UNION EUROPÉENNE

SANCO

19. 11. 2003

Bruxelles, le
D(2003) 521805/HB/vb

Objet: **Réunion du Code zoosanitaire – June/July 2003**

Monsieur le Directeur général,

Nous vous prions de bien vouloir trouver en annexe les commentaires de l'Union Européenne sur le rapport du bureau de la Commission du Code zoosanitaire international de l'Office International des Epizooties, en vue de la préparation de la Session générale de 2004.

Nous vous saurions gré de bien vouloir prendre en compte ces commentaires et les conclusions de la récente conférence 'Fièvre Catarrhale du mouton' à Taormina (IT) lors de la réunion de la Commission du Code zoosanitaire prévue en novembre 2003.

En complément, vous trouverez également en annexe un document sur la position de l'UE en ce qui concerne le chapitre relatif à l'influenza aviaire et un document sur le Maedi Visna et autres lentiviruses.

Nous tenons également à vous remercier pour l'excellente collaboration entre nos services et vous prions d'agréer, Monsieur le Directeur général, l'expression de nos sentiments distingués.

Romano Marabelli
Chief Veterinary Officer

Jaana Husu-Kallio
Directeur Général

Peices jointes: 3

Copie: Tous les directeurs/chefs de service vétérinaire de la Communauté/chefs de service vétérinaire de l'ACs

Dr. B. Vallat
Directeur général OIE
12 Rue de Prony
F-75017 PARIS

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, .10.11.2003

Written comments of the Community on the report of the meeting of the Bureau of the OIE [Office International des Epizooties] International Animal Health Code Commission [Paris July 2003] and the Scientific Commission [Paris August 2003] to be submitted for adoption and consideration in the 72nd General Session to be held in May 2004

ANNEX 1

Original: English

July 2003

DRAFT REPORT OF THE MEETING OF THE BUREAU OF THE OIE INTERNATIONAL ANIMAL HEALTH CODE COMMISSION

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English

July 2003

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

Paris, 30 June to 4 July 2003

The Bureau of the OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters from 30 June to 4 July 2003.

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

The Director General, Dr B. Vallat, welcomed the members of the new Commission and noted that the meeting marked the beginning of a new three-year cycle. He referred to the revised terms of reference for the Code Commission (see Appendix III) in which the close working relationship with the Scientific Commission for Animal Diseases (the Scientific Commission) had been clarified. As a result, Dr Vallat said that he expected enhanced development of scientific bases for the chapters of the *Terrestrial Animal Health Code* (the *Terrestrial Code*).

Dr Vallat recalled the extensive work programme for the Code Commission as a result of discussions at the 71st General Session, and identified the following priorities:

- further revision of the chapter on avian influenza (AI);
- a simplified approach to country categorisation in the chapter on bovine spongiform encephalopathy (BSE);
- further revision of the foot and mouth disease (FMD) surveillance guidelines;
- implementation of the new approach to disease notification.

The Bureau noted that the first meeting of the *ad hoc* Group on the Role of Private Veterinarians and Paraprofessionals in the Provision of Animal Health Services had been held; an extract from the report of the meeting is attached (see Appendix IV) for the information of Member Countries. The second meeting of the *ad hoc* Group is due to be held in October and any comments and suggestions from Member Countries would need to reach the OIE Headquarters by 3 October, to be addressed at that meeting.

The Bureau discussed the progress made by the Working Groups on Animal Welfare and Animal Production Food Safety. The Bureau also noted the upcoming Global Conference on Animal Welfare to be held at the OIE on 23-25 February 2004.

The Bureau examined various draft and revised *Code* chapters and appendices, and comments received on them. The outcome of this part of the Bureau's work is presented as appendices to this report, with insertions and amendments to existing *Code* text and previously circulated drafts being shown as double underlined text, and with text proposed for deletion in strikeout (not in square brackets as previously has been the case). At the request of Member Countries in relation to reports of its December meetings, the Code Commission is examining ways of retaining the changes made at the July meeting while differentiating them from modifications made at the December meeting.

Member Countries are invited to comment on all aspects of the report. Comments need to reach the OIE Headquarters by 7 November 2003 in order to be considered at the next Code Commission meeting in December.

A. TEXTS FOR MEMBER COUNTRY COMMENT

1. Article 1.1.1 General definitions

Community comments:
The Community can support this proposal but would like the comments in Appendix V taken on board.

In response to comments received from Australia, the Bureau of the Code Commission modified the definition of the expression 'artificial insemination centre'. Following examination of comments from the European Union (EU), a minor amendment was made to the definition of the term 'approved'.

The definition of the term 'compartment' was revised on the basis of comments from several Member Countries, including Argentina, Canada, the EU and Japan. The definitions of the terms 'enterprise' and 'zone' were amended accordingly.

An amendment to the definition of the expression 'products of animal origin intended for use in animal feeding' was also made after addressing some comments from the EU.

Suggested changes are shown in Appendix V.

2. Section 1.2 Obligations and ethics in international trade

Community comments:
The Community can support this proposal but would like the comments in Appendix VI taken on board.

The Bureau of the Code Commission modified Article 1.2.1.2 by adding a paragraph on the basis of a suggestion made by Australia (Appendix VI).

3. Chapter 1.3.3 Evaluation of Veterinary Services

Chapter 1.3.4 Guidelines for the evaluation of Veterinary Services

Community comments:
The Community can support this proposal but would like the comments in Appendices V and VI taken on board.

The Bureau of the Code Commission modified Articles 1.3.3.2 and 1.3.4.7 in response to comments from Canada.

The Bureau also examined the definitions proposed by the *ad hoc* Group on the Role of Private Veterinarians and Paraprofessionals in the Provision of Animal Health Services and, with minor amendments, added these to Chapter 1.1.1 (see Appendix V). As a result of the recommendations of this *ad hoc* Group, changes were also made to the existing *Terrestrial Code* text in Chapters 1.3.3 and 1.3.4.

Suggested changes to Chapter 1.3.3 and Chapter 1.3.4 have been incorporated into a revised text (Appendix VII).

4. Chapter 1.3.7 Guidelines for reaching a judgement of equivalence of sanitary measures

Community comments:
The Community can support this proposal but would like the comments in Appendix VIII taken on board.

The Bureau of the Code Commission amended text in point 2 of Article 1.3.7.4 after considering comments from the United States of America (USA). Several comments from Canada and the EU had already been addressed during the meeting held prior to the 71st General Session. Articles 1.3.7.2 and 1.3.7.5 were amended on the basis of comments received from the EU and Canada, respectively.

Suggested changes have been incorporated into a revised text (Appendix VIII).

5. Chapter 2.1.1 Foot and mouth disease

Community comments:

The Community can only support these proposal if the comments in Appendices IX and X taken on board. It also requests the OIE to expand the issues submitted to the Scientific Commission to include sheep and goats as well as pigs and that as these species are not generally vaccinated both unvaccinated and vaccinated caprines, ovines and porcines should be included in the review for the trade of meat. It must be borne in mind that this would be mainly in the context of a systematic vaccination of the bovine population in a country.

The Bureau of the Code Commission examined comments from the EU regarding country categories for FMD and decided that it was preferable to first examine ways of improving surveillance and diagnostic methodologies, especially for countries free with vaccination. These issues will be discussed with the Scientific Commission.

A comment from Japan was included in Article 2.1.1.1.

Proposals received from Argentina, Bolivia, Brazil, Paraguay and Uruguay to delete reference to Appendix 3.8.6 in Articles 2.1.1.3 and 2.1.1.5 were not accepted.

The Bureau considered it necessary to refer to the Scientific Commission comments from Argentina, Bolivia, Brazil, Paraguay and Uruguay relating to the incorporation of risk factors. The Bureau did not believe that such an approach was as applicable to FMD as it was to BSE, because surveillance of the live animal population is an important and practicable factor in determining the FMD status of a country or zone.

Comments received from Argentina, Bolivia, Brazil, Paraguay and Uruguay on Article 2.1.1.7 were not incorporated as the Bureau saw no reason, at this stage, to merge the two categories. Proposals received from the EU, Japan, Canada, Argentina, Bolivia, Brazil, Paraguay and Uruguay on paragraph 2 b) of Article 2.1.1.7, which would have required surveillance for infection were not incorporated because the Bureau considered that the subclauses provided a suitable gradation based on the actions of the vaccinating countries. Other comments on Article 2.1.1.7 were referred to the Scientific Commission.

As deletion of the former Article 2.1.1.9 had just been agreed by the OIE International Committee, it was not considered appropriate to reinstate it.

The Bureau decided to refer an inconsistency in Article 2.1.1.11 (with a comment from Japan) to the Scientific Commission.

EU proposals regarding Articles 2.1.1.14 and 2.1.1.15 were adopted. The Bureau believed that EU concerns regarding Articles 2.1.1.19, 2.1.1.20, 2.1.1.21 and 2.1.1.23 were addressed by the present wording. The Bureau believed that concerns expressed by the EU, Japan and the USA and regarding bone-in meat were addressed by the requirement that the country or zone be free from infection; the OIE International

Committee had adopted the modified chapter on the basis that exports would be permitted once the tools for the required surveillance were available.

The chapeau to Article 2.1.1.16 was modified to reflect the IETS categorisation of *in vivo* derived bovine embryos with regard to FMD.

Article 2.1.1.25 was modified to address the principle underlying the comment from the EU.

Suggested changes have been incorporated into a revised text (Appendix IX).

Regarding surveillance for FMD, the Bureau incorporated comments from South Africa as appropriate into the Appendix on surveillance for FMD (Appendix X). It passed the remainder of comments received to the Scientific Commission to address during its revision of the FMD guidelines in conjunction with the development of general principles for surveillance.

The Bureau examined a comment from Argentina on FMDV inactivation but saw no need to change the current text.

The following additional issues will be referred to the Scientific Commission:

- recommendations on the trade of meat from vaccinated pigs
- a list of commodities which could be safely traded regardless of the FMD status of the exporting country

- a proposal from Uruguay regarding the recovery of free status by countries where vaccination is practised

- definitions for appropriate vaccines and vaccination procedures for FMD.

6. Chapter 2.3.13 Bovine spongiform encephalopathy

Community comments:
The Community can support this proposal but would like to point out that it has commissioned a study on tallow and would like additional changes made to this chapter as indicated below and in Appendices XI and XII. It also reserves its position on tallow pending the outcome of the study described below.

Article 2.3.13.3 was modified with regard to the recommendations concerning progeny to harmonise it with similar articles.

Several countries requested the inclusion of bovine oocytes in the list of safe commodities (Article 2.3.13.8). However, experts consulted by the Bureau of the Code Commission stated that, while there was experimental evidence for the safety of embryos and semen, there was none for oocytes. For this reason, the Bureau left that article unmodified.

The Bureau received comments from the EU and the USA regarding the safety of protein-free tallow. Until the safety of protein-free tallow has been clarified, the Bureau was of the view that protein-free tallow should be removed from the list of safe commodities. The relevant changes were made to Articles 2.3.13.8, 2.3.13.21 and 2.3.13.22. Suggested changes have been incorporated into a revised text (Appendix XI).

The Community has commissioned a study to establish a probabilistic model for the quantitative assessment of residual BSE risk. Pending outcome of this study the Community reserves its position on tallow.

Canada, the EU and the USA requested changes to the lists of specified risk materials. The Bureau determined that, as the current lists are based on country categorisation and as an *ad hoc* Group was to be convened to revise the BSE categorisation system, changes to the lists of specified risk materials should be contingent on the outcome of the revision of this categorisation. A proposal for a complete revision of the chapter was also received and will be referred to the *ad hoc* Group.

In various opinions of the Scientific Steering Committee advising the EU on TSE related matters, the most recent one being the overview adopted on 5 June 2003, an age limit of 12 months for removing CNS tissues as SRM has been recommended. Intestines and tonsils should be removed as SRM from bovines of all ages.

Evidence from the pathogenesis study likewise indicates that infectivity will not be detected in CNS tissues early in the incubation period.

Therefore the Community cannot agree with the age limit of six months for countries with a moderate BSE risk. This age limit is only scientifically justified for high-risk areas. The Community proposes to raise the age limit to 12 months for countries with a moderate BSE risk.

The Community feels that for control reasons the harvesting of mechanically recovered meat from the skull or vertebral column of bovine animals of any age should be prohibited.

The Community reserves its opinion on the age limit for the inclusion of vertebral column pending internal discussions. In view of this the Community suggest replacing article 2.3.13.16 point 5 with:

"5) the fresh meat and meat products destined for export do not contain skull, brain, eyes, tonsils or spinal cord of bovine animals over 12 months, nor intestine of bovine animals of any age, all of which have been removed in a hygienic manner. Neither do they contain mechanically separated meat from skull or vertebral column of bovine animals."

The EU furthermore considers that the factors to be taken into account in the BSE risk assessment should be reviewed in the framework of a possible future review of the BSE Chapter.

The Bureau noted the EU suggestion that the OIE give guidance on statistically significant sample sizes for risk populations. The Bureau welcomes the EU offer to provide guidance on relevant statistics.

The Bureau also examined comments from the EU on 'Guidelines for assessing the BSE risk of a cattle population'. In order to clarify the intended application of this document, the Bureau proposed a change in its title. It is circulated as clean text for further Member Country comment (Appendix XII).

7. **Chapter 2.3.7 Bovine anaplasmosis**

Chapter 2.3.8 Bovine babesiosis

Chapter 2.3.11 Theileriosis

Community comments:

The Community would still like its comments given last time to be taken on board for all the above It thanks the OIE for supporting its proposal for the initiative concerning the treatments and diagnostic tests but would propose it is extended to include vaccines as well.

The Bureau of the Code Commission examined a comment from the EU and decided to make no changes to these chapters.

The Bureau will seek the expert advice on effective treatments for these diseases, and on diagnostic tests for theileriosis.

8. Chapter 2.4.5 Maedi-visna

Community comments:

The Community can only support this proposal if the comments in Appendix XIII taken on board and would ask the OIE to review in the context of freedom the implication of and links with other lentiviruses in particular CAEV. A background document has been attached. If the chapter is not amended there may well be significant trade implications as few if any countries will be able to meet the disease free requirements.

The Bureau of the Code Commission examined the supporting document and draft revised chapter originally submitted in September 2001. It incorporated the new approach proposed in these documents into the existing chapter, and the revised chapter is circulated for Member Country comment (Appendix XIII).

9. Chapter 2.1.13 Classical swine fever

Community comments:

The Community can only support this proposal if the comments in Appendix XIV taken on board.

The Bureau of the Code Commission examined comments from Japan regarding restrictions imposed on countries or zones free from classical swine fever (CSF) (Article 2.1.13.4). The Bureau decided to delete the requirements for the permanent identification of pigs and treatment of swill, as these should not be required to maintain the status of a free country or zone. However, the Bureau acknowledged that the absence of such measures would make recovery from disease incursions more difficult. It decided that serological surveillance (a proposal from Australia and Japan) was not required because experts consulted were of the opinion that clinical signs of CSF would be sufficiently obvious to be readily detected.

