;

3. the species, number, age and size of animals to be killed, and the order of killing them;

4. methods of killing the animals, and their cost;

Written Community comments:
The following text should be added to the next bullet point "*as well as accessibility of the farm*".

Justification: Topographical factors and farm location accessibility can be very important in determining the methods which could be applied.

5. housing, husbandry and location of the animals;

Written Community comments:
The following text should be added to the next bullet point "*as well as the time necessary to kill the required number of animals using such methods*".

Justification: Animal health and biosecurity considerations may imply that animals need to be killed very rapidly. This is an important criterion when considering the method to be used.

6. the availability and effectiveness of equipment needed for killing of the animals;

7. the facilities available on the premises that will assist with the killing including any additional facilities that may need to be brought on and then removed from the premises;

8. biosecurity and environmental issues;

9. the health and safety of personnel conducting the killing;

10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment; and

11. the presence of other nearby premises holding animals.

In designing a killing plan, it is essential that the method chosen be consistently reliable to ensure that all animals are humanely and quickly killed.

Article 3.7.6.5.

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning	3.7.6.7.
	adults only	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	3.7.6.8.
	calves only	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	3.7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before ~~killing~~ death	3.7.6.7.
	all except neonates	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before ~~killing~~ death	3.7.6.8.
	neonates	captive bolt - non-penetrating	yes	non-lethal wounding	3.7.6.8.
	all	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	all	electrical, single application (Method 1)	yes	ineffective stunning	3.7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.

	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats (contd)	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness,	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Pigs	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	3.7.6.7.
	neonates only	captive bolt - non-penetrating	yes	non-lethal wounding	3.7.6.8.
	all §	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	3.7.6.10.
	all	electrical, single application (Method 1)	yes	ineffective stunning	3.7.6.11.
	neonates only	CO_2 / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness,	3.7.6.14.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Poultry	adults only	captive bolt - non-penetrating	yes	ineffective stunning	3.7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy;	3.7.6.9.
	adults only	electrical single application (Method	yes	ineffective stunning	3.7.6.11.

		2)			
	adults only	electrical single application, followed by killing (Method 3)	yes	ineffective stunning; regaining of consciousness before ~~killing~~ death	3.7.6.11.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (contd)	all	CO_2 / air mixture Method 1 Method 2	 yes no	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	all	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	3.7.6.16.

* The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an animal welfare viewpoint.

§ The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

Article 3.7.6.6.

1. FREE BULLET

2. 1. INTRODUCTION

a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

b) The most commonly used firearms for close range use are:

i) humane killers (specially manufactured/adapted single-shot weapons);

ii) shotguns (12, 16, 20, 28 bore and .410);

iii) rifles (.22 rimfire);

iv) handguns (various calibres from .32 to .45).

c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal, to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.

3. 2. REQUIREMENTS FOR EFFECTIVE USE

a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.

b) The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the animal's head.

c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally the ammunition should expand upon impact and dissipate its energy within the cranium.

d) Shot animals should be checked to ensure the absence of brain stem reflexes.

Written Community comments:
A frontal view and a lateral view should be available for all species mentioned here.

Justification: This would provide more comprehensive and clear information on the recommended locations for appropriate stunning.

Pictures are in particular available from the Humane Slaughter Association or in the EFSA Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html

Written Community comments:
It should be mentioned that in adult cattle for example the optimal shooting position for mechanical stunning methods is often up to 2cm paramedian from the midline.

Justification

This has been shown by scientific papers (e.g. Ilgert 1985, Kaegi 1988) and long-standing practical experience in the field. A reason for such paramedian placement is that in the actual midline the bone thickness of the sinus frontalis is several cms thick, which leads to a reduced speed of the captive bolt and thus less effective stunning.

Ilgert, H. (1985). Effizienz der Bolzenschssbetaubung beim Rind mit Berucksichtigung der Einschussstelle und der Eindringtiefe des Bolzens unter Praxisbedingungen. Vet.med.Diss. Freie Universitat Berlin.

Kaegi, B. (1988) Untersuchungen zur Bolzenschussbetaubung beim Rind. Vet.med.Diss. Universitat Zurich

Written Community comments:
For sheep the optimal stunning position should be clarified by adding the words "with the shot aiming at the angle of the jaw".

Justification

See EFSA Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

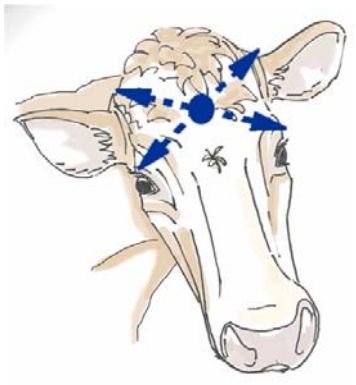


Figure 2. The optimum position for hornless sheep and goats is on the midline ~~just above the eye level, and directing the shot down the line of the spinal cord~~.

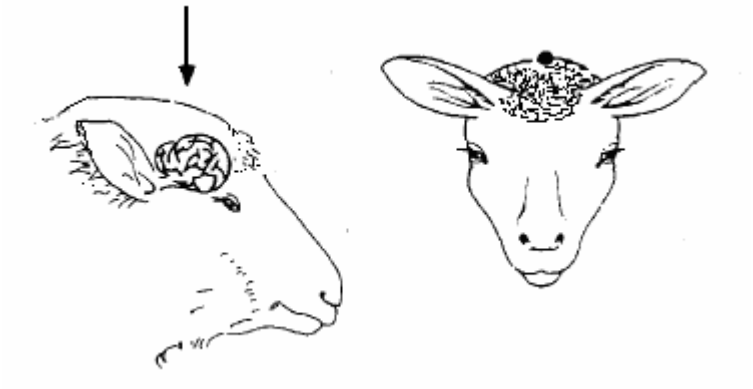
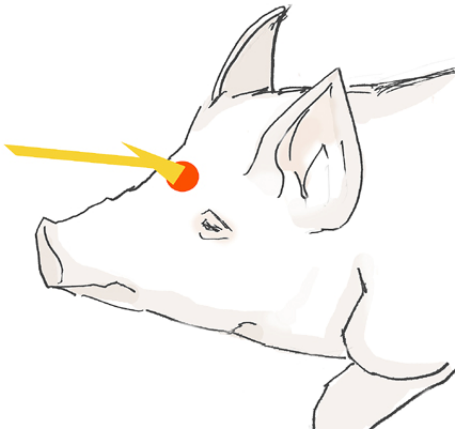


Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

Figure 4. The optimum shooting position for pigs is just above ~~the~~ eye~~s~~ level, with ~~and directing~~ the shot directed down the line of the spinal cord.

4.



5. 3. ADVANTAGES

a) Used properly, a free bullet provides a quick and effective method for killing.

b) It requires minimal or no restraint and can be use to kill from a distance.

c) It is suitable for killing agitated animals in open spaces.

6. 4. DISADVANTAGES

a) The method is potentially dangerous to humans and other animals in the area.

b) It has the potential for non-lethal wounding.

c) Destruction of brain tissue may preclude diagnosis of some diseases.

d) Leakage of bodily fluids may present a biosecurity risk.

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

7. 4. CONCLUSIONS

The method is suitable for cattle, sheep, goats and pigs, including large animals in open spaces.

Article 3.7.6.7.

8. PENETRATING CAPTIVE BOLT

9. 1. INTRODUCTION

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death, however pithing or bleeding should be performed as soon as possible after the shot to ensure the death of the animal.

10. 2. REQUIREMENTS FOR EFFECTIVE USE

a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.

d) Animals should be restrained; at a minimum they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the animal's head is accessible.

Written Community comment:
In the interests of consistency it would be preferable to also refer to figure 2 in f) and transfer the comment on hornless sheep accordingly. The current text seems to apply to horned sheep and not to hornless sheep (see comment of figure 3).

Justification: To ensure better clarity in the text and facilitate proper interpretation of the provisions.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the death of the animal, pithing or bleeding should be performed as soon as possible after stunning.

h) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

11. 3. ADVANTAGES

a) Mobility of cartridge powered equipment reduces the need to move animals.

b) The method induces an immediate onset of a sustained period of unconsciousness.

12. 4. DISADVANTAGES

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated animals.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some diseases.

13. 5. CONCLUSIONS

The method is suitable for cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 3.7.6.8.

Captive bolt - non-penetrating

Written Community comments:
The following text should be added at the beginning of the section:
"As this method is not reliable for cattle and adult sheep, it should only be used for those animals when alternative methods are not available."
Justification: According to the EFSA opinion (Opinion of the Scientific Panel on Animal Health and Welfare on welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29) the use of non-penetrating captive bolt is unreliable and should not be used for cattle (p. 9). In addition there is no available investigation for its use on adult sheep (p. 10) that would prove that it is suitable for them. Consequently other methods should be used.

14. 1. INTRODUCTION

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. ~~In mammals,~~ Bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

15. 2. REQUIREMENTS FOR EFFECTIVE USE

a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.

d) Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.

e) The operator should ensure that the animal's head is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1-4).

g) To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after stunning.

h) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

16. 3. ADVANTAGES

Written Community comments:
In a) "Neonates" should be replaced by a more specific wording such as "neonatal sheep, goats and pigs for example".
Justification: For clarity, proper interpretation and in line with the scientific basis outlined in the EFSA report.

a) The method induces an immediate onset of unconsciousness, and death in birds and neonates.

b) Mobility of equipment reduces the need to move animals

17. 4. DISADVANTAGES

a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after stunning.

b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.

c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.

d) Post stun convulsions may make bleeding difficult and hazardous.

e) Difficult to apply in agitated animals; such animals may be sedated in advance of the killing procedure.

f) Repeated use of a cartridge powered gun may result in over-heating.

g) Bleeding may present a biosecurity risk.

18. 5. CONCLUSIONS

a) The method is suitable for poultry, and neonate sheep, goats and pigs.

b) If bleeding does not present a biosecurity issue, this is a suitable method for cattle (adults only), and non-neonate sheep, goats and pigs when followed by bleeding.

Article 3.7.6.9.

Maceration

18.1. 1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and death in day-old poultry and embryonated eggs.

18.2. 2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

18.3. 3. Advantages

a) Procedure results in immediate death.

b) Large numbers can be killed quickly.

18.4. 4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present a biosecurity issue.

18.5. 5. Conclusion

The method is suitable for killing day-old poultry and embryonated eggs.

Article 3.7.6.10.

Electrical – two stage application

18.6. 1. Introduction

A two stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.

Figure 6. Scissor-type stunning

18.7. 2. Requirements for effective use

Written Community comments:
Line (a) should be replaced by the following text:
"a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	**220**	**1.5**
Sheep	**220**	**1.0**
Pigs > 6 weeks	**220**	**1.3**
Pigs < 6 weeks	**125**	**0.5**

Justification: The EFSA scientists provided the following figures as regards the killing of animals for disease control situations. They always refer to a frequency AC sine wave 50 Hz.
See p. 198 EFSA – AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html)

a) The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made.

Written Community comments:
Paragraph (e) should be replaced by the following text:

"e) A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 10 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 10 seconds."

Justification: Duration of exposure should be extended here as disease control situation is usually not followed by another method of killing and monitoring the effectiveness of the killing may be neglected because of the large number of animals to be killed. A margin of security should therefore be provided in order to ascertain that the killing is ensured for all animals. . In some cases a 10 second head-to-head stun is followed by a 45 second duration of application of electrodes spanning the heart in order to ensure the optimal outcome and the best safeguards for effective killing of all animals.

e) A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

Written Community comments:
The following point should be added:

"h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete"

Justification: This is important to ensure the welfare of the animals

18.8. 3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

18.9. 4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.

c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

18.10. 5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Article 3.7.6.11.

19. ELECTRICAL – SINGLE APPLICATION

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the animal and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the animal will not recover consciousness.

19.1.a) Requirements for effective use

i) The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Animals should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use.

iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.

v) Electrodes should be cleaned regularly between animals and after use, to enable optimum electrical contact to be maintained.

vi) Water or saline may be necessary to improve electrical contact with sheep.

vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

19.2.b) Advantages

i) Method 1 stuns and kills simultaneously.

ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.

iii) A single team member only is required for the application.

iv) Non-invasive technique minimises biosecurity risk.

19.3.c) Disadvantages

i) Method 1 requires individual mechanical animal restraint.

ii) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.

iii) Method 1 requires a reliable supply of electricity.

19.4.d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over 1 week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

19.5.a) Requirements for effective use

i) A mobile waterbath stunner and a short loop of processing line are required.

Written Community comments:
The text of (ii) should be replaced as follows:

"ii) A low frequency (50-60 Hz) current applied for a minimum of 10 seconds is necessary to stun and kill the birds."

Justification: According to scientists of the EFSA minimum figures to be applied in this case should be 50-60 Hz and 10 seconds. See p. 199 of the report EFSA – AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html)

ii) A low frequency (30-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.

iv) The required minimum currents to stun and kill dry birds are:

- Quail - 100 mA/bird
- Chickens – 160 mA/bird
- Ducks & Geese – 200 mA/bird
- Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

19.6.b) Advantages

i) Method 2 stuns and kills simultaneously.

ii) It is capable of processing large numbers of birds reliably and effectively.

iii) This non-invasive technique minimises biosecurity risk.

19.7.c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

ii) Handling, inversion and shackling of birds are required.

19.8.d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a killing method (Article 17).

19.9.a) Requirements for effective use

Written Community comments:
The following sentence should be replaced as follows:

"i) The stunner control device should generate sufficient current to stun.

For constant voltage a minimum RMS or average currents of 240 and 400 mA should be applied for a minimum of 7 seconds to chickens and turkeys respectively (110 V RMS 50 Hz). Killing should be performed within 15 seconds from the end of the stun.

For constant current stunner the following minimum currents are recommended:

Since wave AC (Hz)	Minimum RMS current (mA)
50	**100**
400	**150**
1500	**200"**

Justification: See EFSA report

i) The stunner control device should generate sufficient current (more than 300 mA/bird) to stun.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

Written Community comments:
The following text (iv) should be deleted if the previous Community proposed amendment is accepted.

Justification: Covered by previous suggested amendment.

iv) A stunning current should be applied in a position that spans the brain for a minimum of 3 seconds; immediately following this application, the birds should be killed (Article 17).

v) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

vi) Birds should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

19.10. b) Advantages

Non-invasive technique (when combined with ~~neck~~ cervical dislocation) minimises biosecurity risk.

19.11. c) Disadvantages

Written Community comments:
The following text should be replaced by:

"i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations."

Justification: According to the EFSA scientists this method is not suitable for large-scale operations (see p. 123-124 of the report).

i) Method 3 requires a reliable supply of electricity.

ii) The electrodes must be applied and maintained in the correct position to produce an effective stun.

iii) Birds must be individually restrained.

iv) It must be followed by a killing method.

19.12. d) Conclusion

Method 3 is suitable for small numbers of poultry.

Written Community comments:
The following text should be retained as being "under study" until further information is available.

Justification: Ongoing important scientific advances in this area make the proposed text premature. Accumulating scientific evidence needs to be further analysed by the OIE ad hoc group experts before firm conclusions can be drawn on this matter, gas concentrations to be recommended etc. Under field concentrations a concentration of carbon dioxide such as 90% would be extremely difficult to achieve.

Article 3.7.6.12.
(under study)

20. CO_2 / AIR MIXTURE

21. 1. INTRODUCTION

Controlled atmosphere killing is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2).

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

22. 2. METHOD 1

The animals are placed in a gas-filled container or apparatus.

23. A) REQUIREMENTS FOR EFFECTIVE USE IN A CONTAINER OR APPARATUS

i) Containers or apparatus should allow the required gas concentration to be maintained and accurately measured.

ii) When animals are exposed to the gas individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

iii) Animals should be introduced into the container or apparatus after it has been filled with the required CO_2 concentration, and held in this atmosphere until death is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.

v) Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

24. B) ADVANTAGES

i) CO_2 is readily available.

ii) Application methods are simple.

25. C) DISADVANTAGES

i) The need for properly designed container or apparatus ~~special equipment~~

ii) The aversive nature of high CO_2 concentrations

iii) No immediate loss of consciousness

iv The risk of suffocation due to overcrowding

v) Difficulty in verifying death while the animals are in the container or apparatus.

26. D) CONCLUSION

Method 1 is suitable for use in poultry and neonatal sheep, goats and pigs.

27. 3. METHOD 2

The gas is introduced into a poultry house.

28. A) REQUIREMENTS FOR EFFECTIVE USE IN A POULTRY HOUSE

i) Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration.

ii) The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.

iii) Devices should be used to accurately measure the gas concentration at the ~~highest level~~ maximum height accommodation of birds.

29. B) ADVANTAGES

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

30. C) DISADVANTAGES

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses.

ii) It is difficult to verify death while the birds are in the poultry house.

31. D) CONCLUSION

Method 2 is suitable for use in poultry in closed-environment sheds

Article 3.7.6.13.

Nitrogen and/or inert gas mixed with CO_2

1. Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas eg argon, and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is ≤2%. This method involves the introduction of animals into a container or apparatus containing the gases. Such mixtures do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with ≤30% CO_2 by volume and ≤2% O_2 by volume can be used for killing poultry and neonatal sheep, goats and pigs.

2. Requirements for effective use

a) Containers or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured during the killing procedure.

b) When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

c) Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.

e) Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages

Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

4. Disadvantages

a) A properly designed container or apparatus is needed.

b) It is difficult to verify death while the animals are in the container or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 3.7.6.14.

Nitrogen and/or inert gasses

1. Introduction

This method involves the introduction of animals into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it doesn't induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

a) Containers or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.

b) When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

c) Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.

e) Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

4. Disadvantages

a) A properly designed container or apparatus is needed.

b) It is difficult to verify death while the animals are in the container or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 3.7.6.15.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

a) Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.

b) Prior sedation may be necessary for some animals.

c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

d) Animals should be restrained to allow effective administration.

e) Animals should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

a) The method can be used in all species.

b) Death can be induced smoothly.

4. Disadvantages

a) Restraint and/or sedation may be necessary prior to injection.

b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.

c) Legal requirements may restrict use to veterinarians.

d) Contaminated carcasses may present a risk to other wild or domestic animals.

5. Conclusion

The method is suitable for killing small numbers of cattle, sheep, goats, pigs and poultry.

Article 3.7.6.16.

Addition of anaesthetics to feed or water

1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

c) Must be followed by killing (see Article 3.7.6.17) if birds are anaesthetised only.

3. Advantages

a) Handling is not required until birds are anaesthetised.

b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

a) Non-target animals may accidentally access the medicated feed or water when provided in an open environment.

b) Dose taken is unable to be regulated and variable results may be obtained.

c) Animals may reject adulterated feed or water due to illness or adverse flavour.

d) The method may need to be followed by killing.

e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for killing large numbers of poultry in houses.

Article 3.7.6.17.

Written Community comments:
The heading for this article should be clarified.

Justification

The title "Killing methods in unconscious animals" is open to possible mis-interpretation. It should be clarified whether the intended meaning is that the killing methods described in this article should only be applied to animals which have already been rendered unconscious (for example by the prior application of an effective stunning method, in line with the principles described in the preceding text of these OIE guidelines concerning the application of such stunning methods).

Regarding cervical dislocation it should be considered that this can be an effective killing method and is often used by farmers to cull birds as well as being used in certain circumstances in disease control situations. It is a killing method which can be readily used under conditions where more elaborate killing equipment is not available.

Killing methods in unconscious animals

1. Method 1: Cervical dislocation (manual and mechanical)

31.1.a) Introduction

Poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from asphyxiation and/or cerebral anoxia.

Written Community comments:
The following text should be added here:

"Conscious birds of less than 250 grams may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and death is instantaneous"

Justification: Cervical dislocation is an effective method of killing without prior stunning if used by skilled operators on small birds and for a limited number of animals as to prevent operators' fatigue. See EFSA report for further considerations.

31.2.b) Requirements for effective use

i) Killing should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.

ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.

iii) Birds should be monitored continuously until death to ensure the absence of brain stem reflexes.

31.3.c) Advantages

i) It is a non-invasive killing method.

ii) It can be performed manually on small birds.

31.4.*d) Disadvantages*

i) Operator fatigue.

Written Community comments:
Paragraph ii) should be replaced by the following text:

"ii) The method is more difficult in larger birds and its use should be avoided in any case for birds over 3 kg of live weight".

Justification: The method should be avoided on birds weighing more than 3 kg as the physical efforts required to properly perform it increase with the size of the birds. See EFSA report for scientific basis.

ii) The method is more difficult in larger birds.

31.5.e) Conclusion

This method is suitable for killing unconscious poultry.

2. Method 2: Decapitation

31.6.a) Introduction

Decapitation results in death by cerebral ischaemia using a guillotine or knife.

31.7.b) Requirements for effective use

The required equipment should be kept in good working order.

31.8.c) Advantages

The technique is effective and does not require monitoring.

31.9.d) Disadvantages

The working area is contaminated with body fluids.

31.10. *e) Conclusion*

This method is suitable for killing unconscious poultry.

3. Method 3: Pithing

31.11. a) Introduction

Pithing is a method of killing animals which have been stunned by a penetrating captive bolt, without immediate death. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

31.12. b) Requirements for effective use

i) Pithing cane or rod is required.

ii) An access to the head of the animal and to the brain through the skull is required.

iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

31.13. c) Advantages

The technique is effective in producing immediate death.

31.14. d) Disadvantages

i) A delayed and/or ineffective pithing due to convulsions may occur.

ii) The working area is contaminated with body fluids.

31.15. *e) Conclusion*

This method is suitable for killing unconscious animals which have been stunned by a penetrating captive bolt.

4. Method 4: Bleeding

31.16. a) Introduction

Written Community comments:
Add the following sentence to the end of the next paragraph:

"Bleeding out should be completed and any incision made should ensure the complete severance of both carotid arteries, or the vessels from which they arise (e.g. chest stick)."

Justification: See EFSA report for scientific elaboration on this point.

Bleeding is a method of killing animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and death.

31.17. b) Requirements for effective use

i) A sharp knife is required.

ii) An access to the neck or chest of the animal is required.

iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

31.18. *c)* *Advantages*

The technique is effective in producing death after an effective stunning method which does not permit pithing.

31.19. *d)* *Disadvantages*

a) A delayed and/or ineffective bleeding due to convulsions may occur.

b) The working area is contaminated with body fluids.

31.20. *e)* *Conclusion*

This method is suitable for killing unconscious animals.

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— text deleted

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Principles of validation of diagnostic assays for infectious diseases

Delegations will find attached Commission document SEc(2006) 634 - Principles of validation of diagnostic assays for infectious diseases.

Encl.: SEC(2006) 634

CHAPTER 1.1.3.

PRINCIPLES OF VALIDATION OF DIAGNOSTIC ASSAYS FOR INFECTIOUS DISEASES

INTRODUCTION

Validation is the evaluation of a process to determine its fitness for a particular use. A validated assay yields test results that identify the presence of a particular analyte (e.g. an antibody) and allows predictions to be made about the status of the test subjects. Assays applied to individuals or populations have many purposes, such as aiding in: documenting freedom from disease in a country or region, preventing spread of disease through trade, eradicating an infection from a region or country, confirming diagnosis of clinical cases, estimating infection prevalence to facilitate risk analysis, identifying infected animals toward implementation of control measures, and classifying animals for herd health or immune status post-vaccination. A single assay may be validated for one or several intended purposes by optimising its performance characteristics for each purpose (e.g. setting diagnostic sensitivity [DSe] high [such as 99.99%] with associated lower diagnostic specificity [DSp] for a screening assay, or conversely, setting DSp high with associated lower DSe for a confirmatory assay).

By considering the variables that affect an assay's performance, the criteria that must be addressed in assay validation become clearer. The variables can be grouped into three categories: (a) the sample – host/organism interactions affecting the analyte composition and concentration in the serum sample; (b) the assay system – physical, chemical, biological and technician-related factors affecting the capacity of the assay to detect a specific analyte in the sample; and (c) the test result – the capacity of a test result, derived from the assay system, to predict accurately the status of the individual or population relative to the analyte in question.

Factors that affect the concentration and composition of analyte in the serum sample are mainly attributable to the host and are either inherent (e.g. age, sex, breed, nutritional status, pregnancy, immunological responsiveness) or acquired (e.g. passively acquired antibody, active immunity elicited by vaccination or infection). Nonhost factors, such as contamination or deterioration of the sample, may also affect the analyte in the sample.

The principles of validation discussed in this chapter will focus primarily on methods to detect antibody in sera. However, these same principles could be applied to validation of tests for other analytes in sera or tissues. Chapter 1.1.4 Validation and quality control of polymerase chain reaction methods used for the diagnosis of infectious diseases extends the principles outlined here to a direct method of infectious agent detection, the molecular diagnostic assays.

Factors that interfere with the analytical accuracy of the assay system include instrumentation, technician error, reagent choice (both chemical and biological) and calibration, accuracy and acceptance limits of controls, reaction vessels, water quality, pH and ionicity of buffers and diluents, incubation temperatures and durations, and error introduced by detection of closely related analytes, such as antibody to cross-reactive organisms, rheumatoid factor, or heterophile antibody.

Measures that influence the capacity of the test result to predict accurately the infection or analyte status of the host[1] are DSe, DSp, and prevalence of the disease in the population targeted by the assay. DSe and DSp are derived from test results on samples obtained from selected reference animals. The methods used to select the reference animals are critical to the accuracy of the estimates (5). The degree to which the reference animals represent all of the host and environmental variables in the population targeted by the assay has a major impact on the accuracy of test-result interpretation. For example, experienced diagnosticians are aware that an assay, validated by using samples from northern European cattle, may not give valid results for the distinctive populations of cattle in Africa.

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1 In this chapter, the terms 'positive' and 'negative' have been reserved for test results and never refer to infection or antibody/antigen status of the host. Whenever reference is made to 'infection' or 'analyte', any method of exposure to an infectious agent that could be detected directly (e.g. antigen) or indirectly (e.g. antibody) by an assay, should be inferred.

The capacity of a positive or negative test result to predict accurately the infection status of the animal or population of animals is the most important consideration of assay validation. This capacity is not only dependent on a highly precise and accurate assay and carefully derived estimates of DSe and DSp, but is heavily influenced by prevalence of the infection in the targeted population or the likelihood that an animal is infected based on clinical criteria. Without a current estimate of the disease prevalence in that population or likelihood of infection in an individual animal, the interpretation of a positive or negative test result may be compromised.

Many factors obviously must be addressed before an assay can be considered to be 'validated' (*5, 16*). *However, there is no consensus whether the concept of assay validation is a time-limited process during which only those factors intrinsic to the assay are optimised and standardised, or whether the concept includes an ongoing validation of assay performance for as long as the assay is used. Accordingly, the term 'validated assay' elicits various interpretations among laboratory diagnosticians and veterinary clinicians. Therefore, a working definition of assay validation is offered as a context for the guidelines outlined below. Ideally, all diagnostic assays would be fully validated for one or more purposes, but in practice there are sometimes limitations to the completeness of validation.*

A. DEFINITIONS OF ASSAY VALIDATION

Definition 1. From the perspective of laboratory results obtained from an assay over time, a validated assay consistently provides test results that identify animals as positive or negative for an analyte or process (e.g. antibody, antigen, or induration at skin test site) and, by inference, accurately predicts the infection and/or exposure status of animals with a predetermined degree of statistical certainty[1].

Definition 2. From the perspective of an assay developer, assay validation is the development and verification of test method performance characteristics at a defined level of statistical confidence for a particular target population.

For either definition, the assay is valid only insofar as its performance characteristics are consistent with the purpose for which the assay is intended.

This chapter will focus on the principles underlying development and maintenance of a validated assay. Previous iterations of this chapter (12) were condensed renditions of a review article (9). At that time, the goal was to fulfil Definition 1 of assay validation. In this expanded update, the content is reorganised into the parts of assay validation consistent with the format of the OIE Validation Template, and embraces both Definitions 1 and 2 of assay validation. In addition to the validation process *per* se, guidance is offered on scientifically sound methods for development, maintenance, and extension of validation criteria for a given assay.

It must be emphasised that an assay, when applied to target populations, will minimise misclassifications of animals as false positive or false negative only to the extent that validity is assured for all elements of the assay validation process. This assumes that the assay is fit for the purpose for which it is intended (e.g. a confirmatory assay will likely yield many false-negative results if used as a screening assay). It also assumes that a well designed and documented test method and proper standardised reagents, in combination with well-trained technicians, will give a stable assay within the laboratory. Furthermore, it assumes a thorough use of the most rigorous experimental design and epidemiological and statistical tools. These are required to reduce bias, random error, and false assumptions about the reference population of animals upon which the assay performance estimates are made (5). Finally, it assumes that when placed in practice, the assay is conducted within the context of a rigorous quality assurance programme.

B. ASSAY VALIDATION – INTRODUCTION

1. Selection of an assay fit for its intended purpose

The OIE *Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases* (14) is a specific interpretation of the more generally stated requirements of the ISO/IEC 17025:1999

1 In this definition, the DSe and DSp are performance characteristics of the assay for a given target population. They determine – together with the disease prevalence in the population – the probability that a given test result reflects the true status of the animal. An assay can be recognised as validated if reliable estimates of DSe and DSp for a given target population are available. This does not imply any minimum threshold values for these parameters. In practical applications, low values of DSe and DSp or diagnostic problems due to low disease prevalence are compensated by the sampling design or by combining multiple diagnostic assays into parallel or serial testing regimens. The selection of assays, the sampling process, the combination of multiple assays into a testing regimen and the interpretation rule for the results define the diagnostic process.

international quality standard for testing laboratories (8). The OIE Quality Standard clearly states that test methods and related procedures must be appropriate for specific diagnostic applications in order for the test results to be of any relevance. In other words, the assay must be 'fit for purpose'. The Quality Standard further states that in order for a test method to be considered appropriate, it must be properly validated and that this validation must respect the principles outlined in the validation chapters of the this *Terrestrial Manual*.

While this chapter deals with validation and fitness for purpose from a scientific perspective, it should also be noted that other factors may impact the relevance of an assay with respect to fitness for purpose. These factors include not only the diagnostic suitability of the assay, but also its acceptability by scientific and regulatory communities, acceptability to the client, and feasibility given available laboratory resources.

As outlined in the background information in *Certification of diagnostic assays* on the OIE website (www.oie.int), the first step is selection of an assay type that likely can be validated for a particular use. The intended purpose(s) of an assay have been broadly defined as:

a) to demonstrate population 'freedom' from infection (prevalence apparently zero)

   i) 'free' with and/or without vaccination

   ii) historical 'freedom'

   iii) re-establishment of 'freedom' following outbreaks;

b) to demonstrate freedom from infection in individual animals or products for trade purposes;

c) to demonstrate efficiency of eradication policies;

d) to confirm diagnosis of clinical cases;

e) to estimate prevalence of infection to facilitate risk analysis (surveys, classification of herd health status, implementation of disease control measures);

f) to determine immune status of individual animals or populations (post-vaccination).

As previously stated, when considering an assay for a specific purpose, other 'fitness' factors should be considered in the initial decision making process. Operational requirements are often overlooked and may include; running costs, equipment requirements, kit/reagent availability, shelf life, transport requirements, safety, biosecurity, sample throughput, test turn-around-times, etc.

2. Initial assay development considerations

An indirect enzyme-linked immunosorbent assay (ELISA) for detection of antibody will be used in this chapter to illustrate the principles of assay validation. It is a type of assay that can be difficult to validate because of signal amplification of both specific and nonspecific components (2). This methodology serves to highlight the problems that need to be addressed in any assay validation process. The same basic principles are used in validation of other complex or simple assay formats. Chapter I.1.4 Validation and quality control of polymerase chain reaction methods used for the diagnosis of infectious diseases describes the principles for validating gene-amplification techniques.

Selection of appropriate samples, calibrated instrumentation, and a relevant methodology to achieve the intended purpose are critical elements in assay validation. Continuity in experiments is assured when reagents and samples are chosen, properly prepared, aliquotted, and stored for use in each experiment. This reduces the number of variables to a minimum and guards against failure when the validation process commences.

a) Control samples

It is useful to select four or five samples (serum in our example) that range from high to low levels of antibodies against the infectious agent in question. In addition, a sample containing no antibody is required. These samples will be used to optimise the assay reagents and protocol during feasibility studies, and later as control samples. The samples ideally should represent known infected and uninfected animals from the population that eventually will become the target of the validated assay. The samples should have given expected results in one or more serological assay(s) other than the one being validated. The samples are preferably derived from individual animals, but they may represent pools of samples from several animals. A good practice is to prepare a large volume (e.g. 10 ml or more if possible) of each sample and divide it into 0.1 ml aliquots for storage at or below –20°C. One aliquot of each sample is thawed, used for experiments, and ideally then discarded. If it is impractical to discard the aliquot, it may be held at +4°C between experiments for up to about 2 weeks; however, there is a possibility of sample deterioration under these circumstances. Then, another aliquot is thawed for further experimentation. This method provides the same source of serum with the same number of freeze–thaw cycles for all experiments (repeated freezing and thawing of serum can denature antibodies so should be avoided). Also, variation is reduced when the experimenter uses the same source of serum for all experiments rather than switching among various sera between experiments. This approach has the added advantage of generating a data trail for the repeatedly run samples. After the initial stages of assay validation are completed, one or more of the samples can become the serum control(s) that are the basis for data expression and repeatability assessments both within and between runs of the assay. They may also serve as standards if their activity has been predetermined; such standards provide assurance that runs of the assay are producing accurate data (16).

It is highly desirable to include OIE International Standard Sera or other international standard sera if they are available. This may lead to harmonisation between the assay under development and a standard test method in which international standard sera are normally used (15).

b) Selection of method to achieve normalised results

Normalisation adjusts raw test results of all samples relative to values of controls included in each run of the assay (not to be confused with transformation of data to achieve a 'normal' [Gaussian] distribution). The method of normalisation and expression of data should be determined, preferably no later than at the end of the feasibility studies. Comparisons of results from day to day and between laboratories are most accurate when normalised data are used. For example, in ELISA systems, raw optical density (absorbance) values are absolute measurements that are influenced by ambient temperatures, test parameters, and photometric instrumentation. To account for this variability, results are expressed as a function of the reactivity of one or more serum control samples that are included in each run of the assay. Data normalisation is accomplished in the indirect ELISA by expressing absorbance values in one of several ways (16). A simple and useful method is to express all absorbance values as a percentage of a single high-positive serum control that is included on each plate. (This control must yield a result that is in the linear range of measurement.) This method is adequate for most applications. More rigour can be brought to the normalisation procedure by calculating results from a standard curve generated by several serum controls. It requires a more sophisticated algorithm, such as linear regression or log-logit analysis. This approach is more precise because it does not rely on only one high-positive control sample for data normalisation, but rather uses several serum controls, adjusted to expected values, to plot a standard curve from which the sample value is extrapolated. This method also allows for exclusion of a control value that may fall outside expected confidence limits.

For assays that are end-pointed by sample titration, such as serum (viral) neutralisation, each run of the assay is accepted or rejected based on whether control values fall within predetermined limits. Because sample values usually are not adjusted to a control value, the data are not normalised by the strict definition of the term.

Whatever method is used for normalisation of the data, it is essential to include additional controls for any reagent that may introduce variability and thus undermine attempts to achieve a validated assay. The normalised values for those controls need to fall within predetermined limits (e.g. within an appropriate multiple of the standard deviation of the mean of many runs of each control). The chosen limits should reflect a reasonable and tolerable assay run rejection rate and an acceptable risk that some test samples may be misclassified.

C. ASSAY VALIDATION – PART 1

1. Optimisation and standardisation of reagents

Using control sera as outlined in section B.2 of this chapter, the optimal concentrations/dilutions of the antigen adsorbed to the plate, serum, enzyme–antibody conjugate, and substrate solution are determined through 'checkerboard' titrations of each reagent against all other reagents, following confirmation of the best choice of reaction vessels (usually evaluation of two or three types of microtitre plates, each with its different binding characteristics, to minimise background activity while achieving the maximum spread in activity between negative and high-positive samples). Additional experiments determine the optimal temporal, chemical, and physical variables in the protocol, including incubation temperatures and durations; the type, pH, and molarity of diluent, washing and blocking buffers; and equipment used in each step of the assay (for instance pipettes and washers that give the best reproducibility).

a) Linear operating range of the assay

The range of values that constitute the linear operating range of an assay is best determined by a dilution series in which a high positive serum is serially diluted in a negative serum. Each dilution is then run at the optimal working dilution in buffer, and the results plotted in the form of a 'response-curve'. This curve, sometimes referred to as a 'dose–response curve' as in pharmacological applications, establishes the linear range of assay values that are valid for use in the assay.

b) Calibration against reference reagents

i) International standards

Serum standards and other reagents, available from OIE, WHO, FAO, or other international organisations can be used to harmonise the assay with expected results gained from reference reagents of known activity.

ii) In-house standards

The in-house serum controls (used for normalisation of data) and additional secondary serum standards, such as low positive, high positive, and negative sera (used for repeatability estimates in subsequent routine runs of the assay) can be fitted to the response curve to achieve expected values for such sera.

2. Repeatability

Evidence of repeatability (agreement between replicates within and between runs of the assay) is necessary to warrant further development of the assay. This is accomplished by evaluating results from a minimum of three in-house samples representing activity within the linear range of the assay. Quadruplicates of these samples are tested in at least four runs of the assay to determine within-run (intraplate) variation. Between-run variation is determined by using the same samples in a minimum of 20 runs (total), by two or more operators, preferably on separate days. All runs must be independent of each other.

For reporting purposes, ELISA, raw absorbance values are usually used to calculate repeatability during this part of validation because it is uncertain whether the results of the high-positive control serum, which could be used for calculating normalised values, are reproducible in early runs of the assay format. Also, expected values for the controls have not yet been established. Coefficients of variation (CV: standard deviation of replicates ÷ mean of replicates), generally less than 20% for raw absorbance values for most samples (low-titred samples may have larger CVs), indicates adequate repeatability at this stage of assay development. However, if evidence of excessive variation (>30%) is apparent for most samples within and/or between runs of the assay, more preliminary studies should be done to determine whether stabilisation of the assay is possible, or whether the test format should be abandoned. This is important because an assay that is inherently variable has a high probability of not withstanding the rigours of day-to-day testing on samples from the targeted population of animals.

When new batches of antigen or other reagents are introduced into the assay, or new serials (kit lots) of the assay are produced, repeatability of the assay needs to be re-established using the same criteria as outlined above.

3. Determination of analytical specificity and sensitivity

Analytical specificity of the assay is the degree to which the assay does not cross-react with other analytes and analytical sensitivity is the smallest detectable amount of the analyte in question.

Analytical specificity is assessed by use of a panel of samples derived from animals that have been exposed to genetically related organisms that may stimulate cross-reactive antibodies, or sera from animals with similar clinical presentations. This 'near neighbour analysis' is useful in determining the probability of false-positive reactions in the assay. It is also appropriate to document a group specificity criterion that includes detection of the analyte of interest in sera from animals that have experienced infections/exposure to an entire group or serotype of organisms of interest.

Analytical sensitivity is assessed by end-point dilution analysis, which indicates the dilution of serum in which the analyte is no longer detectable, or at least, is indistinguishable from the activity of negative sera. The earliest time after exposure to an infectious agent that antibody can be detected affects analytical sensitivity. This effect can be deduced by testing serially-drawn blood samples from animals post-exposure to the agent in question. The duration of antibody presence also affects analytical sensitivity, which can be determined by long-term serial testing of experimentally infected/exposed animals.

If the intended purpose of the assay is for screening of animals for antibody activity, analytical sensitivity needs to be high to achieve the greatest probability possible for detecting infected animals. If very high analytical sensitivity is not achievable, the assay may not be fit as a screening assay. Alternatively, if confirmation of another independent diagnostic procedure is the purpose for which the assay is intended, analytical specificity is required that minimises the amount of cross-reactivity. If neither of these objectives is obtainable, the reagents need to be recalibrated, replaced, or the assay should be abandoned.

D. ASSAY VALIDATION – PART 2

1. Determining assay performance characteristics

Estimates of DSe and DSp are the primary performance indicators established during validation of an assay. They are the basis for calculation of other parameters from which inferences are made about test results. Therefore, it is imperative that estimates of DSe and DSp are as accurate as possible. Ideally, they are derived from testing a series of samples from reference animals of known history and infection status relative to the disease/infection in question and relevant to the country or region in which the test is to be used, but that is not always possible. A sampling design must be chosen that will allow estimation of diagnostic performance characteristics. However this is a difficult process complicated by logistical and financial limitations. It is also limited by the fact that reference populations and gold standards may be lacking. The following are examples of reference populations and methodologies that may aid in determining performance characteristics of the test being validated.

a) Reference animal populations

i) *Infected or exposed and uninfected or non-exposed reference animals*

Selection of reference animals to evaluate performance characteristics requires that the variables attributable to the target population are represented in the infected/exposed and uninfected/unexposed reference animal populations. The variables include but are not limited to species, age, sex, breed, nutritional status, pregnancy, stage of infection, immunological status including vaccination history, and historical, epidemiological, and/or clinical data including herd disease history should be noted and considered.

ii) *Reference animal status determined by other assays*

In serology, the 'standard of comparison' is the results of a method or combination of methods with which the new assay is compared. Although the term 'gold standard' is commonly used to describe any standard of comparison, it should be limited to methods that unequivocally classify animals as infected or uninfected. Some isolation methods themselves have problems of repeatability and sensitivity. Gold standard methods include unequivocal isolation of the agent or pathognomonic histopathological criteria.

Because a true gold standard may be lacking or is impossible to achieve, relative standards of comparison are often necessary; the most common of these include results from other serological assays. Calculations of DSe and DSp are most reliable when the gold standard of comparison is available. When only relative standards of comparison are available, estimates of DSe and DSp for the new assay may be compromised because the error in the estimates of DSe and DSp for the relative standard is carried over into those estimates for the new assay. Indeed, when using imperfect reference tests without efforts to control for any biases, the DSe and DSp performance estimates of the new test will be flawed and thus unacceptable.

iii) *Experimentally infected or vaccinated reference animals*

Sera obtained sequentially from experimentally infected or vaccinated animals have been used to 'validate' a new assay. Such repeated observations from the same animals are not acceptable for establishing estimates of DSe and DSp because the statistical requirement of independent observations is violated. Thus, time-point sampling of individual experimental animals is necessitated. Also, exposure to organisms under experimental conditions, or vaccination may elicit antibody responses that are not quantitatively and qualitatively typical of natural infection in the target population (9). The strain of organism, dose, and route of administration to experimental animals are examples of variables that may introduce error when extrapolating DSe and DSp estimates to the target population. For these reasons, validation of an assay should not solely be based on experimental animals.

iv) *Reference animals – Status unknown*

When it is not possible to assemble sera from animals of known infection status, it is possible to estimate DSe and DSp by non-gold standard methods or latent class models (3, 7). As these statistical models are complex, an expert should be consulted to provide assistance on proper ways to conduct and describe the sampling from the target population(s), the characteristics of other tests included in the analysis, the appropriate choice of model and the estimation methods based on peer-reviewed literature.

2. Threshold determination

To achieve performance estimates of DSe and DSp of the new assay, the test results first must be reduced to categorical (positive or negative) status. This is accomplished by insertion of a cut-off point (threshold or decision limit) on the continuous scale of test results. Although many methods have been described for this purpose, three examples will illustrate different approaches, together with their advantages and disadvantages. The first is a cut-off based on the frequency distributions (9) of test results from uninfected and infected reference animals. This cut-off can be established empirically by visual inspection of the frequency distributions, by receiver-operator characteristics (ROC) analysis (6, 17), or by selection that favours either DSe or DSp, depending on the intended use for a given assay (11). A second approach is establishing a cut-off based only on uninfected reference animals, for instance the 99th percentile in a frequency distribution of assay values for uninfected reference animals; this provides an estimate of DSp but not DSe. The third method provides an 'intrinsic cut-off' based on test results from sera drawn randomly from within the target population with no prior knowledge of the animals' infection status (4).

If considerable overlap occurs in the distributions of test values from known infected and uninfected animals, it is difficult to select a cut-off that will accurately classify these animals according to their infection status. Rather than a single cut-off, two cut-offs can be selected that define a high DSe (e.g. inclusion of 99% of the values from infected animals), and a high DSp (e.g. 99% of the values from uninfected animals). The values that fall between these percentiles would then be classified as suspicious or equivocal, and would require testing by a confirmatory assay or retesting for detection of seroconversion.

The selection of the cut-off will typically reflect the intended purpose of the assay. For example, a screening assay designed for high DSe versus a confirmatory assay designed for high DSp will require different cut-offs in the same assay system. Although the intended purpose will dictate the cut-off, a ROC analysis is still desirable, as it will show the potential performance of the assay in other epidemiological settings.

3. Assay performance estimates

a) Number of reference animals required

The number and source of reference samples coupled with the methodologies used to derive DSe and DSp estimates are of paramount importance if the assay is ever to be properly validated for use in the population of animals targeted by the assay. It is possible to calculate the number of reference samples, from animals of known infection/exposure status, required for determinations of DSe and DSp that will have statistically defined limits. Formulae and tables for determining the number of samples required are provided elsewhere (5, 9).

b) DSe and DSp estimates based on reference animals with defined infection status

The selection of a cut-off allows classification of test results into positive or negative categories. Calculations of DSe and DSp are aided by associating the positive/negative categorical data with the known infection status for each animal using a two-way (2 × 2) table (Table 1). After the cut-off is established, results of tests on standard sera can be classified as true positive (TP) or true negative (TN) if they are in agreement with those of the gold standard (or other standard of comparison). Alternatively, they are classified as false positive (FP) or false negative (FN) if they disagree with the standard. Diagnostic sensitivity is calculated as TP/(TP + FN) whereas diagnostic specificity is TN/(TN + FP); the results of both calculations are usually expressed as percentages (Table 1).

Table 1. *Calculations of DSe and DSp aided by a 2 × 2 table that associates infection status with test results from 2000 reference animals*

		Reference animals of known infection status	
		Infected (*n* = 600)	**Uninfected (*n* = 1400)**
Test Result	**Positive**	**570** **TP**	**46** **FP**
	Negative	**FN** **30**	**TN** **1354**
		Diagnostic sensitivity	**Diagnostic specificity**
		$\frac{TP}{TP+FN} = \frac{570}{600} = 95.0\%$	$\frac{TN}{TN+FP} = \frac{1354}{1400} = 96.7\%$

c) DSe and DSp estimates based on animals with infection status not defined

As mentioned above, these statistical models are complex, expert advice should sought not only in the design of the evaluation study but the interpretation of the estimates of DSe and DSp as well. It has been recommended to the OIE that an expert group be formed to address the application of latent class models and to draft guidelines for models as they apply to the validation and certification assays by the OIE.