The Bureau did not consider appropriate the Japanese proposal regarding the recovery of free status after an eradication programme, as the experts consulted had indicated that surveillance of the pig population of 6-12 months of age would provide a sufficient indication of freedom. In order to simplify existing text, the Bureau merged paragraphs f) and g) of Article 2.1.13.4, without changing the recommendation.

The Bureau did not accept the Australian proposal to delete Articles 2.1.13.5, 2.1.13.9, 2.1.13.13 and 2.1.13.19 as the justification given (outbreaks of CSF in domestic pigs in areas with infected wild boar in the EU) was considered to be more indicative of a failure of implementation than of a flaw in the concept of compartmentalisation.

Comments received regarding Article 2.1.13.6 were not accepted as they had been addressed at a previous meeting.

The Bureau did not accept the Australian proposal to modify Article 2.1.13.7 to require general serological surveillance, as wild pigs over the age of 12 months could show serological evidence of previous infections or vaccinations, not reflecting their current status. Serological surveillance should therefore be confined to the wild pig population of 6-12 months of age, as recommended by experts consulted by the Bureau.

The Bureau did not accept the Japanese proposal to modify Article 2.1.13.19 as it was considered that the requirement that the abattoir be approved did address contamination issues appropriately.

Suggested changes have been incorporated into a revised text (Appendix XIV).

The Bureau decided to ask the Scientific Commission for advice regarding a list of commodities which could be safely traded regardless of the CSF status of the exporting country.

The Bureau decided to check the primary sources of the figures for the inactivation of CSF in various meat products, and will report in December.

10. Chapter 2.2.4 Leptospirosis

Community comments:

The Community has some reservation over this proposal to delete the chapter as in bovine semen. The present wording of the Leptospirosis chapter is not very good, and the Community agrees that the current wording can result in excessive use of Dihydrostreptomycin as discussed at the OIE general session in May. But the Community is not really of the opinion that the chapter should be deleted. It is important that an importing country can require testing or treatment of animals, semen, embryos or ova before importation; it is important to ensure that there is no contamination with leptospirosis in the semen. It could perhaps agree on the chapter's deletion provided that this does not have an adverse affect on the Chapters on semen, embryos and ova.

The comments made at the General Session by Australia and the USA led the Bureau of the Code Commission to reassess the usefulness of the recommendations in the current chapter. Noting the ubiquity of the causative organism, the absence of any meaningful official control programmes and that there are no effective treatments, the Bureau proposes that the chapter be removed from the *Terrestrial Code*.

11. Chapter 2.1.9 Bluetongue

Community comments:

The Community could support this proposal if the comments in Appendices XV and XVI taken on board and the questions raised below are addressed in any redraft of the Chapter. The Commission would also like to suggest that the conclusions of the bluetongue conference held in Taormina are also taken into account.

The Bureau of the Code Commission considered a draft appendix on surveillance and monitoring for bluetongue developed by Australia. The Bureau made some modifications and is circulating the draft (as clean text) for Member Country comment (Appendix XV). The Bureau considered that the text would be enhanced were the following questions addressed in more detail, and seeks input from Member Countries:

- How are the cattle and sheep populations to be sampled (sample size and frequency)?
- What defines a population or sub-population?
- How should climate variability be addressed?
- How should the programme be adapted to higher risk parts of the country or zone?
- What constitutes a surveillance and monitoring programme for vectors?
- What features of a surveillance programme are necessary to provide sufficient evidence of the start/end of seasonal activity?

The Bureau has drafted, for Member Countries' comment, guidelines on protecting animals from Culicoides attack during transport (Appendix XVI).

12. Semen and embryo related matters

Community comments:

The Community agrees with the explanation given below and can support this initiative and will comment further when a proposal is received. It would like to draw the attention of the Code Commission to the comments above in relation to Leptospirosis.

The Bureau of the Code Commission received comments on various issues relating to the collection of semen.

The Bureau reviewed comments received on the *Terrestrial Code* Appendix on porcine semen prior to the 70th General Session and comments received from Australia on the *Code* Appendix on bovine semen. It discussed with an expert the issues raised and the need to update the chapter on small ruminant semen. The Bureau decided that, to ensure a harmonised approach, it would update all semen chapters simultaneously. The result of this work would be discussed at the December meeting of the Code Commission.

Comments from Australia and the USA and regarding the transmissibility of enzootic bovine leukosis (EBL) via semen were discussed with an expert. The Bureau recognizes that the available literature supports the contention that semen free from blood cells is unlikely to transmit the EBL virus; however, in practice, the presence of blood cells in semen cannot be ruled out and the Bureau agreed that changes to Articles in the chapter addressing semen were not justified.

13. Chapter 2.1.15 Avian influenza

Community comments:

The Community can only support this proposal if the comments in Appendix XVII are taken on board. It would remind the Code Commission of the extensive comments already submitted and thanks the OIE for inviting its experts to help in the continuation of this work. It will comment further when a new draft text is received but has attached a new outline draft at Annex 2 to help in the work of the OIE.

During the 71st General Session in May 2003, a revised chapter was discussed by the OIE International Committee. As a result of concerns expressed by several Delegates regarding implementation of the recommendations as written, the chapter was not submitted for adoption.

The Bureau of the Code Commission considered in depth the comments received shortly before the 71st General Session from Argentina, Australia, the EU, Japan and the USA, the outcome of the discussion held during the General Session, as well as further written comments. The Bureau made appropriate modifications to the chapter (Appendix XVII).

To address other comments received, the Bureau felt it necessary to seek further advice from the Scientific Commission and relevant experts on:

- the zoonotic aspects of avian influenza,
- the influence of different disease control strategies including vaccination,
- the development of guidelines for avian influenza surveillance and suitable testing methods,
- the risks presented by different commodities from countries of different disease status,
- inactivation procedures for avian influenza virus in different commodities, and
- the incubation period for avian influenza.

The Code Commission will examine this work at its December meeting.

B. OTHER TEXTS

1. Traceability

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

The Bureau of the Code Commission again reviewed the desirability of incorporating traceability into the *Terrestrial Code*. In this respect, the OIE encourages Member Countries to submit proposals and draft texts which could form the basis of guidelines. The Bureau will also examine the OIE *Scientific and Technical Review* and Codex documents for relevant text.

2. Chapter 1.3.5 Zoning and regionalisation

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

The Bureau of the Code Commission commenced work on addressing the requests from several Member Countries for guidelines on the practical application of compartmentalisation. This work will be progressed over the next few months and may be circulated after the December meeting of the Code Commission, for Member Countries' comment.

3. Chapter 2.2.6 Paratuberculosis

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

A revised draft chapter on paratuberculosis is being developed with an expert, in preparation for review by the Scientific and Code Commissions.

4. Chapter 2.2.1 Anthrax

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

The Bureau of the Code Commission is working with an expert on a revision of the Appendix on inactivation, in preparation for review at the December meeting of the Code Commission.

5. **Porcine reproductive and respiratory syndrome**

Community comments:
The Community supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

The Director General will seek an update on the Canadian offer to write a supporting document and develop a draft chapter on porcine reproductive and respiratory syndrome.

6. **Chapter 2.4.8 Scrapie**

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course. The Community will send the results of its survey to the OIE when available.

Based on comments received from the EU on surveillance for scrapie, the Bureau of the Code Commission decided to request the Scientific Commission to develop appropriate guidelines.

7. **Chapter 2.4.9 Ovine pulmonary adenomatosis**

Community comments:
The Community supports this initiative but does not consider it to be a priority for the OIE. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

Comments on the draft chapter have been received from the EU, New Zealand and the USA. The Code Commission will further develop recommendations for this disease when resources permit.

8. **Chapter 2.1.15 Newcastle disease**

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

The Bureau of the Code Commission decided that it would ask the Scientific Commission to revise the current chapter on Newcastle disease to harmonise it with the concepts underpinning the revised avian influenza chapter.

9. **Section 2.9 Diseases of bees**

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

The Bureau of the Code Commission noted that a meeting of an *ad hoc* Group on diseases of bees will take place at the end of July. The report of the *ad hoc* Group will be circulated in the report of the December meeting of the Code Commission, for Member Country comment.

10. **Chapter 2.2.2 Aujeszky's disease**

Community comments:
The Community fully supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

Following requests from Member Countries, the Bureau of the Code Commission will ask the Scientific Commission to develop surveillance guidelines for Aujeszky's disease.

12. **Chapter 2.1.8 Infectious bursal disease**

Community comments:
The Community supports this initiative. Community experts would be pleased to participate in this work. The Community will be pleased to comment when the proposals are received in due course.

In order to update the chapter, the Bureau of the Code Commission is still seeking information from Member Countries on any research they may have conducted on the transmissibility of IBDV by poultry meat.

.../Appendices

Appendix I

MEETING OF THE BUREAU OF THE

OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 30 June to 4 July 2003

List of Participants

MEMBERS OF THE BUREAU

Dr A. Thiermann

President

US Mission to the Organisation for Economic Co-operation and Development

19, rue de Franqueville

75016 Paris

FRANCE

Tel: 33-(0)1 44 15 18 69

Fax: 33-(0)1 42 67 09 87

E-mail: alexthiermann@compuserve.com

Dr W.-A. Valder

Vice President

Ministerialrat

Bundesministerium Verbraucherschutz, Landwirtschaft

Rochusstrasse 1

53123 Bonn

GERMANY

Tel: (49-228) 529 3618

Fax: (49-228) 529 4401

E-mail: wolf-arno.valder@bmvel.bund.de

Dr S. MacDiarmid

Secretary-General

Principal Adviser,

Zoonoses and Animal Health,

Programme Development Group,

New Zealand Food Safety Authority

P.O. Box 2835

Wellington

NEW ZEALAND

Tel: (64-4)

Fax: (64-4) 463 2530

E-mail: stuart.macdiarmid@nzfsa.govt.nz

OIE HEADQUARTERS

Dr B. Vallat

Director General

12, rue de Prony

75017 Paris

FRANCE

Tel: 33-(0)1 44 15 18 88

Fax: 33-(0)1 42 67 09 87

E-mail: oie@oie.int

Dr D. Wilson

Head

International Trade Department

E-mail: d.wilson@oie.int

Dr H. Kamakawa

Chargé de mission

International Trade Department

E-mail: h.kamakawa@oie.int

OTHER PARTICIPANTS

Prof M. Thibier

(Semen and embryos/ova related matters only)

Directeur général

Direction générale de l'Enseignement et de la Recherche

Ministère de l'agriculture, l'alimentation, de la pêche et des affaires rurales

1 ter, avenue de Lowendal

75700 Paris 07 SP

FRANCE

Tel: 01-49-55-42-40

Fax:01-49-55-46-36

E-mail: michel.thibier@agriculture.gouv.fr

Appendix II

MEETING OF THE BUREAU OF THE

OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 30 June to 4 July 2003

Agenda

Item 1 General definitions (Chapter 1.1.1)

Item 2 Evaluation of Veterinary Services (Chapter 1.3.3 and 1.3.4)

Item 3 Traceability

Item 4 Equivalence (Chapter 1.3.7)

Item 5 Obligations and ethics in international trade (Chapter 1.2.1)

Item 6 Zoning and regionalisation (Chapter 1.3.5)

Item 7 Foot and mouth disease (Chapter 2.1.1)

Item 8 Bovine spongiform encephalopathy (Chapter 2.3.13)

Item 9 Bluetongue (Chapter 2.1.9)

Item 10 Enzootic Bovine Leucosis (Chapter 2.3.4)

Item 11 Anthrax (Chapter 2.2.1)

Item 12 Leptospirosis (Chapter 2.2.4)

Item 13 Paratuberculosis (Chapter 2.2.6)

Item 14 Bovine anaplasmosis (Chapter 2.3.7)

Item 15 Bovine babesiosis (Chapter 2.3.8)

Item 16 Theileriosis (Chapter 2.3.11)

Item 17 Maedi-visna (Chapter 2.4.5)

Item 18 Scrapie (Chapter 2.4.8)

Item 19 Ovine pulmonary adenomatosis

Item 20 Classical swine fever (Chapter 2.1.13)

Item 21 Porcine Reproductive and Respiratory Syndrome

Item 22 Aujeszky's disease (Chapter 2.2.2)

Item 23 Newcastle disease (Chapter 2.1.15)

Item 24 Avian influenza (Chapter 2.1.14)

Item 25 Infectious bursal disease (Chapter 2.7.1)

Item 26 Diseases of bees (Chapters 2.9.1-2.9.5)

Item 27 Bovine tuberculosis (Chapter 2.3.3)

Item 28 Semen and embryo related matters

Item 29 Antimicrobial resistance

Item 30 Report of the *ad hoc* Group on private veterinarians and para-professionals

Item 31 Other issues

Community comments

The Community has renumbered the last few Items as they were wrongly numbered and should be re-checked by the OIE

Appendix III

OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

(in brief "Code Commission")

Terms of reference, Internal Rules and Qualifications of the Members

I. Terms of Reference

The terms of reference of the OIE Terrestrial Animal Health Standards Commission shall be:

1. To promote the adoption by the Committee of animal health (including zoonoses), animal welfare and animal production food safety standards, guidelines and recommendations concerning trade or international movement of mammals, birds and bees, and their products. Such standards, guidelines and recommendations are designed to minimise the risks of transmitting diseases (including zoonoses) while avoiding unjustified sanitary barriers.

2. To edit an annual compendium of such standards, guidelines and recommendations (the OIE Terrestrial Animal Health Code — the Terrestrial Code) in formats and languages as required by the Committee.

3. To advise the Director General on the composition and the activities of the Working Groups on animal welfare and animal production food safety, and to coordinate their work.

4. To develop in collaboration with other OIE Specialist Commissions and with relevant experts:

   a) generic chapters in the Terrestrial Code which address general topics such as evaluation of veterinary services, certification, regionalisation, risk analysis methodology, antimicrobial resistance and which are in harmony with similar recommendations in the OIE Aquatic Animal Heath Code.

   b) disease-specific chapters and appendices in the Terrestrial Code which are maintained current with the latest scientific information, and which provide clear guidance to users on terrestrial animal diseases on the OIE list of notifiable diseases.

5. To identify issues that require in-depth review and propose, to the Director General, the composition and terms of reference of experts or Ad hoc Groups of experts convened specifically to study such issues, and if necessary, to participate in the work of these Groups.

6. To advise the Director General on issues relevant to its work arising or being discussed in other international organisations (such as the Codex Alimentarius Commission, the International Plant Protection Convention and the WTO) or fora.

7. To represent the OIE at scientific and specialised conferences upon the request of the Director General.

II. Internal Rules

Article 1

The OIE Terrestrial Animal Health Standards Commission shall consist of a Bureau (comprised of a President, a Vice-President and a Secretary General) and three other Members.

Article 2

The Committee selects the Members of the Bureau individually and then the other three members, taking into account the need for a geographically balanced representation, and the need for relevant expertise.

The members of the Commission are elected for a period of three years.

The mandate of the Commission Members may be renewed.

Positions should be filled as they fall vacant before elections as indicated in the first paragraph.

Article 3

The Commission shall meet at least once during the year to review comments from Members, to revise chapters as appropriate, and to finalise chapters to be presented to the International Committee. At least one of the meetings in the year shall be held in conjunction with the Scientific Commission for Animal Diseases and the Aquatic Animal Health Standards Commission and if necessary with other Specialist Commissions. A special meeting may be organised immediately prior to the General Session.

Article 4

The Bureau of the Commission shall meet as often as the Director General considers necessary, at a venue determined by the Director General, in consultation with the President of the Commission.

Article 5

Where appropriate, specialists from national/regional/international organisations and from OIE Collaborating Centres and Reference Laboratories, appointed by the Director General, shall attend certain parts of meetings of the Commission or Bureau for particular topics relating to their field of competence.

Article 6

After each meeting, the Secretary General of the Commission shall provide the Director General with a report of the proceedings of the meeting, a draft of a work programme and the proposed dates for the next meeting.

Article 7

The Commission shall make available to the Director General, by no later than 1 February each year, all texts which are to be presented for adoption or comments during the following General Session of the Committee. These texts shall be sent by the Central Bureau to Member Countries for examination and comment before the General Session.

Article 8

The President of the Commission will report annually to the Committee the activities of the Commission and the draft of the resolutions that it wishes the Committee to adopt.

Article 9

When reporting to the Committee on the activities of the Commission, the President of the Commission shall present, in the form of chapters of the Terrestrial Code, proposed final texts on which Member Countries have been consulted, in accordance with Article 7 above.

Article 10

All formal correspondence between the Commission and outside individuals or bodies shall be issued through the office of the Director General.

Article 11

The President of the Commission, in concert with the Bureau, shall periodically consult with Member Countries as to whether or not the contents of the Terrestrial Code are continuing to satisfy their needs as international standards.

Article 12

The Central Bureau shall assist the Secretary General of the Commission in recording meetings of the Commission and preparing reports, notably by providing secretarial support, word-processing equipment and translation services.

III. Qualifications of the Members

Commission Members shall be veterinarians with a broad knowledge of the major diseases of animals, experience and expertise in the animal health aspects of international trade in animals and animal products, and an understanding and practical experience of the relevant international trading rules.

1. EXTRACT FROM THE REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE ROLE OF PRIVATE VETERINARIANS AND PARA-PROFESSIONALS IN THE PROVISION OF ANIMAL HEALTH SERVICES

Paris, 10 and 11 February 2003

The OIE *ad hoc* Group on the role of private veterinarians and para-professionals in the provision of animal health services held its first meeting at the OIE Headquarters on 10 and 11 February 2003.

The members of the OIE *ad hoc* Group and other participants are listed in Appendix I. The Agenda adopted is given in Appendix II. Dr H Schneider was appointed Chair of the *ad hoc* Group.

The Director General of the OIE, Dr B Vallat, welcomed the members of the *ad hoc* Group and thanked them for their willingness to be involved in the OIE's work on this very important area of improving Member Countries' veterinary services. He indicated that requests and recommendations had been received from various OIE Regional Commissions asking the OIE to address the issue of the utilisation of private veterinarians and various categories of para-professionals by veterinary services, particularly in Member Countries where veterinary services may be under organisational or financial pressure. Dr Vallat recalled the commitment made by the various international organisations at Doha regarding capacity building in developing countries.

Dr Vallat noted that the current sections of the *Code* dealing with veterinary services may not adequately address the other categories of staff involved in many of the activities of veterinary services. He warned however that the inclusion of private veterinarians and para-professionals needed to be carefully done to ensure that standards were maintained and confidence in countries' ability to trade in safe commodities was not lost. Dr Vallat also reminded the *ad hoc* Group members that their recommendations would need to be applicable to all Member Countries.

Community comments:

The Community fully supports the comments by Dr. Vallat above and has commented further on the proposed amendments concerning para-veterinarians and private veterinarians.

Scope

The *ad hoc* Group believed that its objective was to examine aspects of animal health service delivery (within its terms of reference) and to advise the OIE on how these may be used to improve the quality of veterinary services in OIE Member Countries.

The terms of reference of the *ad hoc* Group were to:

- define the functions and responsibilities of private veterinarians, para-professionals, including community-based animal health workers, in the provision of animal health services;

- provide guidelines on the roles, inter-relationships and regulations required to link them with official veterinary services.

The *ad hoc* Group noted the importance of Chapter 1.3.3 of the *Code* relating to the quality of veterinary services and Chapter 1.3.4 (guidelines for the evaluation of veterinary services) to its work.

Recommendations

Definitions

The *ad hoc* Group examined the current definitions for *official veterinarian* and *veterinary services* and proposed revised definitions. The proposed revised definition for *veterinary services* incorporates private veterinarians and para-professionals. The *ad hoc* Group also proposed new definitions for veterinarian, veterinary statutory body and para-professional. The definitions proposed are in Appendix III.

The *ad hoc* Group discussed the issues which may arise through the placing of all types or categories of para-professionals in one group but felt that, while all para-professionals needed to work under the responsibility and direction of a licensed/registered veterinarian, the tasks authorized for each category of para-professional should be defined by the veterinary statutory body of each Member Country, depending on qualifications and training, and according to need. Categories of para-professionals include veterinary nurses, veterinary technicians, community-based animal health workers, food inspectors, livestock inspectors and others depending on national terminologies.

The *ad hoc* Group recognised that certain categories of para-professionals do not work under the responsibility of a veterinarian and encouraged Member Countries to regulate such categories of para-professionals.

Veterinary statutory body

To ensure adherence to ethical codes and standards by veterinarians and para-professionals, the *ad hoc* Group recommended that a veterinary statutory body be established in each OIE Member Country (see proposed Article 1.3.4.11 bis in Appendix IV).

The *ad hoc* Group considered that a veterinary statutory body would play a vital role in the organisation and delivery of quality veterinary services, and the maintenance of public

confidence in such services. The Group recommended that the body be made responsible for the licensing/registration of veterinarians and para-professionals, the setting and monitoring of professional standards, and for discipline.

Maintaining quality

In order to maintain quality and flexibility in the use of para-professionals within veterinary services, the *ad hoc* Group recommended that the licenses of para-professionals be subject to periodic review. The conditions for review of licenses should be described by the veterinary statutory body and applied by the responsible veterinarian.

The *ad hoc* Group also recommended that the reference in Article 1.3.4.10 of the *Code* to 'in-service training and development programme for staff' be applied to private veterinarians and para-professionals as continuing professional development (CPD) was essential to the maintenance of quality. It recommended that CPD be prescribed by the veterinary statutory body.

The *ad hoc* Group proposed that recognition of veterinary degrees on a regional basis could be a valuable tool in strengthening service delivery in the fields of animal health and veterinary public health, and recommended that OIE Regional Commissions encourage the harmonisation of registration/licensing of veterinarians and eventually that of para-professionals on a regional rather than country basis. It also recommended that *Veterinary Administrations* establish linkages to recognise and regulate trans-boundary veterinary activities, including the movement of veterinarians and para-professionals across national borders in certain areas of the world.

Veterinary medicines

The *ad hoc* Group recommended that Article 1.3.4.9 of the *Code* be revised (see Appendix IV) and that the following sentence be added to strengthen the Article:

The supply of veterinary medicines and biologicals that might impact on international trade (through residues of anti-microbials, hormones or insecticides) should be based on prior diagnosis and specific treatment using licensed products, and only be made to clients whose livestock are under the care of the veterinarian or para-professional working under the responsibility of the veterinarian.

Public health

With regard to the reference in Article 1.3.4.9 of the *Code* to veterinary public health controls, the
ad hoc Group felt that it was important to emphasise that livestock owners and their associations were the first line of defence in early warning, disease surveillance and food safety, and were therefore an essential link in animal health service delivery.

Linkages

The *ad hoc* Group noted that, in certain countries, gaps exist in the provision of animal health and veterinary public health services and the Group considered that this had serious implications with regard to meeting the international standards described in the *Code*.

The *ad hoc* Group recommended that, in order to strengthen animal health and veterinary public health services through improved involvement of private veterinarians and para-professionals, *Veterinary Administrations* build official linkages with service providers, particularly individual veterinarians and veterinary associations, but also with individual para-professionals, para-professional associations, non-governmental organisations and farmers' groups. The Group recommended that linkages between *Veterinary Administrations* and private veterinarians and para-professionals take the form of contracts for the provision of specific services such as disease monitoring and surveillance, animal vaccination, food inspection, and disease prevention and control.

The *ad hoc* Group recommended that, in relevant Member Countries, improvements be made at both undergraduate and postgraduate level to address current inadequacies in veterinary training, to provide the necessary expertise in the private sector to meet the requirements of the *Veterinary Administration*.

Legislation

The *ad hoc* Group recommended that Article 1.3.3.2 be revised to reflect the need for flexible legislation, by including the sentence (see Appendix IV):

Legislation should be suitably flexible to allow changing situations to be addressed, including the incorporation of animal welfare and food safety measures.

Next meeting

The *ad hoc* Group proposed that its next meeting be held after comment had been received on the recommendations arising from this meeting (between the July and November 2003 meetings of the Code Commission).

.../Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON THE ROLE OF PRIVATE VETERINARIANS AND PARA-PROFESSIONALS IN THE PROVISION OF ANIMAL HEALTH SERVICES

Paris, 10 and 11 February 2003

List of participants

2. MEMBERS

Dr Anthony J. Mudd

Landfall Curdridge Lane

Waltham Chase

Southampton UK

Tel: (44) 14 89 89 09 19

Fax: (44) 14 89 89 24 72

E-mail: tonymudd22@aol.com

Dr Eduardo Correa Melo

Director

PANAFTOSA

Av. Presidente Kennedy, 7778, São bento

Duque da Caxias, CEP 2504-000

Rio de Janeiro BRAZIL

Tel: (55-21) 36 61 90 03

Fax: (55-21) 36 61 90 01

E-mail:

ecorrea@PANAFTOSA.ops-oms.org

Dr Emily Mmamakgaba Mogajane (absent)

Assistant Director General

National Regulatory Services

Department of Agriculture

Private Bag X250

Pretoria, 0001

REPUBLIC OF SOUTH AFRICA

Tel: (27-12) 319 6500

Fax: (27-12) 329 0499

E-mail: adgnrs@nda.agric.za

Dr Herbert Schneider

President, World Veterinary Association
P.O. Box 178
Windhoek NAMIBIA
Tel: (264) 61 22 89 09

Fax: (264) 61 23 06 19

E-mail: agrivet@mweb.com.na

Dr Sen Sovann (absent)

Deputy Director

Department of Animal Health and Production

Ministry of Agriculture, Forestry and Fisheries

No 74, Monivong Boulevard

Pnom Penh CAMBODIA

Tel: 855 23 427 590

Fax: 855 23 211 323

E-mail: ssovann@forum.org.kh

Dr Yvon Le Brun

Technical Assistant, Veterinary Legislation and Privatization Unit

OAU-IBAR

P.O. Box 30786

Nairobi KENYA

Tel:

Fax: (254) 2 25 2187

E-mail: yvon.lebrun@oau-ibar.org

Dr Tim Leyland

Head, Community-based Animal Health and Participatory Epidemiology Unit (CAPE) PACE, AU-IBAR

P.O. Box 30786

Nairobi KENYA

Tel: (254) 2 226 447

Fax: (254) 2 212289

E-mail: tim.leyland@oau-ibar.org

3. OTHER PARTICIPANTS

Dr Alejandro Thiermann

President of the OIE International Animal Health Code Commission

Tel : 33- (0) 1 44 15 18 69

Fax : 33-(0) 1 42 67 09 87
E-mail: alexthiermann@compuserve.com

4. OIE CENTRAL BUREAU

Dr Bernard Vallat

Director General

12 rue de Prony

75017 Paris

FRANCE

Tel: 33 - (0)1 44 15 18 88

Fax: 33 - (0)1 42 67 09 87

E-mail: oie@oie.int

Dr David Wilson

Head, International Trade Department

E-mail: d.wilson@oie.int

Dr Dewan Sibate

Deputy Head, Scientific and Technical Department

E-mail: d.sibate@oie.int

Dr Hiro Kamakawa

Chargé de mission, International Trade Department

E-mail: h.kamakawa@oie.int

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Community comments:
The Community can only support this proposal if the comments inserted in the text below are taken on board.

Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

. . .

Approved
means formally approved, accredited or registered by the *Veterinary Administration* for export purposes.

Artificial insemination centre
means a facility ~~for the production of semen~~ approved by the *Veterinary Administration* and which meet the conditions set out in the *Terrestrial Code* for the collection, processing and storage of semen ~~and used exclusively for don or animals which meet the conditions set out in the *Terrestrial Code*.~~

Community comments:
The Community would like to propose that the word 'and' be replaced by the word "or " as the storage site may be separate from the collection and processing site.

Compartment
means an epidemiologically distinct animal population ~~autonomous epidemiological entity~~ defined on the basis of either geography (*zone*) or management (*enterprise*) for the purpose of *international trade*.

Community comments:
The Community would like to propose that the word 'or' be replaced by the word "and" and the word 'either' deleted as it is essential that in all instances there is the need to use some sort of geographical delineation as well as a management component. Please note the Community comments in the AI Chapter.

Enterprise
means one or more *establishments* with an integrated system of animal management forming an epidemiologically distinct animal population ~~autonomous epidemiological entity~~.

Official Veterinarian
means a veterinarian authorised by the *Veterinary Administration* of the country to perform certain official tasks associated with animal health and/or public health and inspections of *commodities* and, when appropriate, to certify ~~perform certification~~ in conformity with the provisions of Section 1.2. of the *Terrestrial Code*.

Community comments:

The Community proposes the word "designated" is inserted after the word 'certain' and this would also be supported by the wording below.

Para-professional

means a person who, for the purposes of the *Terrestrial Code*, is authorised to carry out certain veterinary tasks (dependant upon the category of para-professional) in a country through a license from the veterinary statutory body, and delegated to them under the responsibility and direction of a registered or licensed veterinarian. The veterinary tasks authorized for each category of para-professional should be defined by the statutory body depending on qualifications and training, and according to need.

Community comments:

The Community is concerned that this definition is too flexible and could be misused. It proposes that the word "supervision" be inserted after 'responsibility. In addition an official veterinarian could authorise a para-veterinarian's tasks so "designated" should be inserted after the word 'registered'.

Products of animal origin intended for use in animal feeding

means meat–meal, liver–meal, bone–meal, blood–meal, feather–meal, ~~pork~~ fat, *milk* and *milk products* when intended for use in animal feeding.

Veterinarian

means a person registered or licensed to practice veterinary medicine/science in a country by the relevant veterinary statutory body of that country.

Veterinary Services

~~the Veterinary Services comprise~~ means the *Veterinary Administration*, ~~and~~ all the *Veterinary Authorities*, and all persons registered or licensed by the veterinary statutory body.

Community comments:

The Community proposes that the wording "and all persons registered or licensed by the veterinary statutory body" and in particular the word "persons" needs clarification. The word persons could be replaced by "veterinarians and para-proffessionals". (There could be other persons registered by the body which are not veterinarians or para-professionals nor part of the veterinary service such as veterinary nurses).