3. Comparison and harmonisation of assays

For the most part, new assays are developed to improve on existing techniques. In order to demonstrate that a new assay is an improvement over an existing technique, there must be some form of comparison that demonstrates the improvement. The comparison may be related to analytical and/or diagnostic performance characteristics. It may also be related to operational characteristics such as cost, ruggedness, turn-around-times, throughput, etc. If the new assay is to be incorporated into a diagnostic regimen involving other test methods, the rationale for its use, interpretation of data and decision making should be stated.

When an international standard method (15) is available for detection of an analyte, it is possible to harmonise the performance of that method with the one under development. This process requires use of the same serum controls and/or standards in both assays. If OIE Standard Sera or other international standard sera are available, preferably at least three (negative, low positive, and high positive), they should be included in the assay-comparison study. This could lead to a new assay that is indexed to an international standard method and international standard sera (15). Harmonisation of the two assays may then be realised.

E. ASSAY VALIDATION – PART 3

1. Establishing reproducibility of the assay

An assay intended for distribution to many laboratories (such as a commercial kit) must be evaluated for reproducibility, which is defined as the ability of a test method to provide consistent results when applied to aliquots of the same samples tested at different laboratories. This is accomplished by testing a panel of sera in a minimum of three laboratories using the identical test method and serum panels.

A test panel consisting of a minimum of 20 samples is assembled for this purpose. Ideally, these will be individual samples from animals within the target population, representing the range of assay activity anticipated in that population. If such samples are not available, dilution of a high positive with a negative serum to achieve the range of activity is acceptable but not optimal. Replicates of about 20% of the samples are desirable as a check on repeatability within each participating laboratory. Each sample is aliqotted, rendering a series of identical panels for distribution to other laboratories. The sample identity is encoded for blind testing, and each panel is handled, transported to participating laboratories, and stored identically.

The descriptive statistics for test panel data accumulated from the laboratories includes mean, standard deviation, and range of results for each sample as well as controls. Evaluation of precision and accuracy at each laboratory is facilitated by Youden plots. The data will help to inform the legitimacy of the upper and lower control limits of the assay as established by the developer.

F. ASSAY VALIDATION – PART 4

1. Programme implementation

Ultimate proof of the usefulness of an assay is its successful application(s). These would include international, regional or national programs. As new and improved assays are developed and come on-line, they will ultimately replace existing assays if they prove a better fitness for purpose. However, this will only happen if they are actually put into routine use and their usefulness documented over time. In the natural progression of diagnostic and/or technological improvement, some new assays will become the new standard of comparison. As such, they may progressively achieve national, regional and international recognition. As a recognised standard, these assays will also be used to develop reference reagents for quality control, proficiency and harmonisation purposes. These reference reagents may also become international standards, as well. The last level of validation in the OIE Registry involves documentation related to actual application and levels of recognition for the assay in question. This is intended to provide potential users with an informed and unbiased source of information.

2. Monitoring validity of assay performance

a) Interpretation of test results – factors affecting assay validity

An assay's test results are useful only if the inferences made from them are accurate. A common error is to assume that an assay with 99% DSe and 99% DSp will generate one false-positive and one false-negative result for approximately every 100 tests on animals from the target population. Such an assay may be precise and accurate, but produce test results that do not accurately predict infection status. For example, if the prevalence of disease in a population targeted by the assay is only 1 per 1000 animals, and the false-positive test rate is 1 per 100 animals (99% DSp), for every 1000 tests on that population, ten will be false positive and one will be true positive. Hence, only approximately 9% of positive test results will accurately predict the infection status of the animal; the positive test results will misclassify the animal 91% of the time. This illustrates that the capacity of a positive or negative test result to predict infection status is dependent on the prevalence of the infection in the target population (10). Of course, the prevalence will probably have been determined by use of a serological test with its own inherent misclassification of results.

An estimate of prevalence in the target population is necessary for calculation of the predictive values of positive (PV+) or negative (PV–) test results. When test values are reported without providing estimates of the assay's DSp and DSe, it is not possible to make informed predictions of infection status from test results (9). It is, therefore, highly desirable to provide an interpretation statement with test results accompanied by a small table indicating PV+ and PV– for a range of expected prevalences of infection in the target population. Without provision of such information, test results from the assay may have failed to accurately classify the infection status of animals, and thus do not reflect a fully validated assay.

b) Maintenance of validation criteria

A validated assay needs constant monitoring and maintenance to retain that designation. Once the assay is put into routine use, internal quality control is accomplished by consistently monitoring the assay for assessment of repeatability and accuracy (1).

Reproducibility between laboratories should be assessed at least twice each year. It is highly desirable to become part of a consortium of laboratories that are interested in evaluating their output. In the near future, good laboratory practice, including implementation of a total quality assurance programme, will become essential for laboratories seeking to meet national and international certification requirements (see Chapter I.1.2).

Proficiency testing is a form of external quality control for an assay. It is usually administered by a reference laboratory that distributes panels of samples, receives the results from the laboratories, analyses the data, and reports the results back to the laboratories. If results from an assay at a given laboratory remain within acceptable limits and show evidence of accuracy and reproducibility, the laboratory may be certified by government agencies or reference laboratories as an official laboratory for that assay (13). Panels of sera for proficiency testing should contain a full representation of an analyte's concentration in animals of the target population. If the panels only have high-positive and low-positive sera (with none near the assay's cut-off), the exercise will only give evidence of reproducibility at the extremes of analyte concentration, and will not clarify whether routine test results on the target population properly classify infection status of animals.

c) Enhancement and extension of validation criteria

Because of the extraordinary set of variables that impact on the performance of serodiagnostic assays, it is highly desirable to expand the number of standard sera from animals of known infection status because of the principle that error in the estimates of DSe and DSp is reduced with increasing sample size. Furthermore, when the assay is to be applied in a completely different geographical region, it is essential to re-validate the assay for its new intended use by subjecting it to sera from populations of animals that reside under local conditions. The same is true for establishing DSe and DSp for subpopulations (e.g. age groups, vaccinated/non-vaccinated, etc.).

When a serum control sample is nearing depletion, it is essential to prepare and repeatedly test a replacement before the serum control is depleted. The prospective control sample is included in 10–20 runs of the assay before depletion of the original control to establish its proportional relationship to the nearly depleted control. If the depleted sample was a positive control in ELISAs where the normalised value is expressed as a per cent of that positive control, the proportional difference in ELISA activity between the original and replacement sera must be factored into the normalisation algorithm to retain the same cut-off, and thus the same DSe and DSp in the assay. When other reagents, such as antigen for capture of antibody, must be replaced, they should be produced using the same criteria as for the original reagents, and tested in at least five runs of the assay using a panel of sera that has been designed for this purpose. Reagent lots (serials) need to be evaluated for consistency so variability is not introduced into the assay as new lots are required. Whenever possible, it is important to change only one reagent at a time to avoid the compound problem of evaluating more than one variable at a time.

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Brussels, 7 June 2006

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AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Foot and Mouth Disease

Delegations will find attached Commission document SEC(2006) 634 - Foot and Mouth Disease.

Encl.: SEC(2006) 634

CHAPTER 2.1.1.

FOOT AND MOUTH DISEASE

SUMMARY

Foot and mouth disease (FMD) is the most contagious disease of mammals and has a great potential for causing severe economic loss in susceptible cloven-hoofed animals. There are seven serotypes of FMD virus, namely, O, A, C, SAT 1, SAT 2, SAT 3 and Asia 1. Infection with one serotype does not confer immunity against another. FMD cannot be differentiated clinically from other vesicular diseases, including swine vesicular disease, vesicular stomatitis and vesicular exanthema. Laboratory diagnosis of any suspected FMD case is therefore a matter of urgency.

Typical cases of FMD are characterised by a vesicular condition of the feet, buccal mucosa and, in females, the mammary glands. Clinical signs can vary from mild to severe and fatalities may occur, especially in young animals. In some species the infection may be subclinical, e.g. African buffalo (Syncerus caffer). *The preferred tissue for diagnosis is epithelium from unruptured or freshly ruptured vesicles or vesicular fluid. Where collecting this is not possible, blood and/or oesophageal–pharyngeal fluid samples taken by probang cup in ruminants or throat swabs from pigs provide an alternative source of virus. Myocardial tissue or blood can be submitted from fatal cases, but vesicles are again preferable if present.*

It is vital that samples from suspected cases be transported under secure conditions and according to international regulations. They should only be dispatched to authorised laboratories.

Diagnosis of FMD is by virus isolation or by the demonstration of FMD viral antigen or nucleic acid in samples of tissue or fluid. Detection of virus-specific antibody can also be used for diagnosis and antibodies to viral nonstructural proteins (NSPs) are indicators of infection, irrespective of vaccination status.

Identification of the agent: *The demonstration of FMD viral antigen or genome is sufficient for a positive diagnosis. Due to the highly contagious nature and economic importance of FMD, the laboratory diagnosis and serotype identification of the virus should be done in a laboratory that meets the OIE requirements for Containment Group 4 pathogens.*

Complement fixation (CF) has been replaced in many laboratories by the enzyme-linked immunosorbent assay (ELISA), as it is more specific and sensitive and is not affected by pro- or anti-complement factors. If the sample is inadequate or the diagnosis remains uncertain, sample materials should be inoculated on to cell cultures or into 2–7-day old unweaned mice to amplify any live virus that may be present. The cultures should preferably be of primary bovine (calf) thyroid, but pig, lamb or calf kidney cells, or cell lines of comparable sensitivity may be used. Once a cytopathic effect (CPE) is complete in the cultures, the fluids can be used in CF tests or ELISAs. Similar tests can be performed on homogenised suspensions of the dissected musculo-skeletal tissues of any mice that die.

Nucleic acid recognition tests, such as the polymerase chain reaction (PCR) are being used increasingly as rapid and sensitive diagnostic methods. Electron microscopic examination of lesion material is sometimes used to differentiate FMD from disease caused by other viruses.

Serological tests: *The demonstration of specific antibodies to structural proteins in nonvaccinated animals, where a vesicular condition is present, is sufficient for a positive diagnosis. This is particularly useful in mild cases or where epithelial tissue cannot be collected. Tests for antibodies to some NSPs of FMD virus are useful in providing evidence of previous or current viral replication in the host, irrespective of vaccination status. NSPs, unlike structural proteins, are highly conserved and therefore are not serotype specific and as a consequence, the detection of these antibodies is not serotype restricted.*

Virus neutralisation (VN) tests and ELISAs for antibodies to structural proteins are used as serotype-specific serological tests. VN tests depend on tissue cultures and are therefore more prone to variability than ELISAs; they are also slower and subject to contamination. ELISAs for antibodies have the advantage

of being faster, and are not dependent on cell cultures. The ELISA can be performed with inactivated antigens, thus requiring less restrictive biocontainment facilities.

Requirements for vaccines and diagnostic biologicals: *Inactivated virus vaccines of varying composition are available commercially. Typically, virus is used to infect a suspension or monolayer cell culture and the resulting preparation is clarified, inactivated with ethyleneimine and blended with adjuvant. Many FMD vaccines are multivalent to provide cover against the different serotypes likely to be encountered in a given field situation.*

The finished vaccine must be shown to be free from residual live virus. This is most effectively done using in-vitro *tests on concentrated inactivated virus preparations prior to formulation of the vaccine and freedom from live virus is subsequently confirmed during* in-vivo *and/or* in-vitro *tests on the finished product. Challenge tests are also conducted in vaccinated cattle to establish a* PD_{50} (*50% protective dose*) *value or protection against generalised foot infection* (*PGP*), *although a serological test is considered to be satisfactory where a valid correlation between the amount of antigen present in the vaccine, the observed protection, and the specific antibody response has been established.*

FMD vaccine production facilities should also meet the OIE requirements for Containment Group 4 pathogens.

Diagnostic and reference reagents are available from the OIE Reference Laboratories for FMD or the FAO (*Food and Agriculture Organization of the United Nations*) *World Reference Laboratory for FMD. The Institute for Animal Health Pirbright Laboratory has dual designations as both the FAO World Reference Laboratory and as an OIE Reference Laboratory for FMD.*

A. INTRODUCTION

Foot and mouth disease (FMD) is caused by a virus of the genus *Aphthovirus*, family *Picornaviridae*. There are seven serotypes of FMD virus, namely O, A, C, SAT 1, SAT 2, SAT 3, and Asia 1, that infect cloven-hoofed animals. Infection with any one serotype does not confer immunity against another. Within serotypes, many strains can be identified by biochemical and immunological tests.

In Africa, FMD viruses are maintained by cattle and African buffalo (*Syncerus caffer*) and they are usually the most common host. Available evidence indicates that although other domestic and wild species become infected, they are unable to maintain the infection for more than a few months in the absence of cattle or African buffalo. Elsewhere in the world cattle are usually the main reservoir, although in some instances the viruses involved appear to be specifically adapted to domestic pigs or sheep and goats. It is probable that these adapted viruses are able to modify their adaptation and affect other species if given the opportunity. However, the pig-adapted Cathay strain of FMD virus apparently does not infect large ruminants in the field or experimentally and requires cells of porcine origin for primary isolation. Wildlife outside Africa has not, so far, been shown to be able to maintain FMD viruses. The evidence indicates that infection of deer in the past was derived from contact, direct or indirect, with infected domestic animals.

Of the domesticated species, cattle, pigs, sheep, goats and buffalo are susceptible to FMD (30). In addition, many species of cloven-hoofed wildlife, such as deer, antelope and wild pigs may become infected, although, apart from the African buffalo they have not been shown to play a significant role in the epidemiology of FMD. Strains of FMD virus that infect cattle have been isolated from wild pigs and deer. For the diagnosis of FMD in wild species, procedures similar to those described for farm animals can be applied.

Infection of susceptible animals with FMD virus leads to the appearance of vesicles on the feet, in and around the oral cavity, and on the mammary glands of females. Vesicles can also occur at other sites, such as inside the nostrils and at pressure points on the limbs – especially in pigs. The severity of clinical signs varies with the strain of virus, the exposure dose, the age and breed of animal, the host species and its degree of immunity (41). The signs can range from a mild or inapparent infection to one that is severe. Death may result in some cases. Mortality from a multifocal myocarditis is most commonly seen in young animals: myositis may also occur in other sites.

On premises with a history of sudden death in young cloven-hoofed livestock, close examination of adult animals may often reveal the presence of vesicular lesions if FMD is involved. The presence of vesicles in fatal cases is variable.

In animals with a history of vesicular disease, the detection of FMD virus in samples of vesicular fluid, epithelial tissue, oesophageal–pharyngeal (OP) sample, milk, or blood is sufficient to establish a diagnosis. Diagnosis may also be established by the isolation of FMD virus from the blood, heart or other organs of fatal cases. A myocarditis may be seen macroscopically (the so-called “tiger heart”) in a proportion of fatal cases.

FMD virus can replicate and be excreted from the respiratory tract of animals. Airborne excretion of virus occurs during the acute phase of infection. FMD viruses may occur in all the secretions and excretions of acutely infected animals including expired air. Transmission is generally effected by direct contact between infected and susceptible animals or, more rarely, exposure of susceptible animals to the excretions and secretions of acutely infected animals. Following recovery from the acute stage of infection, infectious virus disappears from all secretions and excretions with the exception of OP fluids from some ruminants, where live virus may continue to be recovered. Animals in which the virus persists in the OP for more than 28 days after infection are referred to as carriers. Pigs do not become carriers. Circumstantial evidence indicates, particularly in the African buffalo, that carriers are able, on rare occasions, to transmit the infection to susceptible animals with which they come in close contact: the mechanism involved is unknown. The carrier state in cattle usually does not persist for more than 6 months, although in a small proportion it may last up to 3 years. In African buffalo individual animals have been shown to harbour the virus for at least 5 years, but it is probably not a lifelong phenomenon. Within a herd of buffalo, the virus may be maintained for 24 years or longer. There is no information on the duration of the carrier state in another domestic buffalo, the swamp buffalo of East Asia. Domestic buffalo, sheep and goats do not usually carry FMD viruses for more than a few months.

Due to the highly contagious nature and economic importance of FMD, the laboratory diagnosis and serotype identification of the virus should be done in a facility that meets the requirements for Containment Group 4 pathogens as outlined in Chapter 1.1.6 of this *Terrestrial Manual.* Countries lacking access to such a specialised national or regional laboratory should send specimens to an OIE FMD Reference Laboratory. Vaccine production facilities should also meet the requirements for Containment Group 4 pathogens.

Diagnostic and standard reagents are available in kit form or as individual items from OIE Reference Laboratories for FMD. The use of inactivated antigens in the enzyme-linked immunosorbent assay (ELISA), as controls in the antigen-detection test or to react with test sera in the liquid-phase blocking or solid-phase competitive ELISA, reduces the disease security risk involved compared to the use of live virus. Reagents are supplied freeze-dried or in glycerol or non-glycerinated but frozen and can remain stable at temperatures between +1°C and +8°C, –30°C and –5°C and –90°C and –50°C, respectively, for many years. The International Atomic Energy Agency has produced a manual that includes a recommended test and quality control protocols.

B. DIAGNOSTIC TECHNIQUES

For laboratory diagnosis, the tissue of choice is epithelium or vesicular fluid. Ideally, at least 1 g of epithelial tissue should be collected from an unruptured or recently ruptured vesicle, usually from the tongue, buccal mucosa or feet. To avoid injury to personnel collecting the samples, as well as for animal welfare reasons, it is recommended that animals be sedated before any samples are obtained.

Epithelial samples should be placed in a transport medium composed of equal amounts of glycerol and 0.04 M phosphate buffer, pH 7.2–7.6, preferably with added antibiotics (penicillin [1000 International Units (IU)], neomycin sulphate [100 IU], polymyxin B sulphate [50 IU], mycostatin [100 IU]). If 0.04 M phosphate buffer is not available, tissue culture medium or phosphate buffered saline (PBS) can be used instead, but it is important that the final pH of the glycerol/buffer mixture be in the range pH 7.2–7.6. FMD virus is extremely labile in low pH and buffering of the transport media is critical for successful sample collection. Samples should be kept refrigerated or on ice until received by the laboratory.

Where epithelial tissue is not available from ruminant animals, for example in advanced or convalescent cases, or where infection is suspected in the absence of clinical signs, samples of OP fluid can be collected by means of a probang (sputum) cup (or in pigs by swabbing the throat) for submission to a laboratory for virus isolation or reverse-transcription polymerase chain reaction (RT-PCR). Viraemia may also be detected by examining serum samples by means of RT-PCR or virus isolation. For the collection of throat swabs from pigs, the animal should be held on its back in a wooden cradle with the neck extended. Holding a swab in a suitable instrument, such as an artery forceps, the swab is pushed to the back of the mouth and into the pharynx.

Before the collection of OP samples from cattle or large ruminants (e.g. buffaloes), 2 ml transport fluid (composed of 0.08 M phosphate buffer containing 0.01% bovine serum albumin, 0.002% phenol red, antibiotics [1000 units/ml penicillin, 100 units/ml mycostatin, 100 units/ml neomycin, and 50 units/ml polymyxin], and adjusted to pH 7.2) should be added to a container of around 5 ml capacity capable of withstanding freezing above solid carbon dioxide (dry ice) or liquid nitrogen.

An OP sample is collected by inserting a probang over the tongue into the oro-pharyngeal area and then passing it vigorously backwards and forwards 5–10 times between the first portion of the oesophagus and the back of the pharynx. The purpose is to collect oro-pharyngeal fluid and especially superficial epithelial cells from these areas, including the proximal part of the oesophagus, the walls of the pharynx, the tonsillar crypts and the surfaces of the soft palate. If the sample does not contain adequate cellular debris the actions may be repeated.

After collection of OP fluid by probang, the contents of the cup should be poured into a wide-necked transparent bottle of around 20 ml capacity. The fluid is examined, and should contain some visible cellular material. Of this, 2 ml is then added to the 2 ml of transport fluid, ensuring that cellular material is transferred; the mixture is shaken gently and should

have a final pH of around pH 7.6. Samples contaminated with ruminal contents may be unsuitable for culture. Samples seen to contain blood are not entirely satisfactory. Repeat sampling can be done after the mouth and throat of the animal have been rinsed with water or PBS. Where several animals are to be sampled the probang must be cleaned and disinfected between each animal. This is done by washing the probang in tap water, then immersing it in a suitable disinfectant (e.g. 0.5% [w/v] citric acid in tap water) and then rinsing off the disinfectant well with water before sampling the next animal.

OP samples from small ruminants are collected by putting 2 ml of transport fluid into a wide-necked bottle of about 20 ml capacity and, after collection, rinsing the probang cup in this transport fluid to discharge the OP sample. This is then transferred to a container of about 5 ml capacity for transport. The small container should be capable of withstanding freezing above solid carbon dioxide or liquid nitrogen (36).

Samples of OP fluid should be refrigerated or frozen immediately after collection. If they are to remain in transit for more than a few hours, they should preferably be frozen by being placed either above solid carbon dioxide or liquid nitrogen. Before freezing, the containers should be carefully sealed using airtight screw caps or silicone. This is particularly important when using solid carbon dioxide, as introduction of CO_2 into the OP sample will lower its pH, inactivating any FMD virus that may be in the samples. Glass containers should not be used because there is a risk that they will explode on defrosting in the event of liquid nitrogen leaking into them. Samples should reach the laboratory preferably in a frozen state or, if this is not feasible, under refrigeration.

Special precautions are required when sending perishable suspect FMD material both within and between countries. The International Air Transport Association (IATA), Dangerous Goods Regulations (DGR) has explicit requirements for packaging and shipment of diagnostic specimens by all commercial means of transport. These are summarised in Chapter 1.1.1 Sampling methods.

1. Identification of the agent

A range of sample types including epithelium, OP samples and serum may be examined by virus isolation or RT-PCR. By contrast, ELISA is suited to the examination of epithelial suspensions, vesicular fluids or cell culture supernatants, but is insufficiently sensitive for the direct examination of OP samples or serum.

a) Virus isolation

The epithelium sample should be taken from the PBS/glycerol, blotted dry on absorbent paper to reduce the glycerol content, which is toxic for cell cultures, and weighed. A suspension should be prepared by grinding the sample in sterile sand in a sterile pestle and mortar with a small volume of tissue culture medium and antibiotics. Further medium should be added until a final volume of nine times that of the epithelial sample has been added, giving a 10% suspension. This is clarified on a bench centrifuge at 2000 ***g*** for 10 minutes. Once clarified, such suspensions of field samples suspected to contain FMD virus are inoculated onto cell cultures or into unweaned mice. Sensitive cell culture systems include primary bovine (calf) thyroid cells and primary pig, calf or lamb kidney cells. Established cell lines, such as BHK-21 (baby hamster kidney) and IB-RS-2 cells, may also be used but are generally less sensitive than primary cells for detecting low amounts of infectivity (19). The sensitivity of any cells used should be tested with standard preparations of FMD virus. The use of IB-RS-2 cells aids the differentiation of swine vesicular disease (SVD) from FMD (as SVD virus will only grow in this cell type) and is often essential for the isolation of porcinophilic strains, such as O Cathay. The cell cultures should be examined for cytopathic effect (CPE) for 48 hours. If no CPE is detected, the cells should be frozen and thawed, used to inoculate fresh cultures and examined for CPE for another 48 hours. Unweaned mice are an alternative to cell cultures and should be 2–7 days old and of selected inbred strains. Some field viruses may require several passages before they become adapted to mice (53). In the case of OP fluids, pre-treatment with an equal volume of chloro- fluoro- carbons may improve the rate of virus detection by releasing virus from immune complexes.

b) Immunological methods

- **Enzyme-linked immunosorbent assay**

The preferred procedure for the detection of FMD viral antigen and identification of viral serotype is the ELISA (28, 48). This is an indirect sandwich test in which different rows in multiwell plates are coated with rabbit antisera to each of the seven serotypes of FMD virus. These are the 'capture' sera. Test sample suspensions are added to each of the rows, and appropriate controls are also included. Guinea-pig antisera to each of the serotypes of FMD virus are added next, followed by rabbit anti-guinea-pig serum conjugated to an enzyme. Extensive washing is carried out between each stage to remove unbound reagents. A colour reaction on the addition of enzyme substrate and chromogen indicates a positive reaction. With strong positive reactions this will be evident to the naked eye, but results can also be read spectrophotometrically at an appropriate wavelength. In this case, an absorbance reading greater than 0.1 above background indicates a positive reaction; the serotype of FMD virus can also be identified. Values close to 0.1 should be confirmed by retesting or by amplification of the antigen by tissue culture passage and testing the supernatant once a CPE has developed. A suitable protocol is given below. Other protocols are available with slightly different formats and interpretation criteria (3, 6).