Veterinary statutory body

means the autonomous national authority regulating veterinarians and para-professionals.

Community comments:

The Community proposes that the word "autonomous" is deleted as in some Member States and other countries the authority of this body is in fact part of the veterinary Administration.

Zone

~~is~~ means a clearly defined part of the territory of a country with an epidemiologically distinct animal population ~~distinct animal health status~~. The following types of zones are recognised: *free zone*, *infected zone*, *surveillance zone* and *buffer zone*.

— text deleted

SECTION 1.2.

OBLIGATIONS AND ETHICS IN INTERNATIONAL TRADE

CHAPTER 1.2.1.

GENERAL OBLIGATIONS

Community comments:

The Community can support this proposal but would like the comment below taken on board as it is important to ensure that any identified disease risk is only in relation to the susceptible species involved. Too many countries are still requiring guarantees concerning diseases which are of no relevance to the species or product being traded.

...

Article 1.2.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the national level of protection that it has chosen for animal and human health. *Importing countries* should restrict their requirements to those justified for such level of protection.

2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal diseases which are present within the territory of the *importing country* and are not subject to any *official control programme*. The requirements applying to pathogens or diseases subject to *official control programmes* in a country or zone should not provide a higher level of protection on imports than that provided for the same pathogens or diseases by the measures applied within that country or zone.

3. The *international veterinary certificate* should not include requirements for disease agents or diseases which are not OIE listed, unless the *importing country* has identified the disease agent as a significant hazard for that country, after conducting an import risk analysis according to the guidelines in Section 1.3.

Community comments:

The Community proposes the words "and only as appropriate for the disease pathogen for the susceptible species (including its product) concerned" be inserted after 'country'. In addition it is necessary to replace the word "hazard" by the word "risk" and add the word "and" after the word "country".

4. The transmission by the *Veterinary Administration* of certificates or the communication of import requirements to persons other than the *Veterinary Administration* of another country, necessitates that copies of these documents are also sent to the *Veterinary Administration*. This important procedure

avoids delays and difficulties which may arise between traders and *Veterinary Administrations* when the authenticity of the certificates or permits is not established.

This information is usually the responsibility of *Veterinary Administrations*. However, it can be the responsibility of *Veterinary Authorities* at the place of origin of the *animals* when it is agreed that the issue of certificates does not require the approval of the *Veterinary Administration*.

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CHAPTER 1.3.3.

EVALUATION OF VETERINARY SERVICES

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Community comments:
The Community can support this proposal.

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

3. Impartiality

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

5. Objectivity

   The *Veterinary Services* shall 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 an appropriate legislation and 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 changing situations to be addressed efficiently, including the incorporation of animal welfare and food safety measures. In particular, they shall 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* shall 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 the *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They shall at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* shall 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 shall be described. These job descriptions shall include the requirements for education, training, technical knowledge and experience.

7. Quality policy

The *Veterinary Services* shall define and document their policy and objectives for, and commitment to, quality, and shall 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* shall develop and document appropriate procedures and standards for the implementation and management of animal health measures and international veterinary certification activities. These procedures and standards may for example relate to:

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

b) prevention and control 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.

j) standards for registration of slaughter establishments.

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

9. Information, complaints and appeals

The *Veterinary Administration* shall 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 shall be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

10. Documentation

The *Veterinary Services* shall 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.

12. Communication

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

• • •

CHAPTER 1.3.4.

GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Community comments:
The Community can support this proposal but would like the comments inserted in the text below are taken on board.

Article 1.3.4.1.

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 the *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*. 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.

   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. While 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 para-professionals is included as an important element of the risk analysis process.

Community comments:
The Community proposes that the word "While " should be replaced by the word "If" for linguistic reasons.

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 organisation structure and functioning of the *veterinary statutory body*.
3. Article 1.3.4.13. 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*.

. . .

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 ~~graduate~~ veterinarians, para-

professionals ~~It should also and should include other qualified professional officers~~, and administrative officials ~~and technical support staff~~. The human resources ~~does not exclude~~ should also include ~~the possibility of employing, in addition,~~ part-time veterinarians and para-professionals ~~and para-veterinary staff,~~ and private sector veterinarians and para-professionals. It is essential that all the above categories of staff be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

Community comments:

The Community proposes the following wording to replace the second and third sentences above as it should not be mandatory that a *Veterinary Service* employs *para-professionals:*

"This core must include ~~graduate~~ veterinarians, and may include para-professionals ~~It should also and should include other qualified professional officers~~, and administrative officials ~~and technical support staff~~. The human resources ~~does not exclude~~ may also include ~~the possibility of employing, in addition,~~ part-time veterinarians and para-professionals ~~and para-veterinary staff,~~ and private sector veterinarians and para-professionals".

2. In addition to raw quantitative data on this resource base, the functions of the various categories of staff 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 ~~animal technical assistants~~ ~~health~~ 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 ~~technical assistant staff~~ 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 ~~practitioners~~ 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 para-professionals ~~animal health technical assistants~~) 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 1.3.4.7.

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 including registration of holdings and animal identification, 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 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 trans-boundary activities, including the movements of veterinarians and para-

professionals. 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.

The information on the veterinary public health legislation should not be limited to the legislation related to the production of products of animal origin for national consumption. Therefore the following amendment is proposed in the last sentence of point 1, Article 1.3.4.7.: delete " for national consumption".

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 animal or product being certified and be independent from the commercial parties.

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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, especially for export. 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 and effective control of the sanitary status of animal products prior to export, especially *meat* and *meat products* throughout the slaughter, processing, transport and storage periods.

In the framework of 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 in general and not in priority in relation to export. The folloiwng amendment is proposed:

"especially for export" at the end of the first sentence should be deleted.

In addition, if the national *Veterinary Services* do not exercise responsibility over these programmes the national *Veterinary Services* should provide guarantees of responsibility for and effective control of the sanitary status of animal products prior to export throughout the slaughter, processing, transport and storage periods and not in priority to meat and meat products. The following amendment is proposed:

" prior to export especially meat and meat products" in the last sentence should be deleted.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified staff 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.

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 or importation, registration, supply 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 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 fresh meat or dairy product establishments and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national epizootiological surveillance scheme.

The scope of the public health controls should not be limited to fresh meat or dairy products establishments but should be broadened to establishments producing products of animal origin

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 1.3.4.11. bis

Evaluation of veterinary statutory body

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

- human resources, including the appropriateness of the body's membership for veterinarians and para-professionals;
- financial resources;
- functional capabilities, including the ability to enforce its decisions (for example regarding standards of conduct, deregistration);
- administration of continuing education programmes for veterinarians and para-professionals;
- legislative basis, including autonomy;
- decision-making procedures, including transparency.

Community comments:

The Community proposes a further indent is added as follows:
"- independence".

In addition it could be relevant to include the basis for licensing /registering veterinarians and para-professionals. (Compare with wording under 1.3.4.13, 2. a) , I) "Veterinarians registered in the country who are graduates from internationally recognised veterinary schools which are registered accordingly in the WHO/FAO World Directory of Veterinary Schools.

. . .

Article 1.3.4.13.

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 in the country who are graduates from internationally recognised veterinary schools which are registered accordingly in the WHO/FAO World Directory of Veterinary Schools;

         – graduate veterinarians not included above.

      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;

         – ~~privately-employed~~ 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;
- ~~privately employed~~ 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.

b) Graduate staff (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) ~~Technical assistants~~ 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 staff

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) Additional information and/or comments.

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— text deleted

CHAPTER 1.3.7.

GUIDELINES FOR REACHING A JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES

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Community comments:
The Community can support this proposal but would like the comments below taken on board.

Article 1.3.7.2.

General considerations

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its animal health status will be appropriately protected. In most cases, the risk management measures drawn up will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, laboratory systems, approaches to the pests and diseases present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country*'s appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the Agreement on Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO).

Benefits of applying equivalence may include:

1) minimising costs associated with *international trade* by tailoring animal health measures to local circumstances;

2) maximising animal health outcomes for a given level of resource input;

3) facilitating trade by achieving the required health protection through less trade restrictive sanitary measures; and

4) decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative sanitary measures for many diseases and pathogenic agents. Equivalence may be gained, for example, by enhanced surveillance and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Member Countries are encouraged to base their sanitary measures on OIE standards, guidelines and recommendations to the extent possible.

It is essential to apply the discipline of risk assessment (the primary scientific component of risk analysis) to the extent practicable in establishing the basis for a judgement of equivalence.

Article 1.3.7.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of sanitary measures should be based on application of the following principles:

1) an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;

2) the *importing country* should be able to describe the reason for each sanitary measure i.e. the level of protection intended to be achieved by application of the identified measure against a hazard;

3) an *importing country* should recognise that sanitary measures different from the ones it has proposed may be capable of providing the same level of protection;

~~4) there are benefits in applying the concept of equivalence to animal health and production systems;~~

5) ~~countries~~ the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;

6) any sanitary measure or combination of sanitary measures can be proposed for judgement of equivalence;

7) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;

8) the *exporting country* should be able to demonstrate objectively how the alternative sanitary measure(s) proposed as equivalent will provide the same level of protection;

9) the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;

10) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate risk assessment principles;

11) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Administration* or other competent authority of the *exporting country*;

12) the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;

13) the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;

14) to facilitate a judgement of equivalence, Member Countries should base their sanitary measures on relevant OIE standards;

Community comments:
In order to be consistent with 1.3.7.2 4th paragraph, the EU proposes to add the following words "to the extent possible."

15) to allow the judgement of equivalence to be reassessed if necessary, the *importing* and *exporting countries* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and

Community comments:
The EU considers that not only changes to infrastructure, health status or programmes but also other measures may have an impact on equivalence. Therefore the EU proposes to add after 'programmes' the words "or any measure".

16) an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

. . .

— text deleted

CHAPTER 2.1.1.

FOOT AND MOUTH DISEASE

Community comments:
The Community in principle welcomes the proposal, however, it cannot support it entirely as it is worded at the moment.
In particular in relation to exports of meat on the bone from countries free of FMD with vaccination, the Community wishes to draw the attention of the OIE to the need for a very careful assessment of the situation prior to granting the status of free with vaccination, in particular in accordance with the procedure provided for in Article 2.1.1.7 (2)(b). Also it appears that Article 2.1.1.7. (2) (b) is in contradiction to the newly proposed definition of a FMD free country practising vaccination in Article 2.1.1.3. or zone in Article 2.1.1.5, which requires evidence for absence of FMDV infection.

It furthermore warns about the risks and dangers associated with such approach. It is therefore proposed to postpone this proposal until a further risk assessment provides sufficient guaranties that suitable tests to rule out infection in vaccinated animals described in detail in the Manual of Standards and incorporated in an ongoing surveillance system would effectively compensate for the loss of sentinels indicating possible incursion of infection.

In addition there must be a procedure following an outbreak or outbreaks limited to an area of the country to allow for the regaining of status of the non-infected region as soon as possible.

Article 2.1.1.1.

For the purposes of this *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 [the presence of] FMD virus (FMDV) [infection].

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 with either epidemiological links to a confirmed or suspected *outbreak* of FMD, or showing clinical signs consistent with recent infection with FMDV.

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

OIE proposal:

Article 2.1.1.1.

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 ~~with either epidemiological links to a confirmed or suspected *outbreak* of FMD, or showing clinical signs consistent with recent infection with FMDV~~ 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 2.1.1.2.

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 XXX (under study) is in operation and that regulatory measures for the prevention and control of FMD have been implemented;

Community comments:

The Community proposes that the correct reference to the Appendix (3.8.6.) be inserted above instead of "XXX (under study)" as in other paragraphs.

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 2.1.1.3.

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 infection for the past 12 months, with documented evidence that:

   a) surveillance for FMD and FMDV infection in accordance with Appendix ~~XXX (under study)~~ 3.8.6. 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 *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 infection has not occurred during that period.

Article 2.1.1.4.

FMD free zone where vaccination is not practised

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

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

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

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

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

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

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

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

4) describe in detail:

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

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

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

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

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

Article 2.1.1.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in an ~~FMD free~~ FMD free country ~~[with an FMD free zone]~~ where vaccination is not practised or in a country of which parts are still infected. Vaccination of zoo animals, animals belonging to rare species or breeds, or animals in research centres as a precaution for conservation purposes is an example of implementation of such a zone. The free zone where vaccination is practised is separated from the rest of the country and, if relevant, from neighbouring infected countries by a *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus must be implemented. 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 infection for the past 12 months, with documented evidence that surveillance for FMD and FMDV in accordance with Appendix XXX (under study) is in operation;~~ and no evidence of FMDV infection for the past 12 months, with documented evidence that surveillance for FMD and FMDV in accordance with Appendix 3.8.6. is in operation

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

4) describe in detail:

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

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

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

   and supply evidence that these are properly implemented and supervised;

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

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

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

Article 2.1.1.6.

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 2.1.1.7.

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 ~~XXX (under study)~~ 3.8.6., or

   b) 3 months after the slaughter of ~~[the last]~~ all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix ~~XXX (under study)~~ 3.8.6., 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 ~~XXX (under study)~~ 3.8.6, 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.

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 ~~XXX (under study)~~ 3.8.6 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection, or

   b) 12 months after the last *case* where a *stamping-out policy* is applied provided that surveillance demonstrates the absence of clinical *cases*, or

Community comments:

The Community's comments and position as stated in 2003 remains for 2004.

It appears that Article 2.1.1.7. (2) (b) is in contradiction to the newly proposed definition of a FMD free country practising vaccination in Article 2.1.1.3. or zone in Article 2.1.1.5, which requires evidence for absence of FMDV infection.

For consistency it is proposed to replace this paragraph by the following:

b) 12 months after the last *case* where a *stamping-out policy* is applied provided that surveillance demonstrates the absence of clinical *cases and* serological surveillance in accordance with Appendix 3.8.6. based on the detection of antibodies to nonstructural proteins of FMDV , demonstrates the absence of infection.

Alternatively a special category of "Freedom of disease with vaccination" could be introduced relevant for meat in accordance with the previous and unchanged Article 2.1.1.22. See comments at introduction

c) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix ~~XXX (under study)~~ 3.8.6 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection.

~~[provided that effective surveillance has been carried out.]~~

~~The application to regain the free status according to one of the procedures described above should be submitted to the OIE by the country in question within 2 years of the loss of free status through the occurrence of [the first] an FMD *outbreak* or [the first] a detection of FMDV infection. In other situations, [otherwise] the provisions of either Article 2.1.1.2., or Article 2.1.1.3., or Article 2.1.1.4., or Article 2.1.1.5., as relevant, are applicable to the country.~~

Article 2.1.1.8.

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

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

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

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

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

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

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

6) all products obtained from the animals must be considered infected and treated in such a way as to destroy any residual virus ~~in accordance with Appendix 3.6.2.~~ in accordance with Appendix 3.6.2. ~~[In particular, meat must be processed in conformity with one of the procedures referred to in Article 3.6.2.1.]~~;

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

Animals moved into a free zone for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 2.1.1. ~~[11.]12~~ 12.

~~[Article 2.1.1.9.~~

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

~~1) domestic and wild ruminants and pigs;~~

~~2) semen of ruminants and pigs;~~

~~3) embryos/ova of ruminants and pigs;~~

~~4) *fresh meat* of domestic and wild ruminants and pigs;~~

~~5) *meat products* of domestic and wild ruminants and pigs which have not 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.;~~

~~6) *products of animal origin intended for human consumption, for use in animal feeding or for agricultural or industrial use*;~~

~~7) *products of animal origin intended for pharmaceutical or surgical use*;~~

~~8) non-sterile biological products.~~

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

Community comment:
As commented on before and taking into acccount the undertaking to define commodities that can be traded safely irrespective of the status of the country, the Community prefers to keep this Article but parts of it could be deleted where the animal or product is covered by another Article in this Chapter. Paragraphs 1, 2, 4 and 5 above may be deleted as they are adequately covered and the last sentence in relation to products not thoutght to constiute a risk must be retained. In addition a reference to Appendix 3.6.2 on agreed inactivation procedures should be introdruced.

Article 2.1.1.~~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.

Article 2.1.1.~~11.~~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

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.

[FMD free countries or zones where vaccination is not practised may require additional guarantees.)

Article 2.1.1.~~12.~~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 for the 30 days prior to quarantine in an *establishment*, 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, 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.*

Community position:

The OIE should decide which level of protection is proposed. Taking into account that in Article 2.1.1.10 the reference to additional guarantees is being deleted, it appears that the rules in article 2.1.1.11 may also be modulated by th eimporting country.

- **Article 2.1.1.11 does not specify the vaccination status of the animals therefore it can be everything**
- **Why should an animal be obliged to stay in an infected country without stamping out for 3 months?**
- **Why is it allowed to have animals isolated in an establishment situated in an environment which is only for 30 days without outbreak?**
- **What does it mean that the animal is free of clinical signs of FMD on the day of shipment, the lesions may have healed by the time the prescribed procedures have been completed.**

The Community therefore proposes a new Article as follows:

Article 2.1.1.~~12.~~ 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) prior to entering the *quarantine station* were kept in the *establishment* of origin since birth or for the past 30 days, and *FMD* has not occurred within a 10-kilometre radius of the *establishment* of origin during that period.

2) were kept in a *quarantine station* for the 30 days prior to shipment, and all animals in the quarantine station were subjected to clinical inspection and 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;

3) were not exposed to any source of FMD infection during their transportation from the establishment to the *quarantine station* and from the *quarantine station* to the *place of shipment.*

4) showed no clinical sign of FMD on the day of shipment and have remained free of clinical signs either since birth or during the 60 days perior to shipment;

Article 2.1.1.~~13.~~ 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 either Appendix 3.2.1. , Appendix 3.2.2. or Appendix 3.2.3.

Article 2.1.1.~~14.~~ 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 either Appendix 3.2.1. or Appendix 3.2.3.

Community position:

The Community proposes the following wording:

"2) the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3."

~~Article 2.1.1.15.14~~

~~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 either Appendix 3.2.1. or Appendix 3.2.3.;~~

~~b) was stored in a country free from FMD for a period of at least one month before export, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.~~

OIE Proposal:

Article 2.1.1.14.

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., Appendix 3.2.2. or Appendix 3.2.3., as relevant;

b) was stored in ~~a country free from FMD~~ the country of origin for a period of at least one month following collection~~before export~~, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Community comment:

The Community again asks the OIE to reword paragraph c) as follows:

"c) In the case of semen collected from a donor animal vaccinated in accordance with 1 (c) (ii) , 5% of the semen from each collection (with a minimum of five straws) shall

be subjected to a virus isolation test for FMD with negative result.."

~~Article 2.1.1.16. 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 either Appendix 3.2.1. or Appendix 3.2.3.;~~

~~b) was subjected, with negative results, to a [virus isolation] test for FMDV infection if the donor animal has been vaccinated within the 12 months prior to collection;~~

~~c) was stored for a period of at least one month between collection and export, and during this period no animal on the establishment where the donor animals were kept showed any sign of FMD.~~

OIE proposal:

Article 2.1.1.15.

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., Appendix 3.2.2. or Appendix 3.2.3., 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~~between collection and export~~, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

~~Article 2.1.1.17.~~

~~Irrespective of the FMD status of the *exporting country* or zone, [When importing from FMD free countries or zones (where vaccination either is or is not practised),] *Veterinary Administrations* should require:~~

Community comments:

It is proposed to add the words "of the importing country " after the words "*Veterinary Administrations*".

~~for *in vivo* derived embryos of cattle~~

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

~~1) the donor females showed no clinical sign of FMD at the time of collection of the embryos;~~

~~[a)]~~

~~[b) were kept in an *establishment* located in a country or zone free from FMD at the time of collection;]~~

~~2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.9.3, as relevant.~~

OIE proposal:

Article 2.1.1.16.

Irrespective of the FMD status of the *exporting country* or zone, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of ~~*Veterinary Administrations* should require:~~

~~for~~ *~~in vivo~~* derived embryos of cattle

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

~~1)~~ ~~the donor females showed no clinical sign of FMD 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. or Appendix 3.3.3., as relevant.

~~[Article 2.1.1.18.~~

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

~~for *in vivo* derived 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 embryos;~~

~~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;~~

~~2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.9., as relevant.]~~

Article 2.1.1.~~19.c~~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 embryos;

   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 2.1.1.13., 2.1.1.14., 2.1.1.15. or 2.1.1.16., as relevant;

3) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.~~1.~~ 2. or Appendix 3.3.9. 3, as relevant.

Community position:

Appendix 3.3.2. deals with the in-vitro fertilisation of oocysts recovered from ovaries, potentially collected on slaughterhouses, it remains therefore unclear which donor femal is ment in 1 (a).

The following is suggested:

Article 2.1.1.17.

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 were kept in a country or zone free from FMD for at least 3 months prior to collection:

2) fertilisation of oocytes was achieved with semen meeting the conditions referred to in Articles 2.1.1.13., 2.1.1.14., 2.1.1.15. or 2.1.1.16., as relevant;

3) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.~~1.~~ 2. or Appendix 3.3.9. 3, as relevant.

Article 2.1.1.~~20.~~ 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 embryos;

Community position:

   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 2.1.1.13., 2.1.1.14., 2.1.1.15. or 2.1.1.16., as relevant;

4) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.~~1.~~ 2.or Appendix 3.3.9. 3., as relevant.

Article 2.1.1.~~21.~~ 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) ~~[which]~~ have been kept in the FMD free country or zone where vaccination is not practised since birth, or which have been imported [from an FMD free country or zone where vaccination is not practised] in accordance with ~~Article 2.1.1.10., Article 2.1.1.11. or Article 2.1.1.12.~~ Article 2.1.1.9, Article 2.1.1.10 or Article 2.1.1.11.;

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

Community comment:

It is proposed to replace paragraph 2 by the following

"2) which have been slaughtered in an *approved abattoir* situated in the free zone and have been subjected to ante-mortem and post-mortem inspections for FMD within 24 hours prior to and after slaughter with favourable results."

Article 2.1.1.~~22.~~ 20.

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

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

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

1) ~~[comes from animals which] have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.1.1.10., Article 2.1.1.11. or Article 2.1.1.12.;~~ have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

~~[a) have remained in the exporting free country or zone for at least 3 months prior to slaughter;]~~

2)~~[b)]~~ have been slaughtered in an *approved abattoir* ~~[located in the free zone, when the animals originate from such a zone)]~~ and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Community comment:

It is proposed to replace paragraph 2 by the following

"2) have been slaughtered in an *approved abattoir* situated in the free zone and have been subjected to ante-mortem and post-mortem inspections for FMD within 24 hours prior to and after slaughter with favourable results."

~~[2) comes from deboned carcasses:~~

~~a) from which the major lymphatic glands 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 of the meat was below 6.0 when tested in the middle of both the longissimus dorsi.~~

~~If the meat is to be imported into a country or a zone of equivalent FMD status or into an infected country in which the virus types used in the vaccines are the same, the maturation and deboning processes may not be required.]~~

Community comment:

The Community is extremely concerned about this proposal and draws the attention to the need for a very careful assessment of the situation prior to granting of the status. It furthermore warns about the imminent risks associated with such approach. In countries free with vaccination surveillance is not done permanently and before a possible introduction of virus has been detected in a vaccinated population by surveillance in accordance with Appendix 3.8.6. infection may get hold in animals destined for slaughter for export.

The Community's concern relates also to the conditions in Article 2.1.1.7. (2) (b).

It is therefore proposed to postpone this proposal until a further risk assessment provides sufficient guaranties that suitable tests to rule out infection in vaccinated animals described in detail in the Manual of Standards and incorporated in an ongoing surveillance system would effectively compensate for the loss of sentinels indicating possible incursion of infection.

Article 2.1.1.~~23.~~ 21.

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

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

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

1) [which] have been kept in the country or zone since birth, or have been imported ~~[from an FMD free country or zone where vaccination is not practised]~~ ~~in accordance with Article 2.1.1.10., Article 2.1.1.11. or Article 2.1.1.12.~~; in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.;

2) [which] have not been vaccinated;

3) [which] have been slaughtered in an *approved abattoir* ~~[(located in the free zone, when the animals originate from such a zone)]~~ and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Community comment:

It is proposed to replace paragraph 3 by the following:

"3) have been slaughtered in an *approved abattoir* situated in the free zone and have been subjected to ante-mortem and post-mortem inspections for FMD

within 24 hours prior to and after slaughter with favourable results."

Article 2.1.1.~~24.~~ 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 bovines (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;

Community comment:

It is suggested to replace Paragraph (1) (c) by the following:

"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; and that the vaccine used complies with the standards described in the *Manual* and is effective against the circulating field virus."

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within 10 kilometres during that period;

Community position:

The OIE should make use of standard formulations where possible: It is proposed to replace (1) (d) by the following:

d) were kept for the past 30 days in an *establishment* of origin, 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 lymphatic glands 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 2.1.1.~~25.~~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;

Community comment:

It is proposed to add the words "within 24 hours before and after slaughter" after the word "results" in order to be consistent with Article 2.1.1.24 point 1. g.

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 2.1.1.~~26.~~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 ~~[from an FMD free country or zone (where vaccination either is or is not practised)] in accordance with Article 2.1.1.10., Article 2.1.1.11. or Article 2.1.1.12.~~ in accordance with Article 2.1.1.9., Article 2.1.1.10. or Article 2.1.1.11.

~~Article 2.1.1.27.~~ 25

~~When importing from FMD infected countries or zones where an official control programme exists, *Veterinary Administrations* should require:~~

~~for *milk*, [and] 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 subjected to any restrictions due to 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.~~

OIE proposal:

Article 2.1.1.25.

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 ~~subjected to any restrictions due to~~ 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 2.1.1.28.~~

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

~~for milk powder and milk products~~

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

~~1) these products are derived from milk complying with the requirements stipulated in Article 2.1.1.27.;~~

~~2) the necessary precautions were taken after processing to avoid contact of the milk powder or the milk products with any potential source of FMD virus.]~~

Article 2.1.1.~~29.~~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 internal temperature of 70°C for at least 30 minutes.

Article 2.1.1.~~30.~~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 2.1.1.~~31.~~ 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 2.1.1.~~32.~~ 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 wild animals susceptible to FMD

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 2.1.1.~~33.~~ 30.

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

for skins and trophies derived from wild animals susceptible to FMD

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.]*

[ ] deleted

APPENDIX 3.8.6.

PRELIMINARY GUIDELINES FOR THE ESTABLISHMENT OR THE REGAINING OF RECOGNITION FOR A FOOT AND MOUTH DISEASE FREE COUNTRY OR ZONE

Community comments:

The Community has already made extensive comments earlier this year and is pleased that the Scientific Commission will examine these in detail. The Community strongly supports these comments that were decided on during a Council working group in March this year.

...

Article 3.8.6.3.

Countries or zones applying for freedom from FMD where vaccination is not practised

1. Introduction

In addition to the general conditions, a Member Country applying for recognition of freedom from FMD where vaccination is not practised should show evidence of an effective surveillance programme in which either the FMD susceptible population undergoes regular clinical examination or a statistically significant sample of this population is examined to show that disease has not been present in the population during the past 12 months. In addition, a statistically significant proportion of the population should be subjected to serological surveillance to demonstrate absence of FMD virus (FMDV) infection during the preceding 12 months. This requires the support of a national or other reference laboratory able to undertake serology for FMDV antibody using tests described in the *Terrestrial Manual.*

2. Survey design

In general, the target population for random surveys for *disease* and *infection* will cover the susceptible species within the country or zone to be declared free from disease. Countries wishing to show freedom from FMD in which a pig-specific strain of virus had been prevalent should concentrate on sampling the national pig population. In countries in which an African buffalo population is present, this population should also be sampled if included in the proposed FMDV infection free zone.

The objective of the random sample design is to use the minimum level of surveillance consistent with demonstrating the absence of *disease/infection* at the required level of statistical confidence. The sample should be selected on a random basis during each of the consecutive sampling campaigns; the frequency of sampling is dependent on the epidemiological situation, but should be at least once during the year preceding the application. Every sampling unit should have an equal probability of being selected. The selection of individual sampling units should not affect the probability of selecting any other sampling unit. It should be emphasised that random selection of the sampling units is essential, or the required level of statistical confidence cannot be achieved.

In order to provide representative information on the infection status of the target population, the random sample survey ought to be completed within the shortest possible period of time.

The population may be divided into sections (strata) with similar epidemiological conditions within each stratum. Stratification implies that a suitable system of separating the target population into a series of sections or strata from which random samples can be drawn has been developed. A stratum should be a subpopulation of the total population that is raised using a similar production and husbandry system under similar ecological conditions within geographical or administrative areas (provinces, states, etc.) with a similar likelihood of infection. Which stratification criteria will be most appropriate will depend on the conditions prevailing in the individual country.

During the process of stratification the following two conditions have to be met:

a) all sampling units (village, flock or herd depending on farming system) within a particular stratum can be accessed during the survey and have an equal chance of being selected;

b) an individual sampling unit is included in only one stratum.

The total number of strata required will depend on the country or zone concerned, and additional strata or an increased level of sampling may be applied to areas within a country or zone considered to be at a higher likelihood of FMDV infection. Care should be taken that the number of strata does not exceed the capacity of the field and laboratory service as the required number of random samples will have to be collected from each of the strata. The number of samples is determined, to a considerable extent, by the number of strata. Hence the number of strata should be kept to a minimum but also reflect major epidemiological differences. Further detail may be obtained from suitable epidemiological texts.

If a Member Country wishes to declare a specific zone within the country free from FMDV infection, this should be taken into consideration in the stratification process. The basis for the sampling process would then be the population within each zone.