Depending on the species affected and the geographical origin of samples, it may be appropriate to simultaneously test for SVD virus or vesicular stomatitis (VS) virus. Ideally a complete differential diagnosis should be undertaken in all vesicular conditions.

Rabbit antiserum to the 146S antigen of each of the seven serotypes of FMD virus (plus SVD virus or VS virus if required) is used as a trapping antibody at a predetermined optimal concentration in carbonate/bicarbonate buffer, pH 9.6.

Control antigens are prepared from selected strains of each of the seven types of FMD virus (plus SVD virus or VS virus if appropriate) grown on monolayer cultures of BHK-21 cells (IB-RS-2 cells for SVD or VS virus). The unpurified supernatants are used and pretitrated on ELISA plates. The final dilution chosen is that which gives an absorbance at the top of the linear region of the titration curve (optical density approximately 2.0), so that the five-fold dilutions of the control antigens used in the test give two additional lower optical density readings from which the titration curve can be derived. PBS containing 0.05% Tween 20 and phenol red indicator is used as a diluent (PBST).

Guinea-pig antisera prepared by inoculating guinea-pigs with 146S antigen of one of the seven serotypes of FMD virus (plus SVD virus if required) and preblocked with normal bovine serum (NBS) is used as the detecting antibody. Predetermined optimal concentrations are prepared in PBS containing 0.05% Tween 20, and 5% dried, nonfat skimmed milk (PBSTM).

Rabbit (or sheep) anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase and preblocked with NBS is used at a predetermined optimum concentration in PBSTM. As an alternative to guinea-pig or rabbit antisera, suitable monoclonal antibodies (MAbs) can be used coated to the ELISA plates as capture antibody or peroxidase-conjugated as detecting antibody.

- **Test procedure**

i) ELISA plates are coated with 50 µl/well rabbit antiviral sera in 0.05 M carbonate/bicarbonate buffer, pH 9.6. Rows A to H receive, respectively, antisera to serotypes O, A, C, SAT 1, SAT 2, SAT 3, Asia 1 and SVD virus or VS virus (optional).

ii) Leave overnight at 4°C in a stationary position or place on an orbital shaker set at 100–120 revolutions per minute in a 37°C incubator for 1 hour.

iii) Prepare test sample suspension (with 10% original sample suspension or undiluted clarified cell culture supernatant fluid).

iv) The ELISA plates are washed five times in PBS.

v) On each plate, load wells of columns 4, 8 and 12 with 50 µl PBST. Additionally, add 50 µl of PBST to wells 1, 2 and 3 of rows A to H on plate 1. To well 1 of row A of plate 1 add 12.5 µl of control antigen type O, to well 1 of row B add 12.5 µl of control antigen type A; continue in this manner for control antigen of types C, SAT 1, SAT 2, SAT 3, Asia 1 and SVDV or VS (if appropriate) in order to well 1, rows C to H. Mix diluent in well 1 of rows A to H and transfer 12.5 µl from well 1 to 2 (rows A to H), mix and transfer 12.5 µl from well 2 to 3, mix and discard 12.5 µl from well 3 (rows A to H) (this gives a five-fold dilution series of each control antigen). It is only necessary to change pipette tips on the micropipette between antigens. The remainder of the plate can be loaded with the test sample(s). Add 50 µl of sample one to wells 5, 6 and 7 of rows A to H, the second sample is placed similarly in columns 9, 10 and 11, rows A to H.

   If more than two samples are to be tested at the same time, the other ELISA plates should be used as follows:

   Dispense 50 µl of the PBST to the wells (rows A to H) of columns 4, 8 and 12 (buffer control columns). Note that the control antigens are not required on these plates. These test samples may be added in 50 µl volumes in rows A to H to columns 1, 2, 3; 5, 6, 7; 9, 10, 11, respectively.

vi) Cover with lids and place on an orbital shaker at 37°C for 1 hour.

vii) Wash the plates by flooding with PBS – wash three times as before and empty residual wash fluid. Blot the plates dry.

viii) Transfer 50 µl volumes of each guinea-pig serum dilution to each plate well in the appropriate order, e.g. rows A to H receive, respectively, antisera to serotypes O, A, C, SAT 1, SAT 2, SAT 3, Asia 1 and SVD virus or VS virus (optional).

ix) Cover the plates with lids and replace on the orbital shaker. Incubate at 37°C for 1 hour.

x) The plates are washed again three times, and 50 µl of rabbit anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase is added to each well. The plates are incubated at 37°C for 1 hour on a rotary shaker.

xi) The plates are washed again three times, and 50 µl of substrate solution, containing 0.05% % H_2O_2 plus orthophenylene diamine or a suitable alternative chromogen, is added to each well.

xii) The reaction is stopped after 15 minutes by the addition of 50 µl of 1.25 M sulphuric acid. The plates are read at 492 nm on a spectrophotometer linked to a computer.

- **Complement fixation test**

In general, the ELISA is preferable to the complement fixation (CF) test because it is more sensitive and it is not affected by pro- or anti-complementary factors. If ELISA reagents are not available, the CF test may be performed as follows:

Antisera to each of the seven types of FMD virus are diluted in veronal buffer diluent (VBD) in 1.5-fold dilution steps from an initial 1/16 dilution to leave 25 µl of successive antiserum dilutions in U-shaped wells across a microtitre plate. To these are added 50 µl of 3 units of complement, followed by 25 µl of test sample suspension(s). The test system is incubated at 37°C for 1 hour prior to the addition of 25 µl of 1.4% standardised sheep red blood cells (SRBC) in VBD sensitised with 5 units of rabbit anti-SRBC. The reagents are incubated at 37°C for a further 30 minutes and the plates are subsequently centrifuged and read. Appropriate controls for the test suspension(s), antisera, cells and complement are included. CF titres are expressed as the reciprocal of the serum dilution producing 50% haemolysis. A CF titre ≥36 is considered to be a positive reaction. Titre values of 24 should be confirmed by retesting an antigen that has been amplified through tissue culture passage.

c) Nucleic acid recognition methods

The PCR can be used to amplify the genome fragments of FMD virus in diagnostic material (7, 13). RT-PCR can be used to amplify genome fragments of FMD virus in diagnostic materials including epithelium, milk, serum and OP samples (7, 13). RT combined with real-time PCR has a sensitivity comparable to that of virus isolation (2, 46) and automated procedures enhance sample throughput (47). Specific primers have been designed to distinguish between each of the seven serotypes. *In situ* hybridisation techniques have been developed for investigating the presence of FMD virus RNA in tissue samples (59). These techniques are only in use in specialised laboratories, although simplified systems for potential field-use are under development (18). These techniques are increasingly being used.

- **Real-time RT-PCR assay**

The procedure used at the OIE Reference Laboratory at Pirbright is described. The RT-PCR assay consists of the three successive procedures of extraction of total RNA or nucleic acid from the test or control sample followed by RT of the extracted RNA/nucleic acid and PCR amplification of the RT product.

- **Test procedure**

i) Add 200 µl of test sample to 1 ml of TRIzol® Reagent in a sterile tube. Store at –70°C until required for RNA extraction.

ii) Transfer 1 ml of the solution from i) into a fresh, sterile tube containing 200 µl of chloroform. Vortex mix for about 10–15 seconds and leave at room temperature for 3 minutes.

iii) Centrifuge for 15 minutes at 20,000 ***g***.

iv) Transfer 500 µl of the aqueous phase into a fresh, sterile tube containing 1 µl of glycogen (20 mg/ml) and add 500 µl of iso-propyl-alcohol (propan-2-ol). Vortex mix for a few seconds.

v) Leave at room temperature for 10 minutes then centrifuge for 10 minutes at 20,000 ***g***.

vi) Discard the supernatant fluid from each tube and add 1 ml of 70% ethanol. Vortex mix for a few seconds.

vii) Centrifuge for 10 minutes at 20,000 ***g***.

viii) Carefully remove the supernatant fluid from each tube taking care not to dislodge or lose any pellet at the bottom of the tube.

ix) Air dry each tube at room temperature for 2–3 minutes.

x) Re-suspend each pellet by adding 20 µl of nuclease-free water to the tube.

xi) Keep the extracted RNA samples on ice if the RT step is about to be performed. Otherwise store at –70°C.

xii) For each sample to be assayed, add 2 µl of random hexamers (20 µg/ml) and 5 µl of nuclease-free water into a sterile 0.5 ml microcentrifuge tube. It is recommended to prepare the dilution in bulk for the total number of samples to be assayed but allowing for one extra sample.

xiii) Add 5 µl of RNA from the extraction procedure described above to give a volume of 12 µl in each tube. Mix by gently pipetting up and down.

xiv) Incubate at 70°C for 5 minutes.

xv) Cool at room temperature for 10 minutes.

xvi) During the 10-minute incubation period, prepare the RT reaction mixture described below for each sample. Prepare the reaction mixture in bulk in a sterile 1.5 ml microcentrifuge tube for the number of samples to be assayed plus one extra sample.

First strand buffer, 5× conc. (4 µl); bovine serum albumin (acetylated), 1 mg/ml (2 µl); dNTPs, 10 mM mixture each of dATP, dCTP, dGTP, dTTP (1 µl); DTT, 1M (0.2 µl); Moloney Murine Reverse Transcriptase, 200 U/ µl (1 µl).

xvii) Add 8 µl reaction mix to the 12 µl of random primer/RNA mix. Mix by gently pipetting.

xviii) Incubate at 37°C for 45 minutes.

xix) Keep the RT products on ice if the PCR amplification step is about to be performed. Otherwise store at –20°C.

xx) Prepare the PCR mix described below for each sample. Again it is recommended to prepare the mix in bulk for the number of samples to be tested plus one extra sample.

Nuclease-free water (6 µl); PCR reaction master mix, 2× conc. (12.5 µl); primer 1, 10 pmol/µl (2.25 µl); primer 2, 10 pmol/µl (2.25 µl); TaqMan® probe, 5 pmol/µl (1 µl).

xxi) Add 24 µl PCR reaction mix to a well of a real-time PCR plate for each sample to be assayed followed by 1 µl of the RT product to give a final reaction volume of 25 µl.

xxii) Spin the plate for 1 minute in a suitable centrifuge to mix the contents of each well.

xxiii) Place the plate in a real-time PCR machine for PCR amplification and run the following programme:

One cycle at 50°C for 2 minutes.

One cycle at 95°C for 10 minutes.

50 cycles at 95°C for 15 seconds, 60°C for 1 minute.

xxiv) *Reading the results:* Assign a threshold cycle (CT) value to each PCR reaction from the amplification plots (a plot of the fluorescence signal versus cycle number; different cut-off values may be appropriate for different sample types; 46). The CT values used to assign samples as either FMDV positive or negative should be defined by individual laboratories using appropriate reference material. For example at the OIE Reference Laboratory at Pirbright, negative test samples and negative controls should have a CT value at >50.0. Positive test samples and positive control samples should have a CT value <40. Samples with CT values falling within the range 40–50 are designated “borderline” and can be re-tested. Strong positive FMD samples have a CT value below 20.0 (46).

- **Stock solutions**

i) Nuclease-free water, TRIzol® Reagent, chloroform, glycogen, iso-propyl-alcohol (propan-2-ol), ethanol, random hexanucleotide primers, First strand buffer, BSA (acetylated), dNTPs, DTT, Moloney Murine Reverse Transcriptase and TaqMan® PCR reaction mix (2×) are commercially available.

ii) Primers at a concentration of 10 pmol/µl: Primer 1 sequence 5’-CACYT-YAAGR-TGACA-YTGRT-ACTGG-TAC-3’ (positive strand); Primer 2 sequence 5’-CAGAT-YCCRA-GTGWC-ICITG-TTA-3’ (negative strand).

iii) TaqMan® probe at a concentration of 5 pmol/µl: 5’-CCTCG-GGGTA-CCTGA-AGGGC-ATCC-3’.

Procedures describing the automated extraction of total nucleic acid from test and control samples followed by automated pipetting programmes for the RT and PCR assay of samples in 32- or 96-well plates are available (47) as an alternative to the described non-automated procedures for extraction of total RNA from samples, RT and PCR amplification (46).

The molecular epidemiology of FMD is based on the comparison of genetic differences between viruses. Dendrograms showing the genomic relationship between vaccine and field strains for all seven serotypes based on sequences derived from the 1D gene (encoding the VP1 viral protein) have been published. Reverse-transcription PCR (RT-PCR) amplification of FMD virus RNA, followed by nucleotide sequencing, is the current preferred option

for generating the sequence data to perform these comparisons. Many laboratories have developed techniques for performing these studies, and reference laboratories hold databases containing over 3000 partial sequences.

The recommended method is to:

i) Extract FMD virus RNA directly from epithelial suspensions or from a low cell culture passage.

ii) Perform an RT-PCR of the complete 1D gene (or if only part of the 1D gene, then the 3' end of the gene is more useful).

iii) Determine the nucleotide sequence of the PCR product (or at least 170 nucleotides [preferably 420 for the SAT types] at the 3' end of the gene).

A protocol, complete with primer sequences, is available from the OIE Reference Laboratories on request or can be downloaded from the following World Wide Web URLs:

http://www.iah.bbsrc.ac.uk/virus/picornaviridae/aphthovirus/fmd.htm

http://bvs.panaftosa.org.br/textoc/SerManDid17.pdf

2. Serological tests

Serological tests for FMD are performed in support of four main purposes namely: 1) to certify individual animals prior to import or export (i.e. for trade); 2) to confirm suspected cases of FMD; 3) to substantiate absence of infection; 4) to demonstrate the efficacy of vaccination. For substantiating freedom from infection, different approaches are required according to whether the population has been vaccinated or not and if vaccination has been used, whether this has been applied as an emergency application or as part of an ongoing programme of vaccination. Different tests and different interpretations of test results will be appropriate according to the above-mentioned purposes and the validation of the selected procedure must take account of the purpose. For example, test cut-offs may be set at a different threshold for herd-based serosurveillance than is appropriate for certifying freedom from infection for individual animals for the purposes of international trade.

Serological tests for FMD are of two types; those that detect antibodies to viral structural proteins (SP) and those that detect antibodies to viral nonstructural proteins (NSPs).

SP tests are serotype-specific and detect antibodies elicited by vaccination and infection; examples are the virus neutralisation (VN) test (32), the solid-phase competition ELISA (SPCE; 38, 43) and the liquid-phase blocking ELISA (LPBE; 33, 34). These tests are serotype-specific and are highly sensitive, providing that the virus or antigen used in the test is closely matched to the strain circulating in the field. They are the prescribed tests for trade and are appropriate for confirming previous or ongoing infection in non-vaccinated animals as well as for monitoring the immunity conferred by vaccination in the field. The VN test requires cell culture facilities and takes 2–3 days to provide results. The ELISA tests are blocking- or competition-based assays that use serotype-specific polyclonal or monoclonal antibodies, are quicker to perform and are not dependent on tissue culture systems and the use of live viruses. Low titre false-positive reactions can be expected in a small proportion of the sera in either ELISA test. An approach combining screening by ELISA and confirming the positives by the VN test minimises the occurrence of false-positive results. Reference sera to standardise FMD SP serological tests for some serotypes and subtypes are available from the Reference Laboratory at Pirbright.

The detection of antibody to the NSPs of FMD virus can be used to identify past or present infection with any of the seven serotypes of the virus, whether or not the animal has also been vaccinated. Therefore the tests can be used to confirm suspected cases of FMD and to detect viral activity or to substantiate freedom from infection on a population basis. For certifying animals for trade, the tests have the advantage over SP methods that the serotype of virus does not have to be known. However, there is experimental evidence that some cattle, vaccinated and subsequently challenged with live virus and confirmed persistently infected, may not be detected in some anti-NSP tests, causing false-negative results (31). These assays measure antibody to NSPs using antigens produced by recombinant techniques in a variety of *in-vitro* expression systems. Antibody to the polyproteins 3AB or 3ABC are generally considered to be the most reliable indicators of infection (10, 13, 33, 34, 41). In animals seropositive for antibody to 3AB or 3ABC, antibody to one or more of the other NSPs can aid in the final interpretation of the test (10, 11, 33, 37, 41). However, lack of vaccine purity may affect diagnostic specificity as the presence of NSPs in some vaccine preparations may result in misclassification in animals that have been repeatedly vaccinated. Procedures for evaluating vaccine purity are covered in Section D of this chapter.

International standard sera for NSP testing of cattle have been developed and are available from the OIE Reference Laboratory, Panaftosa, PAHO/WHO. In the future, standard sera will also be made available for sheep and pigs. Bovine serum panels have been established to compare the sensitivity of NSP tests at OIE Reference Laboratories.

a) Virus neutralisation test (a prescribed test for international trade)

The quantitative VN microtest for FMD antibody is performed with IB-RS-2, BHK-21, lamb or pig kidney cells in flat-bottomed tissue-culture grade microtitre plates.

Stock virus is grown in cell monolayers and stored at –20°C after the addition of 50% glycerol. (Virus has been found to be stable under these conditions for at least 1 year.) The sera are inactivated at 56°C for 30 minutes before testing. The control standard serum is 21-day convalescent or post-vaccination serum. A suitable medium is Eagle's complete medium/LYH (Hank's balanced salt solution with yeast lactalbumin hydrolysate) with hepes buffer and antibiotics.

The test is an equal volume test in 50 µl amounts.

- **Test procedure**

i) Starting from a 1/4 dilution, sera are diluted in a twofold, dilution series across the plate, using at least two rows of wells per serum , preferably four rows, and a volume of 50 µl.

ii) Previously titrated virus is added; each 50 µl unit volume of virus suspension should contain about 100 $TCID_{50}$ (50% tissue culture infective dose) within an accepted range (e.g. 32–320 $TCID_{50}$)

iii) Controls include a standard antiserum of known titre, a negative serum, a cell control, a medium control, and a virus titration used to calculate the actual virus titre used in the test.

iv) Incubate at 37°C for 1 hour with the plates covered.

v) A cell suspension at 10^6 cells/ml is made up in medium containing 10% bovine serum (specific antibody negative) for cell growth. A volume of 50 µl of cell suspension is added to each well.

vi) Plates are sealed with pressure-sensitive tape and incubated at 37°C for 2–3 days. Alternatively, the plates may be covered with loosely fitting lids and incubated in an atmosphere of 3–5% carbon dioxide at 37°C for 2–3 days.

vii) Microscope readings may be feasible after 48 hours. The plates are finally fixed and stained routinely on the third day . Fixation is effected with 10% formol/saline for 30 minutes. For staining, the plates are immersed in 0.05% methylene blue in 10% formalin for 30 minutes. An alternative fixative/stain solution is naphthalene blue black solution (0.4% [w/v] naphthalene blue black, 8% [w/v] citric acid in saline) (32). The plates are rinsed in tap water.

viii) Positive wells (where the virus has been neutralised and the cells remain intact) are seen to contain blue-stained cells sheets; the negative wells (where virus has not been neutralised) are empty. Titres are expressed as the final dilution of serum present in the serum/virus mixture where 50% of wells are protected (Kärber). The test is considered to be valid when the amount of virus used per well is in the range $\log_{10}$ 1.5–2.5 $TCID_{50}$, and the positive standard serum is within twofold of its expected titre.

ix) Interpretation of tests can vary between laboratories in regard to the negative/positive cut-off threshold. Laboratories should establish their own criteria by reference to standard reagents that can be obtained from the OIE Reference Laboratory at Pirbright. In general, a titre of 1/45 or more of the final serum dilution in the serum/virus mixture is regarded as positive. A titre of less than 1/16 is considered to be negative. For certification of individual animals for the purposes of international trade, titres of 1/16 to 1/32 are considered to be doubtful, and further serum samples may be requested for testing; results are considered to be positive if the second sample has a titre of 1/16 or greater. For the purposes of herd-based serosurveillance as part of a statistically valid serological survey, a cut-off of 1/45 may be appropriate. Cut-off titres for evaluating immunological protection afforded by vaccination have to be established from experience of potency test results with the relevant vaccine and target species.

b) Solid-phase competition enzyme-linked immunosorbent assay (a prescribed test for international trade)

Rabbit antiserum to the 146S antigen of one of the seven types of FMD virus is used as the trapping antibody at a predetermined optimal concentration in carbonate/bicarbonate buffer, pH 9.6.

Antigens are prepared by inactivating viruses propagated in cell culture with ethyleneimine using the procedures described for vaccine manufacture. The final dilution chosen is that which, after addition of an equal volume of diluent, gives an absorbance on the upper part of the linear region of the titration curve (optical density approximately 1.5). PBS containing 0.05% Tween 20, 10% normal bovine serum and 5% normal rabbit serum and phenol red indicator is used as a diluent (blocking buffer).

Guinea-pig antisera, prepared by inoculating guinea-pigs with 146S antigen of one of the seven serotypes and preblocked with normal bovine serum, is used as the detecting antibody. Predetermined optimal concentrations are prepared in blocking buffer PBS containing 0.05% Tween 20, and 5% dried, nonfat skimmed milk (PBSTM).

Rabbit (or sheep) anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase and preblocked with NBS is used as conjugate at a predetermined optimum concentration in PBSTM. blocking buffer.

Test sera are diluted in PBST blocking buffer.

Collaborative studies have shown that the solid-phase competitive ELISA is more specific but as sensitive as the liquid-phase blocking ELISA (38).