The objective of the random sample survey is the detection of clinical or serological evidence of FMD within the population, if it is present at a predetermined prevalence. The probability of detecting evidence of FMD or FMDV infection in a given sample of animals depends on the prevalence of FMDV infection in the population and the size of the sample. Hence, the sample size and expected disease prevalence determine the level of confidence in the result of the survey. The lower the prevalence the larger the sample size has to be in order to achieve a given confidence in the outcome of the survey. The sampling strategy should give a 95% probability of detecting evidence of FMD or FMDV infection if it is present in 1% of the primary sampling units. In other words, if at least 1% of herds/flocks are infected with FMD virus, the sample size has to be large enough to give a 95% chance that at least one infected herd/flock will be detected through examination of the random sample of herds/flocks.

3. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of FMD by close inspection of the mouth, feet and udder of a randomly selected sample. It is essential that all animals within the selected primary sampling unit are examined for signs of FMD. Any herd/flock where suspicious animals are detected should be classified as infected until contrary evidence is produced.

4. Serological surveillance

Serological surveillance aims at the detection of antibodies against FMDV. A positive reaction to an FMDV antibody detection test can have four possible causes:

a) natural infection with FMDV;

b) vaccination;

c) maternal antibodies from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age, however, in some individuals and in buffalo calves, maternal antibody can be detected for longer);

d) non-specific reactions, for example to some other unrelated antigen (heterophile reactions).

Thus antibodies detected in animals (other than African buffalo) over 6 months of age and born after a country or region has ceased vaccination should be in response to natural infection and be indicative of circulating virus. This group of animals will be considered eligible as secondary sample units for the purpose of serological surveillance. It may be possible to use serum collected for other survey purposes, but the objective of a statistically valid random survey for the specific presence of FMDV should not be compromised.

If vaccination cannot be excluded as the cause of positive serological reactions, additional testing for the presence of antibodies to the nonstructural proteins (NSPs) of FMDV could indicate the previous presence of live FMDV.

It is unusual to find only one or two sero-positive animals in an infected herd/flock. For this reason and for practical as well as economic reasons, it is considered acceptable to include only a random sample of animals from each primary sampling unit in the serological surveillance. The sample size has to be sufficient to achieve a 95% probability of detecting sero-positive animals. If a herd is infected a significant time after the cessation of vaccination, it would be expected that the serological prevalence will exceed 20%.

FMDV persists in the pharyngeal region of recovered ruminants for up to 3 years in cattle and 9 months in sheep, and therefore oesophageal–pharyngeal (OP) fluid sampling is an additional valuable tool in surveillance for FMDV. OP samples should be collected from herds and flocks selected by positive serology. The collection of OP samples will depend on the availability of collection equipment (e.g. probang), facilities for storing the OP material until testing, and access to a laboratory able to work with live FMDV. Sheep can also be sampled by collecting OP fluid, and a similar sampling strategy can be applied, bearing in mind that the carrier state is shorter in this species.

Staff collecting OP samples should be given specific training on the techniques for the collection, transport and storage of OP fluid. It is essential that the OP fluid is placed in a neutral buffer and immediately frozen in or over liquid nitrogen or solid CO_2 after collection, and kept in this state until thawed in the diagnostic laboratory and placed on susceptible tissue culture (see the *Terrestrial Manual*).

It is preferable to stratify the sampling frame to reflect the possibility of FMD having been present up to 3 years previously. OP samples should be collected from each group of yearlings, 2-year-old and 3-year-old cattle/sheep in the selected herds and flocks.

The results of the random sample survey will provide evidence both to the national authorities and to the OIE that no FMDV infection is present in the country or zone. It is therefore essential that the random sample survey can be audited through clear documentation and the presence of complete records.

. . .

Article 3.8.6.6.

The use and interpretation of serological tests (see Fig 1)

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*. In unvaccinated populations, the screening can be carried out using the liquid-phase blocking ELISA (LPBE) or the solid phase competition ELISA (SPCE). The sensitivity of the LPBE approaches 100% but it can have a specificity in cattle as low as 95%, and will therefore give up to 5% false positive results at a titre greater than 40. Because the objective of the survey is to discover evidence of infection if the latter is

present, it is acceptable for the purposes of the survey to raise the cut-off value for

negative/positive sera. The rationale for raising or lowering the cut-off titre should be given in reports of tests for which this has been used. Raising of the cut-off value may still result in false positive results, and therefore positive sera should be re-tested by the virus neutralisation test (VNT), in which a titre of 45 or greater is classified as positive. Any animals whose sera are positive by the VNT should be re-sampled to confirm this status, and if still positive they should be tested for evidence of infection. The remaining animals in the herd/flock should also be tested for the presence of antibodies to FMDV and, if found positive, sampled by collection of OP material using a probang cup. The SPCE has been shown to have a higher specificity, but similar sensitivity to the LPBE, and should be used in preference to the LPBE where possible.

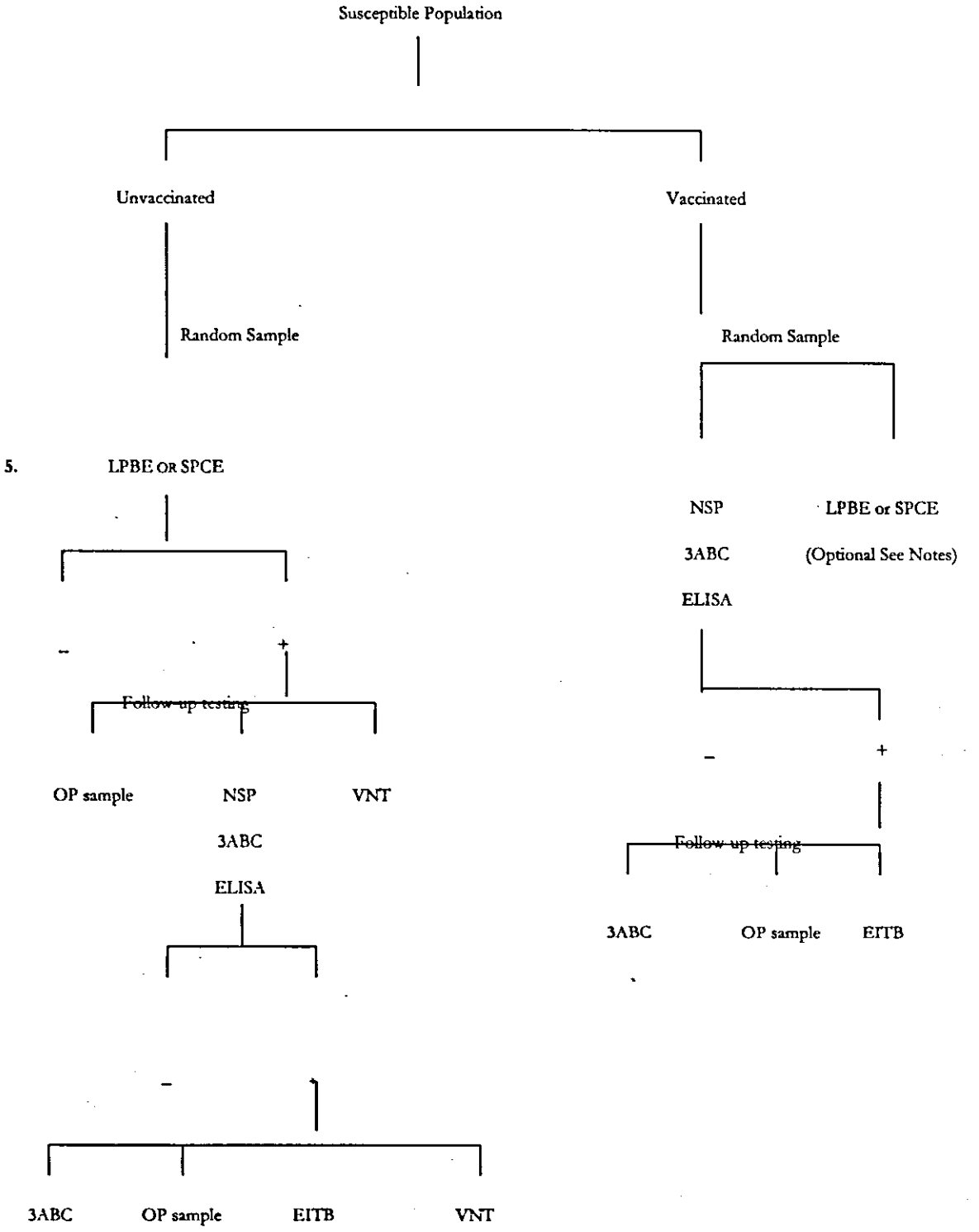
For serological surveillance in countries or zones in which vaccine is, or has been used, the LPBE or SPCE can still be the test of choice in those FMD susceptible species not included in the vaccination programme. Animals that have been vaccinated will have antibodies to the structural proteins of FMD virus, and some may have antibodies to the NSPs, depending on the number of times they have been vaccinated, and the amount of the NSPs present in the vaccine used. However, animals that have recovered from infection with FMD virus will have high levels of antibody to the NSPs. There are eight NSPs associated with the replication of FMD virus, namely L, 2A, 2B, 2C, 3A, 3B, 3C and 3D, and antibodies can be found to all of these in most recovered animals. Some do not persist for more than a few months, and some animals may fail to produce detectable levels to all of them. ELISA tests have been developed to detect 2C, 3B or 3ABC antibodies, the former being detectable for up to one year after infection, and the latter for up to 2 years. A western blot technique (EITB) has also been used to detect the NSP antibodies to 2C, 3ABC, 3A, 3B and 3D; it is particularly specific and sensitive in identifying animals previously infected. All these tests have been validated in cattle.

A class of animal exists, however, that has been infected with FMD virus and could remain carrying the virus without developing detectable antibodies to the NSPs. These are animals which have received highly potent vaccine and then had contact with the virus during an *outbreak*, but, because of their level of immunity, suppress viral replication and show no evidence of disease. Because the virus does not replicate significantly in these animals, there is little expression of the NSPs and therefore development of detectable levels of antibodies may not occur. However, on a herd basis there are always less protected animals following vaccination, and if these animals are challenged with the virus, they will produce antibodies to the NSPs, and can develop clinical disease. It is therefore important that NSP antibody tests be interpreted by assessing the level of these antibodies in the sera of a representative sample from the whole herd.

There is the option to use the NSP antibody test together with the LPBE or SPCE, particularly in areas where vaccination has been used and virus activity is suspected. LPBE titres or SPCE inhibition higher than would be expected from vaccination alone, may suggest FMDV infection and this can be confirmed by testing for the presence of antibodies to the NSPs, and by taking OP samples.

The diagnostic sensitivity of tests used influences the numbers of animals that need to be sampled in a survey to provide evidence of absence of infection. The diagnostic specificity of the test influences the proportion and number of positive results to be expected in the absence or presence of infection, and therefore the selection and use of confirmatory tests. Results of surveys which indicate a significantly higher proportion of positive test results in comparison with that expected from the estimate of the false positive rate derived from the diagnostic specificity (i.e. 100 minus diagnostic specificity) may be interpreted as evidence of infection in the population and therefore a confirmatory test of high specificity, and where appropriate other investigations, should be conducted.

Fig. 1 Schematic representation of laboratory tests for determining evidence of FMDV infection through, or following serological surveys



The above diagram indicates the tests which are recommended for use in the investigation of sampling units in which a positive test result has been obtained.

Key:

ELISA	enzyme-linked immunosorbant assay
LPBE	liquid-phase blocking ELISA
SPCE	solid-phase competition ELISA
VNT	virus neutralisation test
NSP	nonstructural protein(s) of FMDV
3ABC	NSP antibody test
EITB	western blot for NSP antibodies of FMDV
OP	oesophageal–pharyngeal sample

Figure 1 provides a flowchart of the test protocol that could be used to test the samples collected in the random survey. If the population being tested has not been previously vaccinated against FMD, the serum samples can be tested using the LPBE or SPCE. Sera positive on the test used should be retested using the VNT, which is the "gold standard" test for FMDV antibodies. In addition, or in place of the VNT if the laboratory is not able to manipulate live FMDV, the positive sera may be retested using a NSP antibody test, such as the 3B, 3ABC or EITB. If the positive sera are from a ruminant species, OP samples may also be collected and tested for the presence of live FMDV. A positive VNT or NSP test would indicate that live virus had been circulating, and would require further investigation of the herd or flock to show whether it was still present; a positive OP sample would provide definitive evidence. Further investigation should include serum testing of the whole herd or flock from which the positive samples were obtained, in addition to taking further OP samples to show whether live virus is still present.

NSP tests should be used for testing sera from vaccinated herds or flocks, as such sera will be positive by VNT. LPBE and SPCE can be used in addition, as described above. 3ABC or 3B positive samples may be repeat tested using the EITB for confirmation. All animals from herds and flocks from which positive samples are obtained should be re-tested for antibodies to NSP's, and OP samples collected for detection of live FMDV.

Data on the sensitivity and specificity of the NSP tests currently available is not fully documented, in particular for species other than cattle, or for vaccinated animals carrying live FMDV. However, this is under investigation in a number of laboratories worldwide. Member Countries submitting data to the OIE Scientific Commission for Animal Diseases which have been derived using commercial or other NSP tests should provide information on the characteristics of the test being used, and adjust the number of samples collected to accommodate the test parameters. In addition, the testing of OP samples for the presence of FMDV may be less than 50% sensitive, even using very sensitive tissue culture such as primary bovine thyroid cells or lamb kidney cells. If the initial attempt at virus isolation is negative, either repeat OP samples should be collected from serum-antibody positive animals after a 2-week interval, or further tests such as PCR carried out on the samples.

— text deleted

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community comments:

The Community can support this proposal but would like to point out that it has commissioned a study on tallow and therefore the Community reserves its position on tallow.

Furthermore the Community proposes to increase the age limit for removing CNS tissues as SRM to 12 months in countries with a moderate BSE risk. This is based on various opinions of the Scientific Steering Committee (SSC) advising the EU on TSE related matters, the most recent being the overview of all opinions adopted on 5 June 2003. In those opinions the SSC recommends an age limit of 12 months for removing CNS tissues as SRM. Intestines and tonsils should be removed as SRM from bovines of all ages. Evidence from the pathogenesis study likewise indicates that infectivity will not be detected in CNS tissues early in the incubation period. Also, the Community feels that for control reasons the harvesting of mechanically recovered meat from the skull or vertebral column of bovine animals of any age should be prohibited.

The Community reserves its opinion on the age limit for the inclusion of vertebral column pending internal discussions. In view of this the Community suggest replacing article 2.3.13.16 point 5 with:

"5) the fresh meat and meat products destined for export do not contain skull, brain, eyes, tonsils or spinal cord of bovine animals over 12 months, nor intestine of bovine animals of any age, all of which have been removed in a hygienic manner. Neither do they contain mechanically separated meat from skull or vertebral column of bovine animals."

...

Article 2.3.13.3.

BSE free country or zone

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

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

2) either:

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

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

ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

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

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

ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

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

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

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

iii) the affected cattle as well as:

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

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

= where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,

if alive in the country or zone, when slaughtered or at death, are completely destroyed.

comments:

Community

The Community draws the attention to the fact that the above sentence is already included in the first indent and therefore should be deleted..

. . .

Article 2.3.13.8.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

1) *milk* and *milk products*,

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

~~3) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;~~

The Community has commissioned a study to establish a probabilistic model for the quantitative assessment of residual BSE risk. Pending outcome of this study the Community reserves its position on tallow.