- **Test procedure**

i) ELISA plates are coated with 50 µl/well rabbit anti-FMD virus antigen diluted in carbonate/bicarbonate buffer, pH 9.6, and left overnight in a humid chamber at 4°C.

ii) The ELISA plates are washed three times with PBS.

iii) Then 50 µl of the FMD virus antigen diluted in blocking buffer is added to each well of the ELISA plates. (Blocking buffer: 0.05% [w/v] Tween 20, 10% [v/v] normal bovine serum, 5% [v/v] normal rabbit serum.) The plates are covered and placed on an orbital shaker at 37°C for 1 hour, with continuous shaking.

iv) After washing three times with PBS, 40 µl of blocking buffer is added to each well, followed by 10 µl of test sera (or control sera), giving an initial serum dilution of 1/5.

v) Immediately 50 µl of guinea-pig anti-FMD virus antiserum diluted in blocking buffer is added, giving a final serum dilution of 1/10.

vi) The plates are covered and incubated on an orbital shaker at 37°C for 1 hour.

vii) After washing three times with PBS, 50 µl of anti-guinea-pig Ig conjugate (pre-blocked by incubation for 1 hour at room temperature with an equal volume of NBS) diluted in blocking buffer is added. The plates are covered and incubated for 1 hour at 37°C on an orbital shaker.

viii) After washing three times with PBS, 50 µl of substrate solution, containing 0.05% H_2O_2 plus orthophenylene diamine or a suitable alternative chromogen, is added to each well.

ix) The reaction is stopped after 10 minutes by the addition of 50 µl of 1 M sulphuric acid. The plates are read at 492 nm on a spectrophotometer linked to a computer.

x) *Controls:* On each plate two wells are used for conjugate control (no guinea-pig serum), four wells each for strong and weak positive sera, two wells for negative sera, and four wells for 0% competition (no test sera).

xi) *Interpretation of the results:* A percentage of inhibition is calculated for each well, either manually or using a suitable computer programme (100 – [optical density of each test or control value/mean optical density of the 0% competition] × 100%), representing the competition between the test sera and the guinea-pig anti-FMD virus antisera for the FMD virus antigen on the ELISA plate. Laboratories should validate the assay in terms of the cut-off value above which sera should be considered positive in relation to (i) the particular serotypes and strains of virus under investigation (ii) the purpose of testing (iii) the population under test, using the methods described in Chapter 1.1.3. At the OIE Reference Laboratory at Pirbright, for serotype O, for all species, for the purposes of demonstrating freedom from infection in a naïve population, greater than 60% inhibition is considered positive (38). For maximum sensitivity, for example when certifying individual animals for international trade, an inconclusive range may be set between 40 and 60%.

c) Liquid-phase blocking enzyme-linked immunosorbent assay (a prescribed test for international trade)

Antigens are prepared from selected strains of FMD virus grown on monolayers of BHK-21 cells. The unpurified supernatants are used and pretitrated in a twofold dilution series but without serum. The final dilution chosen is that which, after addition of an equal volume of diluent (see below), gives an absorbance on the upper part of the linear region of the titration curve (optical density approximately 1.5). PBS containing 0.05% Tween 20 and phenol red indicator is used as a diluent (PBST). The other reagents used in the test are the same as those in the solid-phase blocking ELISA. An example of the test procedure is described below. Temperature and incubation times can vary depending on the protocol.

- **Test procedure**

i) ELISA plates are coated with 50 µl/well rabbit antisera to the 14S antigen being tested for and left overnight in a humid chamber at room temperature.

ii) The ELISA plates are washed three times with PBS.

iii) In U-bottomed multiwell plates (carrier plates) 50 µl of a duplicate, twofold series of each test serum is prepared, starting at 1/8. To each well, 50 µl of a constant dose of viral antigen that is homologous to the rabbit antisera used to coat the plates is added and the mixtures are left overnight at 4°C, or incubated at 37°C for 1 hour. The addition of the antigen increases the final serum dilution to 1/16.

iv) Then 50 µl of serum/antigen mixtures is transferred from the carrier plates to the rabbit-serum coated ELISA plates and the plates are incubated at 37°C for 1 hour on a rotary shaker.

v) After washing, 50 µl of guinea-pig antiserum homologous to the viral antigen used in the previous step (iv) (pre-blocked with normal bovine serum and diluted in PBST containing 5% skimmed milk powder) is added to each well. The plates are then incubated at 37°C for 1 hour on a rotary shaker.

vi) The plates are washed and 50 µl of rabbit anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase (pre-blocked with normal bovine serum and diluted in PBST containing 5% skimmed milk powder) is added to each well. The plates are incubated at 37°C for 1 hour on a rotary shaker.

vii) The plates are washed again three times and 50 µl of substrate solution, containing 0.05% H_2O_2 plus orthophenylene diamine or a suitable alternative chromogen, is added to each well.

viii) The reaction is stopped after 15 minutes by the addition of 50 µl of 1 M sulphuric acid. The plates are read at 492 nm on a spectrophotometer linked to a computer.

ix) *Controls:* A minimum of four wells each of strong positive, weak positive and negative bovine reference sera at a final dilution of 1/32 should be included on each plate together with an equivalent number of reaction (antigen) control wells containing antigen in diluent alone without serum. For end-point titration tests, duplicate twofold dilution series of positive and negative homologous bovine reference sera should be included on at least one plate of every run.

x) *Interpretation of the results:* Antibody titres are expressed as the 50% end-point titre, i.e. the dilution at which the reaction of the test sera results in an optical density equal to 50% inhibition of the median optical density of the reaction (antigen) control wells (Kärber). The median is calculated as the mean of two mid-values of the reaction control wells, eliminating from the calculation the highest and lowest values (alternatively, the mean value can be used after setting suitable tolerance limits to control for inter-well variation). In general sera with titres greater than or equal to 1/90 are considered to be positive. A titre of less than 1/40 is considered to be negative. For certification of individual animals for the purposes of international trade, titres of greater than 1/40, but less than 1/90 are considered to be doubtful, and further serum samples may be requested for testing; results are considered to be positive if the second sample has a titre of 1/40 or greater. For the purposes of herd-based serosurveillance as part of a statistically valid serological survey, a cut-off of 1/90 may be appropriate. Cut-off titres for evaluating immunological protection afforded by vaccination have to be established from experience of potency test results with the relevant vaccine and target species.

d) Nonstructural protein antibody tests

Antibody to expressed recombinant FMD virus NSPs can be measured by different ELISA formats or immunoblotting. These ELISAs either use purified antigens absorbed directly to microplates or use polyclonal or monoclonal antibodies to trap specific antigens from semi-purified preparations (14, 20, 39, 54). The index screening method used in Panaftosa is described in detail below. Other indirect and competitive ELISAs detecting bovine antibodies to 3ABC have been shown to have equivalent diagnostic performance characteristics (17). This same study corroborates preliminary data from Panaftosa that suggests that the diagnostic performance characteristics of these tests are similar in cattle, sheep and pigs.

- **Indirect enzyme-linked immunosorbent assay**

  - **Preparation of recombinant antigens (see Section B.2.d Enzyme-linked immunoelectrotransfer blot assay below)**

  - **Test procedure**

i) Microplates are coated overnight at 4°C with 1 µg/ml of the fusion antigen 3ABC in carbonate/ bicarbonate buffer, pH 9.6 (100 µl per well). Antigen 3ABC was expressed and purified as indicated for the EITB tests (42).

ii) The plates are washed six times with PBS, pH 7.2, supplemented with 0.05% Tween 20 (PBST).

iii) Test sera (100 µl per well) are added in a 1/20 dilution in blocking buffer consisting of PBS, 0.05% Tween 20, 5% nonfat dry milk, 10% equine sera and 0.1% *Escherichia coli* lysate. Each plate includes a set of strong and weak positive and negative controls calibrated against the International Standard Sera described below.

iv) The plates are incubated for 30 minutes at 37°C and washed six times in PBST.

v) Horseradish-peroxidase-conjugated rabbit anti-species IgG is diluted optimally in the blocking buffer, added at 100 µl per well and the plates are incubated for 30 minutes at 37°C.

vi) After six washings, each well is filled with 100 µl of 3'3', 5'5'-tetramethylbenzidine plus 0.004% (w/v) H_2O_2 in phosphate/citrate buffer, pH 5.5.

vii) The reaction is stopped after 15 minutes of incubation at room temperature by adding 100 µl of 0.5 M H_2SO_4. Absorbance is read at 450 nm and at 620 nm for background correction.

viii) *Interpreting the results:* Test results are expressed as per cent positivity relative to the strong positive control [(optical density of test or control wells/optical density of strong positive control) × 100] or alternatively as a test to control (T/C) index relative to a cut-off (i.e. threshold positive) control. Profiling the NSP antibody reactivity levels in herds along with age/vaccination stratification aids interpretation of herd infection status in vaccinated populations (15). Test cut-off values, with or without suspicious zones, need to be determined considering the purpose of testing and the intended target population. Inconclusive results may be followed up using confirmatory tests. In case of multi- vaccinated animals, EITB is the recommended approach, whereas, in animals that have received only one or two vaccinations, inconclusive results are resolved and positive results confirmed by retesting with a second NSP ELISA (taking account of the conditional dependence of the two tests). This must take into account the overall test system sensitivity and specificity when designing the serosurveillance programme (44). Although not a prescribed test for trade, NSP ELISAs may be a valuable adjunct in circumstances where the serotype or subtype of virus in the originating country is not known.

- **Enzyme-linked immunoelectrotransfer blot assay (EITB)**

The EITB assay has been widely applied in South America as a confirmatory test for the above-described index screening method. Further information is available from the OIE Reference Laboratory, Panaftosa, PAHO/WHO.

- **Preparation of test strips containing the recombinant antigens**

i) The five bioengineered FMD virus NSPs 3A, 3B, 2C, 3D and 3ABC are expressed in *E. coli* C600 by thermo-induction. The 3D polypeptide is expressed in its complete form (42), whereas the rest of the proteins are obtained as fusions to the N-terminal part of the MS-2 polymerase gene (55).

ii) The expressed polymerase is purified over phosphocellulose, followed by poly(U) Sepharose columns. The fused proteins 3A, 3B, 2C and 3ABC are purified by sequential extraction of the bacterial extracts with increasing concentrations of urea. The 7M fraction containing the fusion proteins is further purified on a preparative 10% SDS-PAGE (sodium dodecyl sulphate-polyacrylamide gel electrophoresis). The fusion protein band is excised from the gel and electroeluted (42).

iii) A mixture containing 20 ng/ml of each one of the purified recombinant polypeptides is separated on 12.5% SDS-PAGE and electrophoretically transferred to nitrocellulose (42).

- **Test procedure**

i) The required amount of test strips should be assessed, taking into account that for each nitrocellulose sheet, which defines one transferred gel, a positive, a weakly positive, a cut-off and a negative control serum should be assayed. In general, 24 nitrocellulose strips, each 3 mm wide, should result from a gel.

ii) A volume of 0.8 ml of saturation buffer (50 mM Tris/HCl, pH 7.5; 150 mM NaCl; 0.2% Tween 20; 5% nonfat dry milk; and 0.05% bacterial *E. coli* lysate) is added to each well. The antigen-coated strips are blocked by placing the trays on a rocker and agitating for 30 minutes at room temperature (20–22°C).

iii) A dilution of 1/200 of test sera and of each of the controls is added to the appropriate trough. The strips must be completely submerged and facing upwards, and maintained in that position during the whole process.

iv) Strips are incubated for 60 minutes on a rocker at room temperature.

v) Liquid is removed from the trays, and each test strip is washed three times with washing solution (50 mM Tris/HCl, pH 7.5; 150 mM NaCl; and 0.2% Tween 20) by agitation for 5 minutes.

vi) The alkaline-phosphatase-conjugated rabbit anti-bovine solution is added to each test well, and the strips are incubated with shaking for 60 minutes at room temperature.

vii) The liquid is removed from the trays and each test strip is washed three times with washing solution as above.

viii) Substrate solution (0.015% bromochloroindolylphosphate/0.03% nitroblue tetrazolium) is prepared in substrate buffer (100 mM NaCl; 5 mM $MgCl_2$; and 100 mM Tris/HCl, pH 9.3), and is added to each test well.

ix) Strips are incubated by placing the test tray on the orbital mixer and agitating until the cut-off control shows five distinct, discernible bands. Strips are washed with running deionised water and air-dried.

x) *Interpreting the results:* The EITB may be scanned with a densitometer but visual reading, although more subjective, is considered suitable as well. Individual control sera are run that exhibit minimal but consistent staining for each of the five antigens. A test sample is considered positive if antigens 3ABC, 3A, 3B and 3D (±2C) demonstrate staining densities equal to or higher than that of their appropriate controls. A sample is considered negative if two or more antigens demonstrate densities below their control sera. Test samples not fitting either profile are considered indeterminate.

C. VACCINE MATCHING TESTS

1. Introduction

Vaccination against one serotype of FMDV does not cross-protect against other serotypes and may also fail to protect fully or at all against other strains of the same serotype. The most direct and reliable method to measure cross-protection is to vaccinate relevant target species and then to challenge them by exposure to the virus isolate against which protection is required. This will take account of both potency and cross-reactivity. However, such an approach is slow and expensive, and the use of animals for such studies should be avoided where possible by the use of *in vitro* alternatives.

A variety of *in vitro* serological methods can be used to quantify antigenic differences between FMDV strains and thereby estimate the likely cross-protection between a vaccine strain and a field isolate. Genetic characterisation and antigenic profiling can also reveal the emergence of new strains for which vaccine matching may be required and, conversely, may indicate that an isolate is similar to one for which vaccine matching information is already available.

Appropriate vaccine strain selection is an important element in the control of FMD and is necessary for the application of vaccination programmes in FMD-affected regions as well as for the establishment and maintenance of vaccine antigen reserves to be used in the event of new FMD incursions.

Vaccine potency also contributes to the range of antigenic cover provided by a vaccine. A highly potent vaccine that stimulates a strong immune response may give greater protection against a heterologous virus than an equally cross-reactive vaccine that stimulates a weaker immune response. Furthermore, booster doses of vaccine can increase potency and the subsequent breadth of antigenic cover provided by a given vaccine, although the onset of full protection may be delayed.

2. Selection of field viruses for vaccine matching

Serological matching of field isolates to vaccine strains requires that isolates have been serotyped and adapted to growth in cell cultures. The serotype is usually determined by ELISA or CFT using type-specific serological reagents, although methods based on monoclonal antibodies or genetic typing may also be used. BHK or IB-RS-2 cell cultures are usually used for *in vitro* virus replication. For vaccine matching, preferably, at least two isolates should be evaluated from any outbreak and inconsistent results should be followed up to determine whether this is due to genuine antigenic differences or is an artefact of testing.

Viruses can be selected based on epidemiological information, for instance isolation at different stages of an epidemic, from different geographic locations or from different hosts (4). Field evidence for a suspected lack of vaccine efficacy, as shown by reduced apparent protection, is an important criterion for vaccine matching.

Antigenic profiling by CFT or ELISA, or sequence analysis of the VP1 gene, are suitable approaches for selecting representative virus isolates for vaccine matching. Antigenic profiling is performed by CFT using panels of hyperimmune guinea-pig sera raised against epidemiologically relevant field isolates (16) or by ELISA using panels of well-characterised monoclonal antibodies (5).

3. Selection of vaccine strains to be matched

The serotype of the virus, the region of origin and any information on the characteristics of the field isolate may give indications as to the vaccine strains most likely to provide an antigenic match. The availability of reagents for matching to particular vaccine strains may limit the extent of testing that is possible. Antigenic characterisation has two purposes;

first, to chose the most effective vaccine strain for use in a particular circumstance and, second, to monitor, on an ongoing basis, the suitability of vaccine strains maintained in strategic antigen reserves.

4. Choice of vaccine matching test

The serological relationship between a field isolate and a vaccine virus ('r' value) can be determined by CFT, ELISA or VNT (37, 45, 50). One way testing is recommended (r_1) with a vaccine antiserum, rather than two way testing (r_2) which also requires an antiserum against the field isolate to be matched. Due to the inherently low repeatability of the assays used, tests need to be repeated to be confident of the results (51). *In vitro* neutralisation may be more relevant to *in vivo* protection than other measures of virus-antibody interaction, although non-neutralising antibodies may also be protective (40). Advantages of ELISA are that the test is rapid and utilises smaller volumes of post-vaccination sera which are often available in only limited quantities. ELISA and CFT are recommended to be used as screening methods whereas VNT or the expected percentage of protection (EPP) method provide more definitive results. For either VNT or ELISA, post-vaccination sera are derived from at least five cattle 21–30 days after immunisation. The titre of antibody to the vaccine strain is established for each serum. Sera are used individually or pooled, after excluding low responders. The CFT method utilises guinea-pig sera.

A more thorough evaluation is provided by the Expected Percentage of Protection (EPP) method (4), which measures the reactivity of a panel of post-vaccination antisera using either VNT or ELISA and relates the serological titres to the probability of protection, established through correlation tables associating antibody titres with protection against the relevant vaccine strain. These correlation tables derive from previously performed vaccine-specific challenge tests. However, the requirement for a panel of antisera and accompanying challenge test data for the vaccine in question currently cannot be met for a wide range of vaccine strains.

a) Vaccine matching by ELISA

This test uses an antiserum raised against a vaccine strain. The blocking ELISA titres of this reference serum against antigens prepared from the homologous vaccine strain and are compared with the corresponding titres of the serum against a field isolate to determine how antigenically 'similar' the field virus is to the vaccine virus.

The test procedure is similar to that of the liquid phase blocking ELISA (see Section B.2.c). Additional biological reagents are: 21–30 day post-vaccination bovine vaccine sera (inactivated at 56°C for 45–60 minutes); the homologous vaccine strain; and the test virus, a field isolate of the same serotype as the vaccine strain

- **Test procedure**

i) Grow the field isolate and the vaccine strain in BHK or IB-RS-2 cells. The number of cell culture passages should be kept to a minimum (normally less than four) to avoid selection of antigenic variants unrepresentative of those in the original material. A sufficient quantity of virus should be present if cell cultures show CPE within 24 hours of inoculation.

ii) Harvest and titrate the vaccine and field viruses using a panel of trapping rabbit antisera and detector guinea pig antisera raised against the same or closely related vaccine strains. If necessary, the virus antigens may be inactivated prior to use using binary ethyleneimine.

iii) Select the optimum trapper/detector combination and the working dilution of the field virus. This should not be less than 1/6. If there is no suitable trapper/detector combination then a back-titration of the antigen stock must be performed to confirm that sufficient virus is present. If it is confirmed that the field virus is present at high tire, this indicates that none of the available vaccine strains are suitable.

iv) Titrate 21–30 day post-vaccination serum of a chosen vaccine strain against the field isolate and the homologous vaccine strain. The titre against the vaccine strain should not fluctuate more than two fold either side of the running mean value for the virus stock.

v) To determine the serum titre, calculate the average optical density (OD) of 24 antigen control wells without blocking serum. This represents the maximum OD value for the test, i.e. the 100% control value. Divide this by 2 to determine the 50% inhibition value. Score wells with blocking serum positive if the OD is less than or equal to 50% and negative if the OD value is greater than this. The end-point is defined as the dilution at which half of the wells show 50% inhibition or more (i.e. identify the dilution at which one out of the two duplicate wells has an OD less than 50% of the antigen control). If the end-point falls between two dilutions, it is taken as the mid-point between these dilutions, as estimated by the Spearmann–Kärber method.

Derive the 'r' value, the relationship between the field and the vaccine strain, as:

$$r_1 = \frac{\text{titre of reference serum against field virus}}{\text{titre of reference serum against vaccine virus}}$$

At least two consistent results are needed for acceptance.

vi) *Interpretation of the results:* for r_1 values derived by ELISA the following guidelines are used for interpretation (29):

0.4–1.0: Close relationship between field isolate and vaccine strain. A potent vaccine containing the vaccine strain is likely to confer protection.

0.2–0.39: The field isolate is antigenically related to the vaccine strain. The vaccine strain might be suitable for use if no closer match can be found provided that a potent vaccine is used and animals are preferably immunised more than once.

<0.2: The field isolate is only distantly related to the vaccine strain and the vaccine strain is unlikely to protect against challenge with the field isolate.

b) Vaccine matching by two-dimensional neutralisation test

This test also uses an antiserum raised against a vaccine strain. The titres of this serum against 100 $TCID_{50}$ of the homologous vaccine strain and the same dose of a field isolate are compared to determine how antigenically 'similar' the field virus is to the vaccine strain.

The procedure is similar to that of the microtitre plate virus neutralisation test (see Section B.2.a). Additional biological reagents are: 21–30 day post-vaccination bovine vaccine sera (inactivated at 56°C for 45–60 minutes); the homologous vaccine strain; and the test virus, a field isolate of the same serotype as the vaccine strain

i) Field isolates are passaged on cell cultures until adapted to give 100% CPE in 24 hours. Passages should be kept to a minimum. When adapted, determine the virus titre (log_{10} $TCID_{50}$/ml) by end-point titration.

ii) For each test and vaccine virus a chequerboard titration is performed of virus against vaccine serum along with a back-titration of virus alone. Cells are added and incubated at 37°C for 48–72 hours after which time CPE is assessed.

iii) Antibody titres of the vaccine serum against the vaccine strain and field isolate for each virus dose used are calculated using the Spearmann-Kärber method. The titre of the vaccine serum against 100 $TCID_{50}$ of each virus can then be estimated by regression. The relationship between the field isolate and the vaccine strain is then expressed as an 'r' value as described for vaccine matching by ELISA.

iv) *Interpretation of the results:* in the case of neutralisation, r_1 values greater than 0.3 indicate that the field isolate is sufficiently similar to the vaccine strain that use of the vaccine is likely to confer protection against challenge with the field isolate (49). Conversely, values less than 0.3 suggest that the field isolate is so different from the vaccine strain that the vaccine is unlikely to protect. In these cases, either the field isolate should be examined against alternative vaccine strains or, rarely, it will be necessary to adapt a suitable field isolate to become a new vaccine strain.

v) Tests should always be repeated more than once. The confidence with which 'r' values can be taken to indicate differences between strains is related to the number of times that the examination is repeated. In practice, a minimum of at least three repetitions is advised.

c) Vaccine matching by CFT

The relationship between a field isolate and a vaccine strain can also be determined by complement fixation using a guinea-pig antiserum raised against the relevant vaccine strain.

CFT 50% titres of this reference serum against antigens prepared from the homologous vaccine strain and a field isolate are compared to determine how antigenically 'similar' the field virus is to the homologous vaccine virus.

i) Field isolates are passaged on cell cultures until adapted to give 100% CPE in 24 hours. Passages should be kept to a minimum. When adapted, determine the virus titre that fixes 2.5 CFU_{50} (50% complement fixing units).

ii) A relationship is established by titration of the guinea-pig antisera through a twofold dilution series against 2.5 CFU_{50} of the homologous and heterologous antigens in veronal buffer diluent (VBD) or borate saline solution (BBS) placed in separate tubes. Four haemolysis units of complement are then added to each reaction.

iii) The test system is incubated at 37°C for 30 minutes prior to the addition of 2% of standardised sheep red blood cells (SRBC) in VBD or BSS sensitised with rabbit anti SRBC. Reagents are incubated at 37°C for a further 30 minutes and the tubes are subsequently centrifuged and read.

iv) The CF 50 titres are calculated by the Spearmann-Kärber method and an 'r' value is derived from the relationship between the reactivity of the field isolate and the vaccine strain, as:

$$r_1 = \frac{\text{Reciprocal titre of hyperimmune serum against field virus}}{\text{Reciprocal titre of hyperimmune serum against vaccine virus}}$$

v) *Interpretation of the results:* in the case of CFT, r_1 values greater than 0.25 indicate that the field isolate is sufficiently similar to the vaccine strain that use of the vaccine is likely to confer protection against challenge with the field strain (3).

d) Expected percentage of protection

The expected percentage of protection (EPP) estimates the likelihood that cattle would be protected against a challenge of 10,000 infective doses after a single or boosted vaccination.

i) Individual sera are required from 16 or 30 18–24 month-old cattle at 30 days post-vaccination and 30 days post-re-vaccination, using a full dose of the vaccine strain to be matched.

ii) This panel of sera is tested for antibody titres to the homologous FMD vaccine strain and the field isolate to be matched using VNT or LPB-ELISA (see Sections B.2.a and B.2.c).

iii) If necessary, the antigens used in the ELISA may be inactivated prior to use using binary ethyleneimine.

iv) The EPP is determined from the serological titre obtained, for each individual serum, by reference to predetermined tables of correlation between serological titres and clinical protection. The mean EPP is then calculated from the EPP for each individual serum.

v) The clinical protection data is derived from previously performed experiments carried out on hundreds of cattle that have been immunised using the vaccine strain in question and challenged with a homologous virus (similar to the PGP potency tests described in Section D.4.b). Each animal is scored as protected or not and tables of correlation based on logistic regression models are established between antibody titre and clinical protection.

vi) An EPP <75% (when sera from a group of 16 re-vaccinated animals are used) and < 70% (when sera from a group of 30 re-vaccinated animals are used) is an indication that the vaccines will give a low protection against the field strain (56).