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

5) hides and skins;

6) gelatin and collagen prepared exclusively from hides and skins.

...

Article 2.3.13.21.

Veterinary Administrations of *importing countries* should require:

for tallow ~~(other than protein-free tallow as defined in Article 2.3.13.8.)~~ intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

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

2) a country or zone with a minimal BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.19., or

3) a country or zone with a moderate BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.19.

Article 2.3.13.22.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives ~~(other than those made from protein-free tallow as defined in Article 2.3.13.8.)~~ intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

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

OR

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

Article 2.3.13.23.

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

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

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

2) the age of the donor animals;

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

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

4) precautions to avoid contamination during collection of tissues;

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

6) the amount of material to be administered;

7) the route of administration.

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

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APPENDIX X.X.X.

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

Community comments:

The Community can support this proposal but would like the comments inserted in the text below are taken on board.

Furthermore the EU considers that the factors to be taken into account in the BSE risk assessment should be reviewed in the framework of a possible future review of the OIE Chapter.

Article X.X.X.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) status of the cattle population of a country or zone is the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:

1) the potential for introduction and recycling of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin;

2) importation of *meat-and-bone meal* or *greaves* potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;

3) importation of animals or embryos/oocytes (other than cattle embryos described in Article 2.3.13.8.) potentially infected with a TSE;

4) epidemiological situation concerning all animal TSE in the country or zone;

5) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;

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

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

Article X.X.X.2.

The potential for introduction and recycling of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the major role in BSE transmission.

- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.

- BSE infectivity has not been identified in *milk*, tallow or blood and these products are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the last 8 years (Article 2.3.13.2 in the *Terrestrial Animal Health Code*)?

Rationale: If cattle have not been fed products of animal origin (other than *milk* or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the last 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Evidence required:

- Documentation supporting that *meat-and-bone meal* or *greaves* of ruminant origin has not been fed.

Community comment :
This documentation should include a feed sampling programme

- Documentation supporting that ruminant rations could not have been contaminated with *meat-and-bone meal* or *greaves* of ruminant origin during manufacture and distribution.

Rationale: If cattle have been fed animal protein products potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the last 8 years, then the extent to which this poses a risk needs to be assessed.

Evidence required:

- Documentation describing livestock feeding practices in the country.

- Documentation describing the origin and composition (species, class of stock) of the animal protein products fed.

- Documentation concerning the rendering processes used to produce such animal protein products, supporting why these processes would have inactivated or reduced the titre of BSE agent, should it be present.

- Documentation describing which type of animal were fed animal protein products.

- Documentation describing how contamination of cattle rations with *meat-and-bone meal* or *greaves* of ruminant origin is prevented during production and distribution.

Rationale: If *meat-and-bone meal* or *greaves*, and animal protein products containing them, are, and have been, fed solely to non-susceptible species (swine, poultry), then there is negligible exposure risk.

Evidence required:

- Documentation describing the final use of *meat-and-bone meal* and *greaves* and its monitoring.
- Documentation describing how cross-contamination of cattle rations with *meat-and-bone meal* and *greaves* is prevented on farm, monitored and enforced.
- Documentation supporting that rations intended for non-susceptible species (swine, poultry) could not have been contaminated on farm with *meat-and-bone meal* or *greaves* of ruminant origin.

Article X.X.X.3.

Importation of meat-and-bone meal or greaves potentially contaminated with a TSE

This point is irrelevant if the assessment outlined in Article 2 indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the last 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* were not fed to cattle.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the major role in BSE transmission.

Question to be answered: Has *meat-and-bone meal, greaves*, or feedstuffs containing either been imported within the last 8 years?

Community comment

This questions can be very difficult to answer as to find information about "feedstuffs containing either.....". International trade statistics are not very detailed and have not separated feedstuff containing MBM from feedstuff not containing MBM. Further it is not defined in the statistics which species of animal the feedstuff is intended for.

Also, results of a sampling programme for imported feedstuffs should be provided.

Rationale: Knowledge of the origin of *meat-and-bone meal, greaves* or feedstuffs containing, or potentially containing, either is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

Evidence required:

- Documentation to support claims that *meat-and-bone meal, greaves* or feedstuffs containing them have not been imported OR
- Where *meat-and-bone meal, greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat-and-bone meal, greaves* or feedstuffs containing them imported during the last 8 years.

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

Article X.X.X.4.

Importation of animals or embryos/oocytes potentially infected with a TSE

- Countries which have imported cattle from BSE-infected countries are more likely to experience BSE.
- Animals pose a greater risk than embryos/oocytes (under study).
- Cattle pose the only known risk although other species are under study.
- Animals imported for breeding may pose a greater risk than animals imported for slaughter because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for slaughter.
- 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 animals, embryos or oocytes been imported within the last 7 years?

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;
- feeding and management of the animals in the country of origin;
- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and greaves, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category:
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals (including donors of embryos/oocytes), and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.

- Documentation describing the fate of imported animals, embryos or oocytes, including the age at slaughter.

- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Community comment

The documentation should also include information on how long the imported animal stayed in the country of origin.

Article X.X.X.5.

Epidemiological situation concerning all animal TSE in the country or zone

Assumptions:

- BSE may have originated from scrapie of sheep. Countries with scrapie may be at greater risk than those which have demonstrated scrapie freedom.

- Theoretically, scrapie in small ruminants might mask the presence of BSE and no field methods are available to differentiate between different TSEs.

- Available evidence suggests there is no link between chronic wasting disease of cervids and BSE.

- It has been suggested that transmissible mink encephalopathy may be an indicator of a hitherto undefined and hypothetical TSE of cattle.

- If a hypothetical 'spontaneous' TSE of cattle is assumed to occur, it must also be assumed to occur in all countries at a similar rate.

Question to be answered: Have other animal TSEs been identified in the country? What surveillance is there for TSEs?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of animal TSE. 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.

Evidence required: Documentation on awareness and surveillance programmes targeting all TSEs of livestock, their legal basis, scale, duration, and data generated.

Article X.X.X.6.

Extent of knowledge of the population structure of cattle, sheep and goats in the country or zone

Assumptions:

- The occurrence of scrapie and the uniquely high ratio of sheep to cattle in the United Kingdom may have facilitated the transmission of scrapie into cattle, although such a ratio has not been observed in other countries where BSE has become endemic.

- No breed differences in susceptibility have been demonstrated in cattle, although the BSE risk may be higher where dairy animals are fed greater quantities of supplementary feed containing *meat-and-bone meal* or *greaves*.

Questions to be answered: What systems are in place to identify herds and flocks? What is the size and geographical distribution of the sheep population and what proportion is dairy animals? What is the size and geographical distribution of the cattle population and what proportion is dairy animals?

Rationale:

- If scrapie is present, the risk of endogenously generated release of BSE, originating from scrapie, will be less where the ratio of sheep to cattle is lower.
- Where intensive dairy farming is practiced, access of livestock to concentrate feeds containing *meat-and-bone meal* and *greaves* may be more likely.
- A well structured system for herd and flock identification will provide a solid basis for the knowledge of the structure and distribution of cattle, sheep and goat populations.

Evidence required:

- Documentation describing the structure and geographical distribution of bovine and ovine populations.
- Documentation describing herd and flock identification systems.

Article X.X.X.7.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- TSE of livestock have long incubation periods and insidious onset of signs, so cases may escape detection.
- Pre-clinical TSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of TSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- TSE of livestock may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- TSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Appendix 3.6.3.
- TSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past 8 years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain TSE 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 disposal of fallen stock and materials condemned as unfit for human consumption.

Community comment

The above question as worded only concerns how animal waste has been processed over the past 8 years however it should also include if and how animal waste is collected in the country. In speaking about processing, it must be clearly understood that it should be collected in a certain way. Therefore in order to allow for a proper evaluation of the collection of animal waste, the following wording must replace the first part of the sentence above to provide for the evidence required:

"Documentation describing the collection and disposal of... "

- 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 compliance of the above.

Community comment

It is proposed to add" and effective enforcement" after "compliance".

Article X.X.X.8.

The overall risk of BSE in the cattle population of a country or zone is proportional to the level of known or potential exposure to BSE infectivity 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 or zone is free from BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.

CHAPTER 2.4.5

MAEDI-VISNA

Community comments:

The Community can only support this proposal if the points in the text below are taken on board as otherwise this Chapter will be unworkable. In addition the Community would like a further review targeted to the link between Maedi-Visna and Caprine Arthritis-Encephalitis viruses. It may be difficult to achieve freedom from one without the other. A scientific paper from France is attached as further background material and the Community would be interested to know the author of the OIE scientific paper.

If there are no good scientific reasons for having the 2 year period when it concerns females, it seems better to change the period to 5 years to be consistent with articles. 2.4.5.2 bis), Article 2.4.5.3 and Article 2.4.5.6. It also seems logic to include the possibility to have donor females resident since birth in free countries, zones or flocks (see further comment concerning article 2.4.5.6 above).

Article 2.4.5.1.

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

~~Article 2.4.5.2.~~

~~*Veterinary Administrations of importing countries* should require:~~

~~for sheep and goats for breeding~~

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

~~1) the animals showed no clinical sign of maedi-visna on the day of shipment;~~

~~2) animals over one year of age were subjected to a diagnostic test for maedi-visna with negative results during the 30 days prior to shipment;~~

~~3) maedi-visna was neither clinically nor serologically diagnosed in the sheep and goats present in the flocks of origin during the past 3 years, and also that no sheep or goat from a flock of inferior health status was introduced into these flocks during that period.~~

Article 2.4.5.2.bis

Country or zone free from maedi-visna

A country or zone may be considered free from maedi-visna (MV) if:

Community comments:

The Community believes it is difficult to achieve freedom for Maedi-Visna without

taking into account the situation concerning Caprine Arthritis-Encephalitis. The Community would like the OIE to reconsider this aspect and a technical background paper is attached.

1) it has a record of regular and prompt disease reporting in all livestock;

2) it has reported no clinical, epidemiological, serological or other evidence of MV during the past 5 years;

Community comments:
The Community believes that this is not sufficient and a good surveillance programme must be included if freedom is to be guaranteed. This is a slow virus with a long incubation period.

3) MV is notifiable in the whole country, and all clinical *cases* suggestive of MV are subjected to field and laboratory investigations;

4) all imports of sheep (except for slaughter) from other countries or zones over the past 5 years originated from an MV free country, zone or flock;

Community comments:
The Community believes this will have serious trade implications and would like the OIE to take into account the comments to Article 2.5.4.4. in a similar way in this Article as in all cases it is too long or indeed impossible to achieve freedom.

5) all sheep semen and embryos/ova imported for the past 5 years met the requirements referred to in Article 2.4.5.6 and in Article 2.4.5.7, respectively.

Article 2.4.5.3.

Flock free from maedi-visna

A flock may be considered free from MV if:

1) it is present in a country or zone which has a record of regular and prompt disease reporting in all livestock;

2) no clinical, post-mortem, serological or other evidence of MV has been found in any animal in the herd during the past 5 years;

3) MV is notifiable in the whole country, and all clinical *cases* suggestive of MV are subjected to field and laboratory investigations;

4) all sheep over 3 years of age have tested negative for MV annually for at least 5 years;

Community comments:

The Community would like an interpretation that a flock should continuously sample all animals over three years of age to keep its free status. Considering the nature of the disease is it not necessary to carry out a continuous surveillance of free flocks on an annual or biannual or other specified interval?

5) all sheep introduced into the flock over the past 5 years originated from an MV free country, zone or flock;

6) all sheep, semen and embryos/ova introduced into the flock for the past 5 years fulfilled the requirements referred to in Article 2.4.5.6 and in Article 2.4.5.7, respectively.

Article 2.4.5.4.

Veterinary Administrations of *importing countries* should require:

for sheep for breeding or rearing

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

1) come from a country or zone free from MV, or

2) come from an MV free flock.

Community comments:
The Community proposes the following new wording to replace the above:
"*Veterinary Administrations* of importing countries should require for sheep for breeding or rearing the presentation of an international veterinary certificate attesting that the animals:

(1) come from a country or zone free from maedi visna or

(2) come from a maedi visna free flock, or

(3) the animals showed no clinical signs of maedi visna on the day of shipment and animals over one year of age were subjected to a diagnostic test for maedi visna with negative results during the 30 days prior to shipment, and maedi visna was neither clinically nor serologically diagnosed in the sheep and goats present in the flocks of origin during the past 3 years, and also that no sheep or goats from a flock of an inferior health status were introduced into these flocks during that period. Where no previous testing history for the past three years is available then a representative sample of older animals must be tested"

Unless this amendment is taken on board it will take at least 5 before a country can be declared free and no trade can take place in that period. This will therefore have serious trade implications unless animals can be traded outside of a free system. The same comments apply to other chapters as indicated below.

Article 2.4.5.5.

Veterinary Administrations of *importing countries* should require:

for sheep for slaughter

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

1) are not being exported as part of an eradication programme;

2) showed no clinical sign of MV on the day of shipment.

[Note: Appropriate precautions should be taken both by the exporting country *and the* importing country *to ensure that the sheep are transported directly from the* place of shipment *to the abattoir for immediate slaughter.]*

Article 2.4.5.6.

Veterinary Administrations of *importing countries* should require:

for ovine semen

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

1) the donor animals were resident for a minimum period of 5 years immediately prior to the time of semen collection in an MV free country, zone or flock;

Community comments:
The Community questions this time period during which a ram must be resident for a minimum period of 5 years immediately prior to the time of semen collection in an MV free country, zone or flock. It would probably be as safe to use a ram born in a free country or flock that has been free during at least five years. Therefore the Community proposes the following new wording "...in an MV free country, zone or flock or resident since birth in a MV free country, zone or flock that has been free during a minimum period of five years". This amendment would enable the use of rams younger than 5 years.

In addition the same comment as mentioned in Article 2.4.5.4. applies.

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

Article 2.4.5.7.

Veterinary Administrations of *importing countries* should require:

for ovine embryos/ova

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

1) the donor females were resident for a minimum period of 2 years immediately prior to the time of embryo collection in an MV free country, zone or flock;

Community comments:
The Community would like clarification on the period of 2 years that the females should be resident in MV free country, zone or flock which is much shorter than for the rams (5

years before semen collection). What is the scientific reason for this? It also seems to be contradictory with other parts of the chapter, when compared to article 2.4.5.2. bis, and Article 2.4.5.3; to become a free country or zone, or a free flock, all imports of animals to the country or zone, or to the flock must come from free countries, zones or flocks during the last 5 years (therefore no animal can come from an infected country/zone/flock into a free country/zone/flock without the consequence that the status is lost. If the point is that the country, zone or flock should have been free for a certain period before it is regarded as safe enough then this should be clarified.

In addition the same comment as mentioned in Article 2.4.5.4. applies.