D. REQUIREMENTS FOR VACCINES AND DIAGNOSTIC BIOLOGICALS

The control of FMD is usually a national responsibility and, in many countries, the vaccine may be used only under the control of the Competent Authority.

Guidelines for the production of veterinary vaccines are given in Chapter 1.1.7 Principles of veterinary vaccine production. The guidelines given here and in Chapter 1.1.7 are intended to be general in nature and may be supplemented by national and regional requirements. Varying requirements relating to quality, safety and efficacy apply in particular countries or regions in order for manufacturers to obtain an authorisation or licence for a veterinary vaccine. Where possible, manufacturers should seek to obtain such a license or authorisation for their FMD vaccines as independent verification of the quality of their product.

Virulent FMD virus must be used to produce FMD vaccine; consequently, the FMD vaccine production facility should operate under the appropriate biosecurity procedures and practices. The facility should meet the requirements for Containment Group 4 pathogens as outlined in Chapter 1.1.6 of this *Terrestrial Manual.*

Routine vaccination against FMD is used in many countries or zones recognised as free from foot and mouth disease with vaccination and in countries where the disease is endemic. In contrast, a number of disease-free countries have never vaccinated their livestock but have preferred the use of strict movement controls and culling of infected and contact animals when outbreaks have occurred. Nevertheless, many disease-free countries maintain the option to vaccinate and have their own strategic reserves of highly concentrated inactivated virus preparations. Such antigen reserves offer the potential of supplying formulated vaccine in an 'emergency' at short notice (26).

FMD vaccines may be defined as a fixed formulation containing defined amounts (limits) of one or more chemically inactivated cell-culture-derived preparations of a seed virus strain blended with a suitable adjuvant/s and excipients. The vaccines are formulated for their specific purpose and in the case of vaccines destined for use in swine, oil adjuvants are preferred. Oil adjuvanted vaccines can also be used in ruminants and may have advantages in terms of less interference from maternal antibody and a longer duration of immunity. FMD vaccines may be classified as either 'standard' or 'higher' potency vaccines. Standard potency vaccines are formulated to contain sufficient antigen to ensure that they meet the minimum potency level required (recommended at Section D.4.b as 3 PD_{50} [50% protective dose]). Higher potency vaccines are formulated with an increased amount of antigen such that the potency is in excess of the minimum requirement to provide particular features such as a more rapid onset of immunity and a wider spectrum of immunity against relevant field viruses. Higher potency vaccines are thus well suited for emergency use. Live FMD vaccines are not acceptable due to the danger of reversion to virulence and as their use would prevent the differentiation of infected from vaccinated animals.

Because of the presence of multiple serotypes of the virus, many FMD vaccines are multivalent and it is common practice to prepare vaccines from two or more different virus strains. In certain areas, it may be advisable to include more than one virus per serotype to ensure broad antigenic coverage against prevailing viruses.

1. Seed virus management

a) Characteristics of the seed virus

Selection of master seed viruses (MSVs) should ideally be based on their ease of growth in cell culture, virus yield, stability and broad antigenic spectrum (52). MSVs should be characterised and distributed by the official control laboratories in regions where such laboratories exist; they should be selected in accordance with the epidemiological importance of each variant.

b) Method of culture

Where no suitable established vaccine strain exists, new vaccine strains are derived through the establishment of MSVs from local field isolates by adapting them to growth in suspension or monolayer cells by serial passage. In order to remove the risk of contaminating lipid-enveloped viruses, it is recommended that putative MSVs undergo a validated organic solvent treatment prior to, or during, adaptation. It is preferable to keep the number of passages in cell culture to a minimum as there is evidence of antigenic 'drift' of FMD virus during this procedure.

c) Validation as a vaccine strain

MSVs must be antigenically and, if possible genetically, characterised and proven to be pure and free from all extraneous agents listed by the appropriate licensing authorities. Homology should be established with the original candidate isolates and effectiveness against the circulating strains from which they were developed should be proven. This often encompasses a number of methods, the most reliable being *in vivo* cross protection assays. Alternatively, *in vitro* tests (preferably virus neutralisation) can also be used, which require the availability of post-vaccination sera against these master seeds. Seed viruses may be stored at –20°C if glycerinated or at a lower temperature (e.g. –70°C) if not glycerinated. Working seed viruses may be expanded in one or a few more passages from the master seed stock and used to infect the final cell culture at an approximate rate of 1 PFU (plaque-forming unit) per 100 cells. Whenever possible, the exact source of the isolate should be recorded and should include details such as the location, species and the type of material from which the virus was derived. The *in-vitro* passage history of the virus should be recorded. Consideration should also be given to minimising the risk of transmission of transmissible spongiform encephalopathy agents (TSEs) by ensuring that TSE risk materials are not used as the source of the virus or in any of the media used in virus propagation.

2. Method of manufacture

The recommended method of virus propagation for antigen production is the growth of FMD virus in large-scale suspension cultures or monolayers using cell lines under sterile conditions. Primary cell culture may be acceptable for vaccine production in some countries but only if the method of production is entirely compliant with Good Manufacturing Practice (GMP), a validated procedure is applied to ensure inactivation of all possible extraneous agents and adequate in-process and final products tests are in place to ensure consistency and safety of the final product. It is essential that all pipework and vessels be thoroughly sterilised ensuring that no areas in the system harbour microorganisms. In addition

to general considerations of sterility, it is important to note that the virus is vulnerable to attack by proteolytic enzymes, such as those produced by microorganisms (22). Control of pH and temperature are also critical because of the acid and temperature lability of the virus (21). Optimum temperature for cell, virus growth and inactivation, normally around 37°C and 26°C, respectively, should be precisely controlled. During other stages of manufacture, the temperature should be reduced to 4–6°C. Virus should be maintained at approximately pH 7.6 and should never be below pH 7.0.

A suitable strain of the virus is used to infect a suspension or monolayers of an established cell line, such as BHK. Such cell cultures should be proven to be free from contaminating microorganisms. It is common practice to keep stocks of BHK cells over liquid nitrogen and revive as necessary. On revival, they are expanded in nutrient medium to a volume and cell density appropriate to seeding the main culture. As an approximation, the main culture is seeded to give an initial density of 0.2–0.5 × 10^6 cells/ml, which is allowed to multiply to 2–5 × 10^6 cells/ml before being infected with virus.

When the virus has reached its maximum titre, which is variously determined by infectivity, CF or other tests, the culture is clarified, often by chloroform treatment followed by centrifugation and filtration. The virus is subsequently inactivated by addition of ethyleneimine, usually in the form of binary ethyleneimine (BEI). This is usually prepared by dissolving, to a concentration of 0.1 M, 2-bromoethylamine hydrobromide in 0.2 N sodium hydroxide solution, and incubating at 37°C for 1 hour (9, 10). The BEI formed is then added to a virus suspension held at 26°C, to give a final concentration of 3 mM. Inactivation is usually continued for 24 hours, followed by a second dose of BEI for a further 24 hours. The time period for BEI treatment and temperature used for inactivation must be validated for the actual conditions and equipment used. After inactivation any residual BEI in the harvest can be neutralised by adding sodium thiosulphate solution to a final concentration of 2%. To decrease the likelihood of live virus failing to contact the EI at the second application, it is essential to transfer the vessel contents immediately to a second sterile vessel where inactivation is allowed to go to completion at 48 hours.

The inactivated virus may be concentrated by ultrafiltration, polyethylene glycol precipitin or polyethylene oxide adsorption (1, 58) concentrated inactivated virus may be purified further by procedures such as chromatography. These concentrated antigens can be kept at –70°C or lower temperatures for many years, if necessary, and made into vaccine when required by dilution in a suitable buffer and addition of adjuvants (24).

Conventional FMD vaccines are usually formulated as aqueous or oil adjuvanted. The aqueous vaccine, which is most commonly used for cattle is prepared by adsorbing the virus on to aluminium hydroxide gel, one of the adjuvant constituents of the final vaccine blend. Other components of the final blend include antifoam, phenol red dye (if permitted by the country requiring vaccine), lactalbumin hydrolysate, tryptose phosphate broth, amino acids, vitamins and buffer salts. A second adjuvant, saponin, derived from the South American tree *Quillaja saponaria mollina*, is also incorporated, as well as a preservative such as merthiolate or chloroform.

Oil-adjuvanted vaccines are usually formulated using mineral oils, such as Marcol and Drakeol, as adjuvants. These preparations offer a number of advantages over the standard aluminium hydroxide/saponin vaccine, not least of which is their efficacy in pigs. They are widely used for vaccinating cattle in South America because of the longer duration of immunity. The mineral oil is usually premixed with an emulsifying agent, such as mannide monooleate, before the addition of a proportion, or all, of the aqueous phase of the vaccine, and emulsified by use of a colloid mill or continuous mechanical or flow ultrasonic emulsifier. More complex double emulsions (water/oil/water) may be produced by emulsifying once more in an aqueous phase containing a small amount of detergent such as Tween 80 (35).

A further alternative are the 'ready-to-use' oil adjuvants. Oils containing esters of octadecenoic acid and 2,5 anhydro-d-mannitol, for example, readily form double or mixed emulsions (water/oil/water) that are both stable and of low viscosity, without the requirement of sophisticated emulsification equipment (11, 26). When using novel components, including adjuvants, in any vaccine it is important to take into account that its status with regard to residues in products derived from food producing species must be assessed to ensure that adequate assurance can be giving to licensing authorities in relation to safety for consumers. This requirement limits considerably the choice of adjuvants for use in food producing species.

3. In-process control

In general, virus titres reach optimum levels within about 24 hours of the cell culture being infected. The time chosen to harvest the culture may be based on a number of assays; for instance cell death. Virus concentration may be assessed by infectivity test, sucrose density gradient (23) or serological techniques. It is preferable to use a method for measuring antigenic mass, such as sucrose density gradient analysis, as well as one that measures infectivity, as the two properties do not necessarily coincide and the different methods may complement one another.

During inactivation of the virus, timed samples should be taken at regular intervals for the purpose of monitoring the rate and linearity of the inactivation process. Virus titres in the samples are determined by inoculation of cell cultures proven to be highly susceptible to FMD virus, e.g. BHK or bovine thyroid cells. Such cultures permit the testing of statistically meaningful samples under reproducible conditions. The $\log_{10}$ infectivities of the timed samples are plotted against time, and the inactivation procedure is not considered to be satisfactory unless at least the latter part of the slope of the line is linear and extrapolation indicates that there would be less than one infectious particle per 10^4 litres of liquid preparation at the end of the inactivation period.

4. Tests on the final product

a) Safety

Tests for innocuity (non-infectivity) are most effectively carried out on the bulk, concentrated, inactivated viral harvest (see Sections D.3 and D.5.b, below). Although it may be possible to confirm innocuity by testing virus eluted from the vaccine, this is not universally applicable to all formulations and is not as reliable as testing concentrated antigens. For example, saponin influences greatly the elution of FMD virus from aluminium hydroxide/saponin vaccines (25). If the elution procedure is appropriate to a particular formulation, then it may be validated by seeding parallel samples of vaccine with trace amounts of live virus (12).

For the purposes of gaining regulatory approval, a trial batch of vaccine should be tested for local and systemic toxicity by each recommended route of administration in an *in-vivo* test in an appropriate number of cattle (27). Double dose and repeat dose tests using vaccines formulated to contain the maximum permitted amount and number of antigens should be conducted using a similar protocol described below for batch safety tests.

b) Potency

Cattle of at least 6 months of age, obtained from areas free from FMD that have not previously been vaccinated against FMD and are free from antibodies to the different types of FMD virus should be used. Three groups of no fewer than five cattle per group should be vaccinated by the route recommended by the manufacturer. The vaccine should be administered at different doses per group by injecting different volumes of the vaccine. For example, if the label states that the injection of 2 ml corresponds to the administration of 1 dose of vaccine, a 1/4 dose of vaccine would be obtained by injecting 0.5 ml, and a 1/10 dose would be obtained by injecting 0.2 ml. These animals and a control group of two nonvaccinated animals are challenged either 3 weeks (aqueous) or up to 4 weeks (oil) after vaccination with a suspension of bovine virus that is fully virulent and appropriate to the virus types in the vaccine under test by inoculating a total of 10,000 ID_{50} (50% infectious dose) intradermally into two sites on the upper surface of the tongue (0.1 ml per site). Animals are observed for at least 8 days. Unprotected animals show lesions at sites other than the tongue. Control animals must develop lesions on at least three feet. From the number of animals protected in each group, the PD_{50} (50% bovine protective dose) content of the vaccine is calculated. There are a variety of methods for calculating PD_{50} (25), but procedures based on the Kärber method are generally preferred. The vaccine should contain at least 3 PD_{50} per dose for cattle, when employed for routine prophylactic use, although 6 PD_{50} per dose is more commonly preferred. In some cases, vaccine of high potency will prevent the development of local tongue lesions at the site of challenge. For the PGP test (percentage of protection against generalised foot infection) a group of 16 bovines of 18–24 months of age, with the same characteristics described for the PD_{50} test, are vaccinated with a full vaccine dose by the route recommended by the manufacturer. These animals and a control group of two nonvaccinated animals are challenged 4 weeks or more after vaccination with the challenge strain, which is a suspension of bovine virus that is fully virulent and appropriate to the virus types in the vaccine under test by inoculating a total of 10,000 BID_{50} (50% bovine infectious dose), intradermally into at least two sites on the upper surface of the tongue. Unprotected animals show lesions at sites other than the tongue within 7 days after inoculation. Control animals must develop lesions on at least three feet; for routine prophylactic use, the vaccine should protect at least 12 animals out of 16 vaccinated. Animals are observed at 7–8 days after challenge (57).

Potency tests in other target species, such as sheep, goats or buffalo are not yet standardised. In general, a successful test in cattle is considered to be sufficient evidence of the quality of a vaccine to endorse its use in other species. Under circumstances where a vaccine is produced for use primarily in a species other than cattle, it may be more appropriate to potency test the vaccine in that same species. With respect to African or Asiatic buffalo (*Bubalus bubalis*) and sheep, due to the often inapparent nature of the disease in these species, potency results from a cattle test may be a more reliable indicator of vaccine quality than attempting a potency test reliant on the detection of clinical signs in these other species.

A similar protocol to the cattle test can be adopted for potency testing FMD vaccines in pigs using three groups of five pigs, not less than 2 months old and free from antibodies neutralising the different types of FMD virus. One group is vaccinated with the full pig dose recommended by the manufacturer, one group receives a reduced dose e.g. 1/4 dose, and a third group receives a further reduced dose e.g. 1/16 dose of the vaccine. Traditionally, the response to oil vaccine is allowed longer to develop, and not until day 28 after vaccination are the three groups, plus two unvaccinated control pigs challenged. However, depending on the formulation, this interval could be reduced to that used in the cattle test. It is important that the different dose groups are individually separated from each other during the trial and that animals are removed as soon as they develop generalised FMD to avoid excessive challenge to those remaining. Challenge is by intradermal injection into the heel bulbs of one foot with 10,000 $TCID_{50}$ (0.2 ml), as calculated by growth in a suitable pig cell culture, of a virulent challenge virus homologous to a strain used in the vaccine and that normally results in generalised disease in the pig. The animals are observed daily for 10 days after challenge for clinical signs of FMD. Both control animals should develop clinical signs on more than one foot. From the number of animals protected in each group, the PD_{50} content of the vaccine is calculated. There are a variety of methods for calculating PD_{50} (31), including procedures based on Kärber. The vaccine should contain at least 3 PD_{50} per dose for pigs. Likewise, a similar protocol to the PGP test in cattle can be adopted for pigs using a group of 16 animals vaccinated with a full vaccine dose and two non-vaccinated controls.

Challenge is by intradermal injection into the heel bulbs of one foot with 10,000 BID_{50} (0.2 ml) of a virulent challenge virus homologous to the strain used in the vaccine and that is known to induce clinical signs in pigs.

Indirect tests, including measurement following vaccination of virus neutralising antibodies in cell culture, or ELISA antibodies, or serum-protecting antibodies in suckling mice, may be used to assess the potency of a vaccine provided that a statistical evaluation has established a satisfactory correlation between the results obtained by the test on the relevant vaccine serotype and the potency test in cattle (57). For example, the expected percentage of protection is used to analyse the sera of a group of at least 16 vaccinated cattle and to express the probability of an animal being protected by measuring neutralising, ELISA or protecting antibodies. In a single group of animals given a full dose of vaccine, the mean individual expected percentage protection should be equal to or greater than 75% when 16 animals are used or 70% when 30 animals are used in the experimental group.

The presence of more than one serotype in a vaccine does not diminish the induction of antibodies against another serotype or the correlation of antibody titre with protection.

c) Purity: testing for antibody against non-structural proteins

The OIE *Terrestrial Animal Health Code* stipulates that a criterion for regaining FMD free status following an outbreak, if vaccine is used, is to test the vaccinated animals for antibody against NSP. Likewise, countries wishing to be recognised as FMD free with vaccination must demonstrate the absence of virus circulation by showing that vaccinated animals are free from antibody to NSPs arising as a result of infection. Consequently, FMD antigens used to formulate vaccines that may be used in these circumstances should be purified to reduce the NSP content. With current manufacturing techniques it is possible to exclude the majority of NSPs so that they induce little, if any, NSP specific antibody. Under these circumstances, detection of NSP antibodies can provide evidence that vaccinated animals have been exposed to FMD virus. Vaccine manufacturers may with to exploit this potential by including a claim that their vaccines do not induce antibody to one or more NS proteins and can be used in conjunction with an appropriate diagnostic test. In addition to providing supporting documentation on the processes involved in such purification, manufacturers should demonstrate lack of immunogenicity against NS proteins as part of the licensing procedure in order to make such a claim on their product literature. A test method that can be used is to vaccinate an appropriate number of calves, preferably with at least a double dose of a trial blend of the vaccine containing the maximum number and amounts of antigen permitted on the authorisation (these calves may be the same as those used for the safety test described in Section D.4.a of this chapter). Calves should be vaccinated at least three times over a period of 3–6 months and then tested 30–60 days after the last vaccination for the presence of antibody to NSPs using the tests described in Section B.2.d of this chapter. Negative results in these NSP assays support a claims that the vaccine does not induce antibody to NSPs.

At the batch level, confirmation of vaccine purity can be shown by demonstrating a lack of increase in reactivity against NS proteins of the sera from the animals used in the potency test obtained 30 days after primovaccination and before challenge, when compared with the sera of the same animals prior to vaccination.

d) Duration of immunity

In order to establish a satisfactory level of immunity it is usual to give a primary course consisting of two inoculations, 2–4 weeks apart, followed by revaccination every 4–12 months. The frequency of revaccination will depend on the epidemiological situation and the type and quality of vaccine used. Where access to the animals is difficult, it is preferable to use oil adjuvanted vaccine at 4 months and 1 year of age, followed by annual revaccination. Wherever possible, vaccine manufacturers should demonstrate the duration of immunity for their specific formulation in each species for which it is indicated.

For calves born of vaccinated dams, the first vaccination should be delayed as long as possible to allow decline of maternal antibody. This period should not be extended beyond 4 months, as by this age a high proportion can be expected to respond effectively to vaccination. For calves born to non-vaccinated dams, the first vaccination may be administered from as early as 1 week of age for some vaccines (8).

e) Stability

The shelf life of conventional FMD vaccines is usually 1–2 years at 4°C (max range 2–8°C), but they are temperature labile and should never be frozen nor stored above a target temperature of 4°C. The stability of all vaccines, but particularly oil emulsion vaccines, should be demonstrated as part of the shelf life determination studies for authorisation.

f) Preservatives

The most commonly used preservatives are chloroform and merthiolate. The latter is used at a final concentration of 1/30,000 (w/v).

g) Precautions (hazards)

Current FMD vaccines are innocuous and present no toxic hazard to the user. Care must be taken to avoid self-injection with oil-emulsion vaccines.

5. Batch control

a) Sterility

The bulk inactivated antigen, the adjuvants, the dilution buffers and the final formulated product should all undergo sterility testing. This may be carried out directly with components of the vaccine and the final product, but the preferred method is to collect any contaminating microorganisms by membrane filtration of the material to be examined and to detect any organisms present by incubation of the membranes with culture media. The latter procedure allows the removal of preservatives, etc., which may inhibit the detection of microorganisms. Guidelines on techniques and culture media, which allow the detection of a wide range of organisms, are described in the European Pharmacopoeia 2005 (27; also refer to Chapter 1.1.5).

b) Innocuity

The test for innocuity is an in-process test that should be carried out for every batch of antigen. Following inactivation, a sample of each batch of inactivated antigen representing at least 200 doses should be tested for freedom from infectious virus by inoculation of sensitive monolayer cell cultures, preferably of the same origin as those used for the production of antigen. It may be preferable to concentrate the antigen to do this, in which case it must be shown that the concentrated material does not interfere with the sensitivity or reading of the assay. The cell sheets are examined daily over a period of 3 days, after which the spent medium is transferred to fresh monolayers and the original monolayers are replenished with fresh medium. Using this method, traces of live virus can be amplified by the passage procedure and detected on the basis of CPE observed. Two to three passages of the original virus preparation are commonly used. A variant on this method is to freeze–thaw the old monolayers to release intracellular virus, which can be detected by further passage.

c) Safety

This final product batch safety test is conducted to detect any abnormal local or systemic adverse reactions. The test may also confirm innocuity but is not as sensitive as the *in- vitro* tests described above. For the purposes of batch release, each of at least two healthy seronegative cattle is inoculated by the recommended route of administration with double the recommended dose of vaccine. The animals are observed for local and systemic reactions to vaccination for no fewer than 14 days. Should any of the animals develop clinical signs of FMD, the vaccine fails the safety test. Equally, any undue toxicity attributable to the vaccine should be assessed and may prevent acceptance of the batch. Ideally, vaccines prepared for species other than cattle should also be safety tested in the species for which they are intended, administering a double dose of vaccine according to the manufacturer's recommended route and dose volume. The animals should be examined daily for a minimum of 14 days for evidence of toxicity or signs of FMD.

d) Potency

Potency is only examined on the final formulated product (see Section D.5.b). Antigen load can be used as an indirect indicator of potency, provided a correlation has previously been established between antigen load, serological response and protection against challenge, and provided that a suitable alternative test measuring the serological response to immunisation has been carried out with satisfactory results.

6. Storage and monitoring of antigen concentrates

The process of storing concentrated antigens at ultra-low temperature for later formulation into FMD vaccine is becoming an increasingly popular option for vaccine manufacture. It not only forms the basis for the storage of antigens in a strategic reserve for emergency purposes (see Chapter 'Guidelines for International Standards for Vaccine Banks'), but allows the manufacturer immediate access to many different antigen strains which can be rapidly formulated and dispatched to the customer. Such stockpiling minimises delays subsequent to an order, particularly where a multivalent vaccine is requested. Another advantage of this procedure is that much of the quality testing can be completed well in advance of shipment.

a) Pre-storage criteria

It is necessary to state that antigens have to be controlled using standards indicated in Sections D.1–4.

Special attention should be paid to the following:

- freedom from extraneous agents;

  antigens should be proven free from all extraneous agents listed by the appropriate licensing authorities.

- sensitivity of the cell line used to detect residual virus;

  Cells used to test for absence of residual live virus are not suitable if use of an amount of virus corresponding to 1 µg of 146S antigen gives a titre of less than 10^6 CC ID_{50} (27).

- emergency procedures for provisional acceptance of new Master Seed Virus (MSV), and subsequent release of formulated vaccines.

In the case of incursion in a region of a new strain that is antigenically distinct from existing vaccine strains, it may be necessary to develop a new vaccine strain from a representative field isolate. Before the new MSV can be accepted, full compliance should be demonstrated with the relevant guidelines to demonstrate freedom from all extraneous agents listed by the appropriate licensing authorities using both general and specific tests, and to establish homology to the original candidate isolates. The time taken to raise the specific antisera necessary to neutralise the new strain for use in the general tests for detection of extraneous agents and to conduct other specific tests that require specialised techniques may be lengthy. Therefore, in emergency situations where there is insufficient time to complete full testing of the MSV, provisional acceptance of the new strain should be based on a risk analysis of the possibility of contamination of the antigen produced from the new MSV with extraneous agents. This risk assessment should take into account that a validated procedure to inactivate enveloped viruses must be used when establishing the MSV and that the virus is inactivated using a chemical inactivant with first order kinetics. Further assurance is provided by the requirement for the kinetics of inactivation to be monitored and recorded for each production batch.

In order to accelerate the release of batches of vaccine formulated to contain new vaccine strains, it may be acceptable for batch potency testing to be carried out using a vaccine formulated using an intermediate antigen lot pending production of all of the batches of antigen that are intended to constitute the final antigen lot. This will allow the potency of antigen derived from a new MSV to be determined whilst the manufacturer continues to build up stocks of this new antigen.

b) Storage criteria

- **Facilities**

It is important that all aspects of the storage of antigen concentrate conform fully to internationally accepted standards of Good Manufacturing Practice.

- **Containment of stored antigens**

The dose numbers or volumes stored are an important consideration, particularly where a reserve is shared between Member Countries and there is variation in number of doses perceived to be needed by each member in an emergency. It may be advisable to store antigen concentrates in user-friendly units to allow better usage of storage space and capability in producing smaller vaccine batches. One to two litre sized containers can accommodate in excess of 30,000 bovine doses. Where the requirement is for a large stockpile of a particular vaccine strain that can only be produced from several separate production runs, vaccine bank managers must consider the need to either formulate each lot into a representative final blend for testing purposes or mixing the individual batches, at some convenient point, for ease of formulating and/or testing.

The type of container used to hold antigen concentrate is important. Under ultra-low temperature conditions it is important to use containers made from materials that do not become brittle and fragile, a good example being fluoropolymer based moulded bottles. Polyfluoro-alkoxy (PFA) based bottles, for example, have a temperature resistance range of between –270°C and +250°C.

- **Labelling of stored antigens**

Although there are national and international guidelines on the required labelling of veterinary medical products, there are no such guidelines for emergency stored materials such as the antigen component of a vaccine, as these are essentially regarded in regulatory terms as 'in process' materials. Under ultra-low temperature conditions, the method of labelling must be of a durable nature. From experience, wire tagging bottles is the most preferred option using a metal tag sizeable enough to allow the necessary detail. Such detail should include the antigen/vaccine strain, batch number, date received and should also include an individual container or stock number. This information should be clear to read and marked on the tag using an indelible marker pen. Aluminium metal tags have been used for such purpose and these can be obtained with different colour coatings to allow better identification and accessibility, particularly when different antigen strains are housed in the same container. Metal tags also allow information to be permanently engraved.

- **Monitoring**

It is vitally important that antigen concentrates are optimally maintained and routinely monitored in order to have some assurance that they will be efficacious when needed. Therefore arrangements should be made to monitor these antigen concentrates on a routine basis and to include where necessary, and at appropriate time intervals, a testing regime to ensure integrity of the antigen component or acceptable potency of the final product. For example, storage temperature monitoring is normally undertaken and recorded in FMD vaccine banks, as well as periodic inspection of the bottles containing the antigen for cracks or leakage. Depending on type, volume and how they are stored, there may also be value in weighing antigen deposits annually to ensure they have not lyophilised. Some FMD vaccine banks have incorporated physico-chemical tests like sucrose density gradient analyses to monitor

virus integrity and hence stability and some have also carried out in-vivo tests. However, since it has been shown that the shelf-life of FMD antigen concentrates are likely to be well in excess of 15 years when stored at ultra-low temperature, a physico-chemical approach would appear sufficient.

The following timetable of tests is proposed as suitable for validation and re-validation of stored antigens.

Time	Test
On receipt (year 0) and every 5 years thereafter	146S quantification* Potency test in cattle that may rely on serological techniques where potency has been adequately correlated with immunogenicity for the antigen concerned or, at the discretion of the bank holder, may be a 'truncated' test** to demonstrate that the minimum potency of the vaccine remains greater than the minimum requirement; however, trunication may underestimate vaccine potency
Years 2 and 4, and immediately before formulation if the need arises	146S quantification
Every 5 years	Evaluation of all data for the preceding 5 years to assess need to replace antigen

* Other physiochemical tests such as SDS-PAGE have been used to evaluate integrity of VP1 but are not sufficiently validated for routine use.

** In a truncated test all animals in the next lower volume group are assumed to have not been protected. The test therefore gives an artificially low PD_{50} value but reduces the number of animals required.

To support these testing requirements for depositories of antigen, concentrates should include a number of small samples that are representative of the larger stock. Small aliquots/stocks of FMD antigen have usually consisted of a volume representing approximately one milligram of antigen.

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NB: There are OIE Reference Laboratories for Foot and mouth disease (see Table in Part 3 of this *Terrestrial Manual* or consult the OIE Web site for the most up-to-date list: www.oie.int).

COUNCIL OF THE EUROPEAN UNION

Brussels, 7 June 2006

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LIMITE

AGRILEG 92

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 May 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT Draft position and written comments of the Community on the OIE Terrestrial Animal Health Code to be submitted for adoption and consideration in the 74th General Session to be held in May 2006 - Principles of veterinary vaccine production

Delegations will find attached &Commission& document SEC(2006) 634 - Principles of veterinary vaccine production.

Encl.: SEC(2006) 634

CHAPTER 1.1.7.

PRINCIPLES OF VETERINARY VACCINE PRODUCTION

SUMMARY

A reliable supply of pure, safe, potent, and effective vaccines is essential for maintenance of animal health and the successful operation of animal health programmes. Immunisation of animals with high quality vaccines is the primary means of control for many animal diseases. In other cases, vaccines are used in conjunction with national disease control or eradication programmes.

The requirements and procedures described here are intended to be general in nature and to be consistent with published standards that are generally available for guidance in the production of veterinary vaccines. The approach to ensuring the purity, safety, potency, and efficacy of veterinary vaccines may vary from country to country depending on local needs. However, proper standards and production controls are essential to ensure the availability of consistent, high quality products for use in animal health programmes.

As the pathogenesis and epidemiology of each disease varies, the role and efficacy of vaccination as a means of control also varies from one disease to another. Some vaccines may be highly efficacious, inducing an immunity that not only prevents clinical signs of the disease, but also prevents infection and replication of the disease-causing agent. Other vaccines may prevent clinical disease, but not prevent infection and/or the development of the carrier state. In other cases, immunisation may be completely ineffective or only able to reduce the severity of the disease. Thus the decision whether to recommend vaccination as part of an animal disease control strategy requires a thorough knowledge of the characteristics of the disease agent and its epidemiology, as well as the characteristics and capabilities of the various available vaccines. There is also growing public interest in the beneficial implications for animal welfare of the use of veterinary vaccines as a means of disease control. In any case, if vaccines are used, successful performance requires that they be produced in a manner that ensures a uniform and consistent product of high quality.

NOMENCLATURE

The nomenclature for veterinary biological products varies from country to country. For example, in the United States of America (USA) the term 'vaccine' is used for products containing live or inactivated viruses or protozoa, live bacteria, or nucleic acids. Products containing killed bacteria and other microorganisms are identified as bacterins, bacterial extracts, subunits, bacterintoxoids, or toxoids, depending on the type of antigen they contain. For example, products containing antigenic or immunising components of microorganisms may be called 'subunits' or 'bacterial extracts', and those produced from the inactivation of toxins are called 'toxoids'. In the European Union (EU), Immunological Veterinary Medicinal Products are defined as 'products administered to animals in order to produce active or passive immunity or to diagnose the state of immunity', see Directive 2001/82/EC, as amended by Directive 2004/28/EC. For this chapter, however, the term 'vaccine' will include all products designed to stimulate active immunisation of animals against disease, without regard to the type of microorganism or microbial toxin from which they may be derived or that they contain. This use is more consistent with international nomenclature. 'Vaccine' will not be used in this discussion in reference to biological products recommended for passive immunisation, immunostimulation, treatment of allergies, or diagnosis.

VACCINE TYPES OR FORMS

Vaccines may be prepared as live or inactivated (killed) products. Some live vaccines are prepared from low virulence, mild, field isolates of a disease-causing agent that have been found to be safe and effective when administered by an unnatural route or under other conditions where exposure to the microorganism will immunise

rather than cause disease. Other live vaccines are prepared from isolates of disease-causing agents that have been modified by passage through laboratory animals, culture media, cell cultures, or avian embryos to select an isolate of reduced virulence. The development of recombinant DNA (rDNA) procedures has provided some unique opportunities for vaccine production. Modified live vaccines may now be specifically produced by deletion of virulence-related genes from a microorganism. Others are produced by the insertion of genes that code for specific immunising antigens from a disease-causing microorganism into a nonvirulent vector microorganism. Nucleic-acid-mediated vaccines containing plasmid DNA are being developed. The DNA is usually in plasmid form and codes for immunising antigens from disease-causing microorganisms.

Killed products may contain: 1) Cultures of microorganisms that have been inactivated by chemical or other means; 2) Inactivated toxins; or 3) Subunits (antigenic parts of microorganisms) that have been extracted from cultures or that have been produced through rDNA procedures.

Both live and inactivated vaccines may be formulated with adjuvants designed to enhance their efficacy. Frequently used adjuvants are typically water-in-oil emulsions (either single or double), made with mineral or vegetable oil and an emulsifying agent. Other adjuvants, such as aluminium hydroxide gel or saponin, are also used. In addition to these traditional adjuvants, vaccines are being developed that include additional ingredients that induce immunomodulatory effects in the host animal and serve to enhance the efficacy of the product. These ingredients may include immunogenic microorganisms such as killed bacteria, which stimulate the immune response to other fractions contained in the vaccine, or cytokines, which may be used to regulate specific aspects of the immune system and are included in rDNA constructs used in products manufactured through biotechnology.

QUALITY ASSURANCE

The consistent production of pure, safe, potent, and efficacious vaccines requires quality assurance procedures to ensure the uniformity and consistency of the production process. As production processes for vaccines provide a great opportunity for variability, care must be taken to control variability to the greatest extent possible, preferably using validated procedures, and to protect the product from contamination through all stages of production.

Vaccine purity, safety, potency, and efficacy must be ensured by consistency in the production process. Consistent product quality (batch-to-batch uniformity) must be built in at each stage. Final product testing is used as a check to verify that the controls on the production procedures have remained intact and that the released product meets the specification previously agreed with the licensing authority.

Regulatory authorities in different countries have developed various approaches to ensuring the quality of vaccines. Although alike in their ultimate goal, these systems may vary in the emphasis given to control of the production process (process standards) in comparison with control through testing of the final product (performance standards). The control procedures selected should be those that best fit the conditions under which vaccines are being produced and, where possible, comply with good manufacturing practice.

The control standards and procedures established for a product define the risk or possibility of producing and releasing a product that is worthless, contaminated, dangerous, or harmful. The acceptable degree of risk may depend on the benefits to be gained by having the product available to prevent disease losses. Thus standards may justifiably vary from country to country or product to product, depending on local animal health conditions. However, control authorities should strive to establish control standards and procedures that ensure a finished product of the highest purity, safety, potency and efficacy possible.

The optimal quality assurance system should address both production procedures and final product testing in proper balance. An absolutely fail-safe system that would result in no risk of releasing an unsatisfactory product would probably be too expensive with regard to cost of production as well as control. Thus regulatory officials and manufacturers of vaccines must select control procedures that are capable of ensuring an acceptable low level of risk in relation to hazard. Such procedures, however, must not be burdensome to the extent that they inhibit the development and availability of the products needed to provide proper preventative medical care at a cost that is acceptable to the consumer.

PRODUCTION FACILITIES

Facilities used for the production of vaccines should be designed to protect the purity of the product throughout the production process and to safeguard the health of the personnel. They must be constructed so that: 1) they can be readily and thoroughly cleaned; 2) they provide adequate separation of preparation rooms; 3) they have adequate ventilation; 4) they have ample clean hot and cold water and efficient drainage and plumbing; and 5) they have dressing rooms and other facilities for personnel that are accessible without passing through biological product preparation areas. Facilities must be adequate to provide for all applicable production functions, such as: storage of master seeds, ingredients, and other production materials; preparation of growth media and

cell cultures; preparation of glassware and production equipment; inoculation, incubation, and harvest of cultures; storage of in-process materials; inactivation, centrifugation, addition of adjuvant, and formulation of product; filling, desiccation, sealing of containers, labelling and storage of final product; quality control testing of in-process materials and final product; and research and development.

Separate areas are generally required for different activities. All rooms and air-handling systems must be constructed so as to prevent cross-contamination from other products and to prevent contamination by people or equipment. Virulent or dangerous microorganisms must be prepared and stored in rooms separate from the remainder of the establishment. In particular, challenge organisms must be completely separated from vaccine strains. All equipment that comes into contact with product must be sterilised using validated procedures.

Production facilities have to be designed in such a way that contamination of the environment is prevented. Any material used during production has to be made safe before leaving the facility. If highly contagious microorganisms are propagated, the exhaust air must be treated to prevent escape of infectious agents. Personnel must follow safety procedures such as showering, and avoid contact with susceptible animals after leaving the production facilities.

Although the quality and design of production facilities may vary significantly, they must always meet standards considered to be appropriate for the vaccines that are to be produced. For example, the requirements for facilities for the production of chicken embryo vaccines administered by oral, intranasal or intraocular routes may not need to be quite as demanding as those for the production of cell culture vaccines administered subcutaneously or intramuscularly.

FACILITIES PLAN

For each vaccine made in a facility, there should be a detailed production plan that describes where each step in the production process will occur. This plan should be documented in a detailed standard operating procedure (SOP) or by a blueprint (building plan) and blueprint legend. Each room in the establishment should be uniquely identified, and all functions performed and all microorganisms involved should be specified for each room. Disinfection procedures, monitoring of equipment and other procedures used in the operation of the facilities to prevent contamination or errors during production should also be documented. This plan should be updated as new products or microorganisms are added to the facility, or other changes or improvements in procedures are developed.

DOCUMENTATION OF THE MANUFACTURING PROCESS

A detailed Outline of Production, a series of SOPs, or other documents should also be prepared to describe the protocol for the manufacture and testing of each product produced in an establishment. Criteria and standards for source materials should be clearly and accurately documented. Documentation should also address such things as: the source, isolation, and passage (subculturing) history of each strain of microorganism; the source and sequence of nucleic acid elements, amino acids, or peptides included in products derived from biotechnology, including plasmids or other vectors used in the construction of genetically modified microorganisms for use as master seeds; methods for identifying the microorganisms and determining their virulence and purity; the medium or cell culture system used for seed and production cultures, including the methods used to demonstrate that media are free from contamination; the source of ingredients of animal origin; methods of media sterilisation; storage conditions of cell lines and seed cultures; size and types of containers used for growth of cultures; methods for preparing seed cultures and inoculating production cultures; time and conditions for incubation; observations during growth; criteria and specifications for satisfactory harvest material; and harvest techniques. There should be documentation on measures implemented by the firm to minimise the risk of transmissible spongiform encephalopathies (TSE; prion) contamination in ingredients of animal origin and procedures to insure that fetal bovine serum is free of pestiviruses. It should also include: a description of all tests conducted to assess the purity and quality of the product as it proceeds through the production process; each step in the formulation of the final product; the tests used for assessing the purity, safety, potency, and other requirements of each batch of completed product; the specifications for finishing, including packaging and labelling with complete indications and recommendations for use; and the expiry date established for the product.

Guidelines for the preparation of such documents for veterinary vaccines are published by competent control authorities. This documentation is intended to define the product and to establish its specifications and standards. It should serve along with the blueprints and blueprint legends (or production plan and SOPs) as a uniform and consistent method of producing the product that should be followed in the preparation of each batch.

RECORD KEEPING

The producer should establish a detailed record-keeping system capable of tracking the performance of successive steps in the preparation of each biological product. Records kept should indicate the date that each essential step was taken, the name of the person who carried out the task, the identity and quantity of ingredients added or removed at each step, and any loss or gain in quantity in the course of the preparation. Records should be maintained of all tests conducted on each batch. All records relevant to a batch of product should be retained for at least 2 years after the expiry date on the label, or in line with the requirements of the competent control authority. In addition, a record should be maintained of all labels used on all products, with each label identified as to its name, product number, product licence number, package size, and label identification number. All labels printed should be accounted for. Records must be kept concerning sterilisation and pasteurisation procedures. These are usually made by means of automatic recording devices. The manufacturer must also keep complete records for all animals at the establishment, including health prior to being used for any tests, results of tests performed, treatment administered, maintenance, necropsy, and disposal.

MASTER SEED

A master seed should be established for each microorganism used in the production of a product to serve as the source of seed for inoculation of all production cultures. Working seeds and production seeds may be prepared from the master seed by subculturing; generally the final production cultures should not be more than five (sometimes ten) passages from the master seed. The number of passages should be determined by data and designated in each case. Using a master seed and limiting the number of passages of seed microorganism in this manner assists in maintaining uniformity and consistency in production. Records of the source of the master seed should be maintained. For products based on genetically modified microorganisms, the source of the gene(s) for the immunogenic antigens expressed in a different vector microorganism should be identified, as well as any non-expressed gene sequences introduced into the seed microorganism genome during construction of the modified seed. The master seed should consist of a single uniform batch of seed that has been mixed and filled into containers as one batch. Master seed should be frozen or desiccated and stored at low temperatures such as –40°C or –70°C, or under other conditions found to be optimal for maintaining viability. Each master seed should be tested to ensure its identity, safety and efficacy. Genetically modified seeds should also be tested to ensure stability and safety of the inserted gene sequences. Purity should also be established by testing to ensure freedom from extraneous bacteria, fungi, mycoplasma, and viruses.

MASTER CELL STOCKS

When cell cultures are used to prepare a product, a master cell stock (MCS) should be established for each type of cell to be used. Records of the source of the master cell stock should be maintained. For each product, the highest and lowest passage levels of cells that may be used for production should be established and specified in the Outline of Production or SOP. Some control authorities do not permit more than 20–40 subcultivations. Each MCS should be characterised to ensure its identity, and its genetic stability should be demonstrated when subcultured from the lowest to the highest passage used for production. The karyotype of the MCS should be shown to be stable with a low level of polyploidy. Freedom from oncogenicity or tumorogenicity should be demonstrated by *in-vivo* studies in appropriate species using the highest cell passage that may be used for production. Purity of MCSs should be established by testing to ensure freedom from extraneous bacteria, fungi, mycoplasma, and viruses.

• Primary cells

These are defined as a pool of original cells derived from normal tissue up to and including the tenth subculture used in the production of biologicals. In the case of products for use in poultry, these cells are usually obtained from specific pathogen free embryonating chicken eggs that have originated in an unvaccinated flock subjected to intensive microbiological monitoring. Other primary cells are derived from normal tissue of healthy animals and are tested for contamination with a wide variety of microorganisms as appropriate, including bacteria, fungi, mycoplasmas, and cytopathic and/or haemadsorbing agents and other extraneous viruses. The use of primary cells has an inherently higher risk of introducing extraneous agents compared with the use of continuous cell lines and should be avoided where alternative methods of producing effective vaccines exist. Indeed, some control authorities only allow the use of primary cells in exceptional cases.

• Embryonating eggs

These are also commonly used in the production of biologicals. In almost all cases they should be derived from specific pathogen free chicken flocks that have been intensively monitored for infectious agents and have not

been vaccinated. The route of inoculation of the egg and the choice of egg material to be harvested are dependent on the particular organism that is being propagated.

INGREDIENTS

The specifications and source of all product ingredients should be defined in the Outline of Production, SOP, or other appropriate documents. The Outline of Production must be approved by the National licensing agency. All ingredients of animal origin that are not subject to a validated sterilisation procedure should also be tested to ensure freedom from extraneous bacteria, fungi, mycoplasma, and viruses. Their country of origin should be known. Measures should be implemented by the firm to minimise the risk of TSE (prion) contamination in ingredients of animal origin. Some control authorities discourage the use of preservatives or (more importantly) antibiotics as a means of controlling adventitious contamination during production and prefer the use of strict aseptic techniques to ensure purity. However, they sometimes allow the use of preservatives in multidose containers to protect the product during use. These control authorities usually limit any addition of antibiotics in the manufacture of the product to cell culture fluids and other media, egg inocula, and material harvested from skin or possibly other tissues. They normally permit the use of no more than three antibiotics in the same product. Some control authorities also prohibit the use of penicillin or streptomycin in vaccines administered by aerosol or parenterally. If the antibiotics used are not recommended for use in the target species, they should be shown to have no harmful effects in the vaccinated animals and not result in the contamination of food derived from vaccinated animals.

EFFICACY TESTS

The efficacy of veterinary vaccines should be demonstrated by statistically valid vaccination–challenge studies in the host animal, using the most sensitive, usually the youngest, animals for which the product is to be recommended. Data should support the efficacy of the vaccine in each animal species by each vaccination regimen that is described in the product label recommendation, including studies on the onset of protection when claims for onset are made in the product labelling and for the duration of immunity. The tests should be performed under controlled conditions starting, wherever possible, with seronegative animals. Where validated potency tests are available, target species vaccination–challenge studies may not be required if predictive serological test results are available. The application of procedures to replace, reduce, and refine animal tests (the 'three Rs rule') should be encouraged whenever possible.

Efficacy studies should be conducted with final product vaccine that has been produced at the highest passage level from the master seed that is permitted in the Outline of Production, or other documentation of the manufacturing process. This will have specified the minimum amount of antigen per dose that must be in the final product throughout the entire authorised shelf-life. Where a range of antigen level per dose is permitted, the antigen level per dose in the vaccine tested for efficacy must be at or below the minimum permitted amount. The precise challenge method and the criteria for determining protection vary with the immunising agent and should be standardised whenever possible.

Field efficacy studies may be used to confirm the results of laboratory studies or to demonstrate efficacy when meaningful vaccination–challenge studies are not feasible. However, it is generally more difficult to obtain statistically significant data to demonstrate efficacy under field conditions. Protocols for field studies are more complex, and care must be given to establish proper controls to ensure the validity of the data. Even when properly designed, field efficacy studies may be inconclusive because of uncontrollable outside influences. Some problems include: a highly variable level of challenge; a low incidence of disease in nonvaccinated controls; and exposure to other organisms causing a similar disease. Therefore, efficacy data from both laboratory and field studies may be required to establish the efficacy of some products.

INTERFERENCE TESTS

For products with two or more antigenic components, tests must confirm that there is no interference between individual components, that is, one component causing a decrease in the protective immunological response to another component. Interference testing should be conducted for each combination product prior to approval.

A loss of potency may also result when residual inactivating agent in a killed liquid product used as a diluent for a desiccated live fraction reduces the viability of the live organisms because of viricidal or bacteriocidal activity. Each batch of liquid killed vaccine that is to be used as a diluent for live vaccines must, therefore, be tested for viricidal or bacteriocidal activity prior to release.

Consideration must also be given to possible interference between two different vaccines from the same manufacturer recommended to be given to the same animal within a 2-week period.

INCREASE IN VIRULENCE TESTS

With live vaccines, there is concern that the organism might be shed from the host and transmitted to contact animals, causing disease if it retains residual virulence or reverts to virulence. Therefore, all live vaccines should be tested for virulence by means of passage studies. Vaccine organisms are propagated *in vivo* by inoculating a group of target animals with master seed, usually using the natural route of infection for that organism. The vaccine organism is recovered from tissues or excretions and is used directly to inoculate a further group of animals, and so on. After not less than five passages (more for poultry products), the isolate must be fully characterised, using the same procedures used to characterise the master seed. Regulatory authorities vary in whether or not it is acceptable to propagate *in vitro* between passages organisms that otherwise cannot be passaged five times because of their degree of attenuation. The vaccine organism must retain an acceptable level of attenuation after propagation in this way.

ASSESSING RISK TO THE ENVIRONMENT

The ability of each live vaccine to shed, to spread to contact target and non-target animals, and to persist in the environment must be evaluated to provide information for assessing the risk of the vaccine to the environment. In some cases this may be done in conjunction with the increase in virulence tests. These and additional considerations are especially important in the case of products based on biotechnology or recombinant DNA techniques; more information about such products is provided in the sections at the end of this chapter.

CONSISTENCY OF PRODUCTION

Prior to marketing approval of any new product, each establishment should produce in its facilities three consecutive production batches of completed product to evaluate the consistency of production. These batches should be prepared according to the procedures described in the Outline of Production and blueprints and legends, SOPs or other documentation of the manufacturing process. The size of each of the three batches should be at least one-third the size of the average batch that will be produced once the product is in production.

The manufacturer should test each of these batches for purity, safety, and potency as provided in the Outline of Production or other documentation of the manufacturing process. Applicable Standard Requirements and test procedures, for example those described in CFR (Code of Federal Regulations) Title 9 part 113, in the Annex to EU Directive 2001/82/EC (as amended), in the European Pharmacopoeia, or as described in this *Terrestrial Manual* may be used. Satisfactory test results should be demonstrated for all three batches prior to approving the production of the product in the facilities and its release for marketing. Each subsequent batch should be tested in the same manner with satisfactory results prior to release for marketing.

BATCH POTENCY TESTS

Batch potency tests, required for each batch prior to release, are designed to correlate with the host animal vaccination–challenge efficacy studies. For inactivated viral or bacterial products, potency tests may be conducted in laboratory or host animals, or by means of quantitative *in-vitro* methods that have been validated reliably to correlate *in vitro* quantification of important antigen(s) with *in vivo* efficacy. The potency of live vaccines is generally measured by means of bacterial counts or virus titration. Recombinant DNA or biotechnology-based vaccines should also be tested. Live genetically modified organisms can be quantified like any other live vaccine by titration, and expressed products of recombinant technology are quantified by *in vitro* tests, which are easier to perform compared with naturally grown antigens because of the in-process purification of the desired product.

When testing a live bacterial vaccine for release for marketing, the bacterial count must be sufficiently greater than that shown to be protective in the master seed immunogenicity (efficacy) test to ensure that at any time prior to the expiry date, the count will be at least equal to that used in the immunogenicity test. When testing a live viral vaccine for release, the virus titre must, as a rule, be sufficiently greater than that shown to be protective in the master seed immunogenicity test in order to ensure that at any time prior to the expiry date, the titre will be at least equal to that used in the immunogenicity test. Some control authorities specify higher bacterial or viral content than these. It is evident that the appropriate release titre is primarily dependent on the required potency and

secondarily dependent on the rate of decay of the bacteria or viruses in the vaccine, as indicated by the stability test.

Standard Requirements have been developed and published by competent authorities for potency testing several vaccines. These tests can be found in CFR Title 9 part 113, in the European Pharmacopoeia, and in this *Terrestrial Manual*.

STABILITY TESTS

Stability studies (based on an acceptable potency test) are required to establish the validity of the expiry date that appears on the product package. Some authorities allow the use of accelerated stability tests to determine a provisional expiry date for new products, e.g. incubating at 37°C for 1 week for each year of dating. Such estimates must be confirmed by periodic real-time potency tests on at least three different batches through the period of time indicated by the expiry date, and 3–6 months beyond. For products containing viable organisms, testing should be done at release and at the approximate expiry date until a statistically valid record has been established. For non-viable products, each batch presented for licensing is tested at release and at periodic intervals through, or past, the requested expiry date. If at the end of the dating period (shelf life) specified, the product is tested and found still to be above the release quality, consideration can be given to extending the designated shelf life, by request to the control authority. Stability testing also provides the opportunity to test for residual moisture and for other important parameters, such as the stability of adjuvant emulsions.

SAFETY TESTS

The intrinsic safety of vaccines should be demonstrated early in the development stage and documented as part of the licensing dossier. Safety studies during development and licensing for all products should include the safety of a single dose, of an overdose and of repeated single doses. Additional data are derived for live vaccines from the increase in virulence tests and by assessing risk to the environment and in-contact animals, as discussed above. Safety should be demonstrated in each species for which the product is indicated. The required safety test for a poultry product is described in the specific Standard Requirement or the Outline of Production for that product. As a general rule, overdose studies are required for all vaccines: ×10 for live and ×2 for inactivated vaccines (if this is not practical, an indication of safety may be obtained from the results of the potency tests). For inactivated virus or bacterial products, where host animals are used for potency testing, safety may be determined by measuring local and systemic responses following vaccination and before challenge in the potency tests. Further evidence concerning the safety of products is derived from field safety trials (discussed below). Vaccines derived through biotechnology should be evaluated as discussed in the classification of biotechnology-derived vaccines and release of live rDNA vaccines below.

Batch safety tests are required for the release of each batch and typical tests are described in CFR Title 9 part 113, in the European Pharmacopoeia, in this *Terrestrial Manual* and elsewhere. Standard procedures are given for safety tests in mice, guinea-pigs, cats, dogs, horses, pigs, and sheep and are generally conducted using fewer animals than are used in the safety tests required for licensing. Batches are considered satisfactory if local and systemic reactions to vaccination with the batch to be released are in line with those described in the registration dossier and product literature. Some authorities do not permit batch safety testing in laboratory animals, requiring a test in one of the target species for the product.

PURITY TESTS

Purity is determined by testing for a variety of contaminants. Tests to detect contaminants are performed on: master seeds, primary cells, MCSs, ingredients of animal origin if not subjected to sterilisation (e.g. fetal bovine serum, bovine albumin, or trypsin), and each batch of final product prior to release.

Purity test procedures have been published, for example in CFR Title 9 part 113, in the annex to EU Directive 2001/82/EC (as amended), in the European Pharmacopoeia, or in this *Terrestrial Manual,* for the detection of extraneous viruses, bacteria, mycoplasma and fungi, including for example: *Salmonella*, *Brucella,* chlamydial agents, haemagglutinating viruses, avian lymphoid leukosis, pathogens detected by a chicken inoculation test, pathogens detected by a chicken embryo inoculation test, lymphocytic choriomeningitis, cytopathic and haemadsorbing agents, and pathogens detected by enzyme-linked immunosorbent assay, polymerase chain reaction, or the fluorescent antibody technique. Procedures used to ensure that fetal calf serum and other ingredients of bovine origin are free of pestiviruses should be of high concern and well documented. Tests to be used to ensure purity vary with the nature of the product, and should be prescribed in the Outline of Production or other documentation of the manufacturing process. As tests for the detection of bovine spongiform

encephalopathy agents in ingredients of animal origin have not been developed, vaccine manufacturers should document in their Outlines of Production or SOPs the measures they have implemented to minimise the risk of such contamination in ingredients of animal origin. This relies on three principles: first, verification that sources of all ingredients of animal origin in production facilities are from countries recognised as having the lowest possible risk of bovine spongiform encephalopathy; second, that the tissues or other substances used are themselves recognised as being of low or nil risk of containing TSE agents; third, where relevant, that the processes applied to the material have been validated for inactivation of TSE agents. Methods of production should also document the measures taken to prevent cross contamination of low risk materials by higher risk materials during processing.

OTHER TESTS

Depending on the form of vaccine being produced, certain tests may be indicated and should be provided as appropriate in the Outline of Production or other documentation of the manufacturing process. These tests may concern: the level of moisture contained in desiccated products, the level of residual inactivant in killed products, the complete inactivation of killed products, pH, the level of preservatives and permitted antibiotics, physical stability of adjuvants, retention of vacuum in desiccated products, and a general physical examination of the final vaccine. Tests for these purposes may also be found in CFR Title 9 part 113, in EU Directive 2001/82/EC (as amended), in the European Pharmacopoeia, or in this *Terrestrial Manual*.

SAMPLING

Samples should be selected from each batch of product. The selector should pick representative final containers from each batch and store these samples at the storage temperature recommended on the label. The producer should keep these reserve samples at the recommended storage temperature for a minimum of 6 months after the expiry date shown on the label, so that they are available to assist in evaluating the cause of any field problems reported from the use of the vaccine. The samples should be stored in a secure storage area and be tamper-evident.

LABELLING

Standards for labelling products will vary from country to country; however, the label indications and all claims that are made on the label should be supported by appropriate data that have been reviewed and approved by competent authorities. It is recommended that all labels for veterinary vaccines be water-proof and contain the following information, although for very small containers, the label may instead refer to the carton label or to an enclosed package insert for some of the less prominent information:

1. The true name of the product, prominently lettered and with equal emphasis on each word;
2. The name and address of the producer (and also the importer for imported products);
3. The recommended storage temperature;
4. A statement that the product is ‘for veterinary (or animal) use only’. Full instructions for use, including all required warnings;
5. For food animals, a statement indicating that the animals should not be vaccinated within a specified number of days before slaughter. This will depend on the vaccine (e.g. type of adjuvant) and is not required for all products;
6. The expiry date;
7. The batch number by which to identify the product in the producer’s record of preparation;
8. The licence number for the product; in some countries this is replaced by the licence number of the establishment/manufacturer;
9. The recoverable quantity and number of doses;
10. A statement that the entire contents of a multidose container should be used when the container is first opened (or with appropriate holding time for certain products, as supported by data) and that any unused portions should be disposed of in a proper manner;
11. A safety warning to the operator, if appropriate, e.g. accidental self-injection with oil emulsion vaccines.

12. Where it is allowed for an antibiotic to be added to a vaccine during the production process, the statement "Contains (antibiotic name) as a preservative" or an equivalent statement indicating the antibiotic added should appear on the carton or enclosures if used. If cartons are not used, such information should appear on the final container label.

Labels may also include other factual statements that are not false or misleading. Special restrictions concerning the use or handling of the product, when applicable, should also be indicated.

Similar information should also be given in a Product Data Sheet that is provided as a package insert. This will also contain much more detail about method of use and possible adverse reactions.

FIELD TESTS (SAFETY AND EFFICACY)

All veterinary biological products administered to animals should be tested for safety and, if possible, for efficacy in the field, using good clinical practice, before being authorised for general use. Field studies are designed to demonstrate efficacy under working conditions and to detect unexpected reactions, including mortality, that may not have been observed during the development of the product. Under field conditions there are many uncontrollable variables that make it difficult to obtain good efficacy data, but demonstration of safety is more reliable. The tests should be done on the host animal, at a variety of geographical locations, using large numbers of susceptible animals. The test animals should represent all the ages and husbandry practices for which the product is indicated; unvaccinated controls must be included. The product tested should be one or more production batches. A protocol should be developed indicating the observation methods and the recording methods.

INSPECTION OF PRODUCTION FACILITIES

Establishments that are approved to produce veterinary biologicals should be subject to in-depth inspections of the entire premises by national competent authorities to ensure compliance with the Outline of Production and blueprints and legends, SOPs, or other documentation of the manufacturing process. These inspections may include such items as: personnel qualifications; record keeping; general sanitation and laboratory standards; research activities on products being developed; production procedures; operation of sterilisers, pasteurisers, incubators, and refrigerators; filling, desiccating, and finishing procedures; care and control of animals; testing procedures; distribution and marketing; and product destruction. It is desirable to have good manufacturing practice (for manufacturing) and good laboratory practice (for quality assurance testing). (See chapter 1.1.2. for guidelines.)

The inspectors should prepare a comprehensive report documenting the findings of the inspection and stating the actions that the establishment must take to improve its production processes. The establishment should receive a copy of the report. When necessary a follow-up inspection should be conducted to determine whether appropriate action has been taken to correct deficiencies. Continued reassessment in this manner is needed to ensure that production facilities continue to be operated in an acceptable manner. Periodic inspections also encourage continual improvements in production procedures and facilities that are consistent with advances in technology.

TESTING PRIOR TO RELEASE FOR DISTRIBUTION

Prior to release, the manufacturer must test each batch for purity, safety, and potency, as well as perform any other tests described in the firm's Outline of Production or other documentation of the manufacturing process for that product. In countries that have national regulatory programmes that include official control authority re-testing (check testing) of final products, samples of each batch should also be submitted for testing in government laboratories by competent authorities. If unsatisfactory results are obtained for tests conducted either by the manufacturer or by competent authorities, the batch should not be released. In such cases, subsequent batches of the product should be given priority for check testing by competent authorities.

UPDATING THE OUTLINE OF PRODUCTION

Before production procedures are changed, the corresponding Outline of Production or other documentation of the manufacturing process should be changed. Establishments should have internal review procedures to evaluate all changes in production before they are initiated. Changes should also be reviewed and approved by competent authorities prior to their implementation. In cases where a significant production step is altered, revisions may require additional data to support the purity, safety, potency, and/or efficacy of the product. In

countries with regulatory programmes that include check testing the final product at national laboratories, revisions should entail testing of the new product by competent authorities.

PERFORMANCE MONITORING

Manufacturers are required to maintain an adverse reaction notification system and an effective mechanism for rapid product recall. These should both be subject to audit by regulatory bodies. In many countries, the manufacturer must notify all adverse reactions immediately to the regulatory authority, along with any remedial action taken. An alternative used in some countries is that if at any time, there are indications that raise questions regarding the purity, safety potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing or distribution of a product, the manufacturer must immediately notify the regulatory authorities concerning the circumstances and the action taken.

After release of a product, its performance under field conditions should continue to be monitored by competent authorities. Consumer complaints may serve as one source of information; however, such information needs to be investigated to determine whether or not the reported observations are related to the use of the product. Users of veterinary vaccines should be informed of the proper procedures for making their complaints. The manufacturer of the product should be informed of all complaints received by competent authorities. Competent authorities should also ascertain whether they have received other similar complaints for this product and, if so, whether the manufacturer has taken appropriate action. Control laboratories may test samples of the batch of product involved, if necessary.

When the investigation is complete, a final report should be prepared and a summary of the findings sent to the complainant and to the manufacturer. When it is determined that a product is causing serious problems, immediate action should be taken to remove the product from the market and to notify animal health authorities.

ENFORCEMENT

National programmes established to ensure the purity, safety, potency, and efficacy of veterinary vaccines must have adequate legal authority to ensure compliance with product registration conditions and other programme requirements. The goal should be to obtain voluntary compliance with established regulatory requirements. However, when violations occur, competent authorities must have adequate legal authority to protect animal health. Authority for detention, seizure, and condemnation of products found to be worthless, contaminated, dangerous, or harmful may be valuable for this purpose. Under such authority, product may be detained for a period of time, and if during that time compliance cannot be achieved, competent authorities may seek a court order or decree for seizure and condemnation.

The authority to remove or suspend establishment and/or product licenses, obtain injunctions, and stop the sale of product is also needed. Civil penalties or criminal prosecution may also be necessary for serious or deliberate violations.

LICENSING OF PRODUCTS DERIVED THROUGH BIOTECHNOLOGY

Recent advances in biotechnology have made possible the development and commercialisation of new biological products with useful antigenic and diagnostic properties. Many such products have now been licensed or approved, and more are being developed. Products of rDNA technology do not differ fundamentally from conventional products. Therefore, existing laws and regulations are fully applicable to these new products.

CLASSIFICATION OF BIOTECHNOLOGY-DERIVED VACCINES

Each competent authority with power to regulate organisms and products derived from recombinant techniques should ensure that the public health and the environment are protected from any potentially harmful effects. For the purpose of evaluating licence applications, veterinary vaccines derived through rDNA technology may be divided into three broad categories. The division is based on the products' biological properties and on the safety concerns they present.

Category I consists of nonviable or killed products that pose no risk to the environment and present no new or unusual safety concerns. Such products include inactivated microorganisms, either whole or as subunits, created by using rDNA techniques.

Category II products contain live microorganisms modified by adding or deleting one or more gene(s). Added genes may code for marker antigens, enzymes, or other biochemical by-products. Deleted genes may code for virulence, oncogenicity, marker antigens, enzymes, or other biochemical by-products. The licence application must include a characterisation of the DNA segments added or deleted, as well as a phenotypic characterisation of the altered organism. The genetic modifications must not result in any increase in virulence, pathogenicity, or survivability of the altered organism in comparison with the wild-type form. It is important that the genetic modification does not cause a deterioration in the safety characteristics of the organism.

Category III products make use of live vectors to carry recombinant-derived foreign genes that code for immunising antigens. Live vectors may carry one or more foreign gene(s) that have been shown to be effective for immunising target host animals. The use of DNA vaccines containing recombinant-derived foreign genes that code for immunising antigens (plasmid DNA vaccines) constitutes a new approach to vaccine development. The proper categorisation of this type of rDNA-derived product will be established as biological properties and safety characteristics are determined. These new vaccines may find application in a wide variety of situations much as conventional products have. Guidelines for the development, production, characterisation, and control of these new products are still preliminary and subject to change as new data and knowledge are developed. Information concerning the current thinking on regulatory guidelines for plasmid DNA vaccines may be found on the Internet at the following addresses:
http://www.fda.gov/cber/points.htm; http://www.cba.unige.it/VL/bio-info.html
http://www.orcbs.msu.edu/biological/biolsaf.htm; http://www.pestlaw.com/index.html;
http://www.emea.eu.int/pdfs/vet/iwp/000798en.pdf

RELEASE OF LIVE rDNA PRODUCTS

The release of live rDNA and plasmid DNA vaccines (Categories II and III) for field testing or general distributions as an approved or licensed product may have a significant effect on the quality of the human and animal environment. Before release is authorised, the manufacturers of the vaccine should conduct a risk assessment to evaluate the impact on the human and animal environment. In the USA, for example, a procedure is adopted that could be used as a model system in other countries. The European Union has adopted a similar system. It is performed as follows:

A risk assessment is carried out that should contain the following information: the purpose and need for the proposed action; the alternatives considered; a list of the government agencies, organisations, and persons consulted; and the affected environment and the potential environmental consequences. The topics discussed should include: the characteristics of the vaccine organism, human health risks, animal health risks for both target and nontarget animals, persistence in the environment, and increase in virulence.

If the risk assessment results in a finding by competent authorities that the proposed release of the recombinant vaccine into the environment for field trials or general distribution would not have a significant impact on the environment, a notice should be published and distributed to the public announcing this and that the risk assessment and findings are available for public review and comment. If no substantive comments are received to refute the findings, competent authorities may authorise the field testing or grant the license or approval for general distribution.

The preparation of a risk assessment and the findings made from the assessment may also include the scheduling of one or more public meetings if a proposed action has ecological or public health significance. Such meetings should be announced through a public notice. Interested persons should be invited to make presentations, along with presentations by the producer of the product, and government personnel. The transcripts of such meetings should become part of the public record.

If, in the course of preparing a risk assessment, competent authorities conclude that the proposed action may have a significant effect on the human environment, an Environmental Impact Statement (EIS) should be prepared. The EIS provides a full and fair discussion of the significant environmental impacts, and informs decision-makers and the public of any reasonable alternatives that would avoid or minimise the adverse impacts. (Environmental documents are considered in CFR Title 40 part 1508.) See also EU Directive 2001/18/EC.

FURTHER READING

The following are some suggested texts that contain guidelines on aspects of vaccine production.

548 A. EUROPEAN Commission (2006) The Rules Governing Medicinal Products in the European Union. Eudralex.
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551 B. COUNCIL OF EUROPE (2005). European Pharmacopoeia, Fifth Edition. Editions of the Council of Europe,
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553 C. ESPESETH D.A. (1993). Licensing Veterinary Biologics in the United States. The First Steps Towards an
554 International Harmonization of Veterinary Biologicals; and Free circulation of vaccines within the EEC. *Dev.*
555 *Biol. Stand.,* **79**, 17–25.

556 D. ESPESETH D.A. & GOODMAN J.B. (1993). Chapter 13. *In:* Licensing and Regulation in the USA. Vaccines for
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558 E. GAY C.G. & ROTH H.J. (1994). Confirming the safety characteristics of recombinant vectors used in veterinary
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560 105.

561 F. ROTH H.J. & GAY C.G. (1996). Specific safety requirements for products derived from biotechnology. *In:*
562 Veterinary Vaccinology, Pastoret P.-P., Blancou J., Vannier P. & Verschueren C., eds. Elseviers Science
563 Publishers B.V. Amsterdam, The Netherlands.

564 G. PASTORET P.P., BLANCOU J., VANNIER P. & VERSCHUEREN C., EDS (1997). Veterinary Vaccinology. Elsevier
565 Science, Amsterdam, The Netherlands.

566 H. UNITED STATES DEPARTMENT OF AGRICULTURE (USDA) (2000). Code of Federal Regulations, Title 9, Parts 1–
567 199. US Government Printing Office, Washington DC, USA.

568 I. USDA-APHIS[3]-VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1999). Categories of Inspection for
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570 Veterinary Biologics, 510 S. 17th Street, Suite 104, Ames, Iowa 50010, USA.

571 J. USDA-APHIS-VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1999). Veterinary Biological Product
572 Samples. Veterinary Services Memorandum No. 800.59. Center for Veterinary Biologics, 510 S. 17th Street,
573 Suite 104, Ames, Iowa 50010, USA.

574 K. USDA-APHIS- VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1995). Guidelines for Submission
575 of Materials in Support of Licensure. Veterinary Biologics Memorandum No. 800.84. Center for Veterinary
576 Biologics, 510 S. 17th Street, Suite 104, Ames, Iowa 50010, USA.

577 L. USDA-APHIS-VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1995). Veterinary Biologics General
578 Licensing Considerations No. 800.200, Efficacy Studies. USDA-APHIS-Veterinary Biologics, 4700 River
579 Road, Riverdale, Maryland 20737, USA.

580 M. USDA-APHIS-VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1995). Veterinary Biologics General
581 Licensing Considerations No. 800.201, Back Passage Studies. Center for Veterinary Biologics, 510 S. 17th
582 Street, Suite 104, Ames, Iowa 50010, USA.

583 N. USDA-APHIS-VETERINARY SERVICES (1964–1994). Standard Assay Methods, Series 100–900. National
584 Veterinary Services Laboratories, Ames, Iowa 50010, USA.

585 O. USDA-APHIS- VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1984). Basic License Requirements
586 for Applicants. Veterinary Biologics Memorandum No. 800.50. Center for Veterinary Biologics, 510 S. 17th
587 Street, Suite 104, Ames, Iowa 50010, USA

588 P. USDA-APHIS-VETERINARY SERVICES-CENTER FOR VETERINARY BIOLOGICS (1988). Guidelines for the
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590 Veterinary Biologics, 510 S. 17th Street, Suite 104, Ames, Iowa 50010, USA.

3 United States Department of Agriculture (USDA), Animal and Plant Health Inspection Services (APHIS). USDA-APHIS-CENTER FOR VETERINARY BIOLOGICS HOME PAGE: http://www.aphis.usda.gov/vs/cvb/index.html

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