2) the embryos/ova have been collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

— text deleted

SUPPORTING DOCUMENT ON MAEDI-VISNA

1. Introduction

Ovine lentiviruses, maedi-visna virus (MVV) and South African ovine maedi-visna virus (SA-MVV), can infect sheep causing maedi-visna disease (MV) (Banks *et al*, 1983). The ovine lentiviruses are closely related to, but genetically and serologically distinct from, caprine arthritis encephalitis virus (CAEV) (Pasick, 1998; Valas *et al*, 2000).

2. Current world situation

It is difficult to assess the prevalence of MV globally because in some countries the disease is not reported. This may be due to the nature of the disease, which is usually latent and expressed mainly in older animals. Some under-reporting of MV may be due to alternative names for the disease; ovine progressive pneumonia, Montana sheep disease, zwoegersiekte, la bouhite, lungers, Marsh's progressive pneumonia and Graaff-Reinet disease.

3. Clinical signs

MV is a slowly progressive, insidious disease of sheep usually manifested either in the respiratory or central nervous system (CNS). Experimental infection can result in acute disease in young animals with very high mortality (Andresson *et al*, 1993).

6. DIFFERENTIAL DIAGNOSIS

The disease must be differentiated from other causes of chronic respiratory and nervous system disease, including pulmonary adenomatosis, parasitic pneumonia, chronic bacterial pneumonia, scrapie, listeriosis, pregnancy toxaemia, plant poisoning and parasitic CNS invasion, e.g. *Coenuris cerebralis*.

4. Pathology

Lymphoproliferation caused by MVV may affect the lungs, mediastinal lymph nodes, brain, joints and mammary glands (Verwoerd *et al*, 1994). Demyelination in the presence of leucoencephalomyelitis is common in the central nervous system. The lymphocytic component of the inflammatory infiltrates is thought to be responsible for the observed neurological damage (Sanders *et al*, 2001). Not all strains of MVV lead to progressive encephalopathy (Campbell and Robinson, 1998).

5. Epidemiology

7. SPREAD

Sihvonen *et al* (1999) warns that if introduced into a free country, MV can spread widely before clinical cases are detected. This has happened in Iceland, Sweden and Finland (Fridriksdottir *et al*, 2000; Hugoson, 1978; Sihvonen *et al*, 2000). In Sweden the disease was first recognised in 1974 and by 1975, a limited survey revealed 23 flocks were positive (Hugoson, 1978). The introduction of MV into Finland was traced to the importation of infected seronegative sheep in 1981 (Sihvonen *et al*, 1999).

8. COURSE OF INFECTION

MVV infections are characterised by a long and variable incubation period and life-long viral persistence (Cutlip *et al*, 1988) and clinical signs are rarely seen in sheep less than 3 years old (Constable *et al*, 1996). The antibody response confers no resistance to disease and the clinical course of disease is progressive (Carey and Dalziel, 1993; Verwoerd *et al*, 1994).

Viraemia develops shortly after infection and plays a major role in distribution of monocyte associated virus throughout the body (Georgsson, 1990).

9. PREVALENCE

Studies in Canada, the United States of America (USA) and some countries of the European Union have shown the average flock seroprevalence of MV can range from 19% to 97% (Constable *et al*, 1996; Lujan *et al*, 1993; Houwers *et al*, 1987).

10. LATERAL TRANSMISSION

The target cells for MVV replication are mononuclear cells and transmission of virus occurs via these cells (Joag *et al*, 1996). Transmission predominantly occurs from ewe to lamb via ingestion of colostrum (Sihvonen, 1980). Lateral transmission can also occur during close contact, mainly via respiratory secretions. This form of spread is enhanced if an animal is coinfected with other pulmonary infections, particularly pulmonary adenomatosis.

11. VERTICAL TRANSMISSION – VIA EMBRYOS

The evidence for transplacental transmission of MVV is equivocal. Preventing colostral transfer and early contact with infected dams has been regarded as an effective means of obtaining MV free progeny (De Boer *et al*, 1979; Cutlip *et al*, 1988; Sihvonen, 1980). Long-term absence of MVV infection was demonstrated in a group of approximately 40 lambs separated from infected ewes immediately after birth and reared in isolation (De Boer *et al*, 1979). Similar results were reported by Light *et al* (1979) and Houwers *et al* (1987). Other studies suggest that the potential for transplacental infection cannot be entirely dismissed. Cutlip *et al* (1981) reported prenatal transmission based on the detection of MVV from 1 foetus and 2 newborn lambs out of 70 progeny. Cross *et al* (1975) reported infection in a small proportion of hysterectomy derived lambs from infected dams. More recently, Brodie *et al* (1994) detected MVV DNA in the peripheral blood mononuclear cells (PBMC) of 11% of lambs removed from their infected dams immediately after birth.

Viraemia which develops shortly after infection might expose embryos to virus. Using PCR techniques, Woodall *et al* (1993) failed to detect MVV in either uterine washes or washed embryos collected from 10 infected ewes. Further studies, involving increased numbers of animals at different stages of infection, are required to conclude that exposure of embryos to MVV during infection does not occur.

12. VERTICAL TRANSMISSION – VIA SEMEN

Transmission of infection via semen has not been demonstrated (Dawson, 1987). However, ovine lentivirus was detected in the semen of rams concurrently infected with *Brucella ovis* (de la Concha-Bermejillo *et al*, 1996). These authors suggest that inflammatory lesions of the genital tract causing leucocytospermia, as caused by *B. ovis*, predispose infected rams to shed ovine lentivirus in their semen. Moreover, semen may contain blood or plasma and MVV capsid antigen has been detected in plasma of infected sheep (Brodie *et al*, 1994). These studies do not provide clear evidence that MVV is transmitted to recipient ewes or offspring via infected semen but do suggest the potential for venereal transmission.

13. BREED SUSCEPTIBILITY

Differences in breed susceptibility to MVV have been reported (Houwers *et al*, 1989). Icelandic breeds appear to be more susceptible than British breeds and Texels and Border Leicester are more susceptible to disease than Columbia sheep (Cutlip *et al*, 1986; Joag *et al*, 1996). Also, Snowder *et al* (1990) determined significant differences in the seroprevalence of MV between the 6 breed types comprising a flock of 2,976 sheep. Nevertheless, complete breed-associated resistance has not been demonstrated (Houwers, 1990). Houwers *et al* (1989) suggest that apparent susceptibility may also depend on the strain of MVV.

14. HOST RANGE

Disease due to MVV has only been reported in sheep and very rarely in goats (Castro *et al*, 1999; Banks *et al*, 1983).

6. Adverse consequences of MVV

A significantly lower reproduction rate was observed in seropositive ewes and their lambs suffered from significantly higher death and lower growth rates, probably due to a reduced milk production, resulting in economic losses (Scheer-Czechowski *et al*, 2000). This observation contrasts with that of Dungu *et al* (2000) who reported minimal difference between the pre-weaning growth of lambs born of ewes naturally infected with South African strains of maedi visna virus (MVV) and uninfected ewes kept under similar conditions.

In general, introduction of the MVV into a free country or zone results in an adverse economic impact. In most situations, the disease causes significant losses due to deaths, 'ill thrift' and the cost of control and eradication measures. In recognition of this adverse impact, eradication programmes have been implemented in the Netherlands (Houwers, 1990), Canada (Williams-Fulton and Simard, 1989), Iceland (Zanoni *et al*, 1994), Finland (Sihvonen *et al*, 1999), Sweden (Lindqvist, 1994), USA (Young, 1993) and Germany (Scheer-Czechowski *et al*, 2000).

7. Risk management

14.1.1. *a)* *Disease freedom of animals in country, zone or flock*

15. COUNTRY/ZONE FREEDOM

Reporting country status to the OIE with respect to MV is currently unreliable (Brodie *et al*, 1994; Constable *et al*, 1996; Handistatus II). Reliance on country or zone freedom as an effective risk management option therefore requires the specification of extra measures to ensure that a country or zone claiming freedom has adopted strategies to ensure this to be the case. MV should be notifiable in the whole country, and all clinical cases suggestive of MV should be thoroughly investigated. If serosurveys are not conducted, measures to prevent the introduction of the disease via animals or their genetic products should have been in place for at least 5 years. This period of time is expected to allow expression of disease if present in flocks before controls were implemented.

16. FLOCK FREEDOM

Because serological testing is not always reliable and the disease has a long latency period, assurances of flock freedom within an infected country or zone may be difficult. Johnson *et al* (1992) observed that the absence of clinical signs over a 5 year period alone can not be regarded as evidence of flock freedom. Similarly, Williams-Fulton and Simard (1989) advise that a longer time period than 4 years is required to ensure that MV has been completely eradicated from a flock. Houwers (1990) recommends certification of MVV freedom for flocks based on recent serological examination of the whole flock with negative results. Continuous surveillance was found to be necessary during the eradication programme in the Netherlands. This was expected due to the delay or absence of seroconversion in some infected animals (Houwers *et al*, 1987).

Sihvonen *et al* (1999) advise that surveillance of MV has to be continuous, requiring extensive, repeated serological testing and restrictions on the movement of sheep between flocks.

16.1.1. *b)* *Embryo washing*

Limited studies indicate that MVV does not transmit from infected sheep through transfer of embryo (Dawson and Wilmot, 1988; Young, 1993). IETS (1998) regard this disease agent as Category 4 in sheep (that is, "Diseases or disease agents on which preliminary work has been conducted or is in progress").

16.1.2. *c)* *Testing and examination*

Clinically normal infected animals may be detected by serology or virus isolation, however both techniques can be unreliable.

17. PERIOD FROM INFECTIONS TO ANTIBODY DEVELOPMENT

The period between exposure to virus and the detection of antibodies varies with the route of infection, form of exposure and breed of sheep. Seroconversion occurs from

4 to 6 weeks following experimental infection and antibody levels tend to stay relatively constant (Petursson, 1990). The first appearance of antibodies following natural infection can range from 11 months to over 5 years (Houwers *et al*, 1987). Persistent high antibody titres are usual in infected animals but disease in the absence of positive serology has been described (Houwers *et al*, 1987). A complicating factor is that significant viral antigenic variation can occur in MVV infected animal over time (Narayan *et al*, 1977). Also, the serological response to MVV varies with age and breed of sheep (Constable *et al*, 1996).

Sihvonen *et al* (1999) documents the failure of quarantine measures to prevent introduction of the disease into Finland. Introduction of infected seronegative sheep in 1981 were thought to be responsible for introduction of the disease, detected 13 years later during serosurveillance (Sihvonen *et al*, 1999).

18. AGE EFFECTS

Viral RNA can be detected in PBM cells taken from naturally infected lambs less than 1 year of age by *in situ* hybridisation. However, animals less than 1 year of age rarely show seropositivity when infected (Johnson *et al*, 1992) and an increased seroprevalence occurs with age (Simard and Morley, 1991). Snowder *et al* (1990) determined the average seroprevalence to be 11% at one year of age and 93% in sheep 7 years or older. Cutlip *et al* (1992) found that prevalence increased from 4% at less than 1 year to 34 % at 4 years, with variability associated with breed type.

19. AVAILABLE SEROLOGICAL TESTS

The agar gel immunodiffusion (AGID) test and the enzyme linked immunosorbent assay (ELISA) are the most commonly used serological tests (Simard and Briscoe, 1990). The sensitivity of both tests is dependent on the antigen used (Knowles, 1997; Rosati *et al*, 1994; Saman *et al*, 1999).

Other detection methods

MV virus can be detected by virus isolation or nucleic acid detection methods. Even though virus cannot be recovered directly from tissue homogenates virus can be detected if explanted or by co-cultivating with a permissive cell type (Carey and Dalziel, 1993). A number of polymerase chain reaction (PCR) assays have been described which detect MV DNA in infected tissues, especially bone marrow, PBM cells and pulmonary leucocytes (Brodie *et al*, 1992; Celer *et al*, 2000; Johnson *et al*, 1992). A PCR test has been used to detect infected sheep in the Dutch National MVV/CAEV control programme (Wagter *et al*, 1998).

20. SUMMARY – THE RELIABILITY OF SEROLOGICAL TESTING FOR DETECTING INFECTED ANIMALS

Viral infections are characterized by a window period during which the host is infected but diagnostic test (e.g. antibody) results are negative. Animals determined to be infected by *in situ* hybridisation, PCR and co-cultivation were negative on serology (Johnson *et al*, 1992). Infection of other animals can occur during this period of seronegativity. To detect infections reliably, it is important to conduct

antibody tests after the host animal has been given sufficient time to mount a detectable immune response. Houwers *et al* (1987) based accreditation of flocks on testing for MVV antibodies twice with an interval of 6 months. However, eradication efforts in Finland relied on five consecutive serological tests at 12 to 16 month intervals. Repeated testing of all animals over 1 year of age was determined to be necessary because of the lack of sensitivity of serological testing. It was reasoned that if infected animals were missed, transmission would occur and eventually produce seropositive animals within the flock (Sihvonen *et al*, 2000).

In summary, the time required for seroconversion following infection can be relatively prolonged and unpredictable. An infected animal may give a negative result to a single antibody test so more than one test over a period, and reliance on flock testing rather than individual animal testing would be expected to increase the likelihood of sourcing non-infected animals.

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CHAPTER 2.1.13.

CLASSICAL SWINE FEVER

Community comments:
The Community can only support this proposal provided the comments in the text below are taken on board.

...

Article 2.1.13.4.

Country or zone free of CSF in domestic and wild pigs

1) Historically free status

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

2) Free status as a result of an eradication programme

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

a) it is a notifiable disease;

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

Community comments:
The Community strongly requests that the above deletion is reinstated. It is very important that identification and thereby tracebility for disease control purposes is maintained.

~~c) the feeding of swill is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.1.1.;~~

Community comments:
The Community strongly requests that the above deletion is reinstated. The first introduction of disease agents into a country have been linked to swill feeding whether legal or illegally on many occasions and it is very important that the risks of feeding swill continue to be highlighted.

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

AND EITHER

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

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

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

AND

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

. . .

— text deleted

APPENDIX 3.8.X

GUIDELINES FOR SURVEILLANCE AND MONITORING FOR BLUETONGUE VIRUS

Community comments:

The Community can in principle support this proposal however the following comments should be taken on board:

Firstly the OIE code should be written in such a way as to take account of different situations of countries in particular in relation to climatic conditions and factors. Secondly all the questions noted by the OIE need to be answered and addressed. The Community is of the opinion that the proposed draft will not bring a significant improvement to the difficulties raised by article 2.1.9.1 of the Code for countries which

- have part of their territory between latitudes of approximately 40°N and 35°S,

-or are adjacent to a country or zone adjacent to a country or zone not having free status

-or face a regionalisation problem.

If the objective is to replace the "95 % level of confidence of detecting an annual sero-conversion incidence of 2%" by a more flexible approach (which is relevant) the proposal does not achieve its end in the sense that it shall not put an end to the endless discussions on the features of a programme necessary to prove the free status of a zone.

Th real question is the size and frequency of the sampling of a cattle population at risk considering:

-the knowledge of the vector's population dynamic

-the climate, the geographical and ecological data

-the structure and repartition of the host's population.

Considering the ecology of the vectors and the experience we have on the way the disease extends (waves) a targeted approach should be considered and precisely defined.

In addition, the absence of virus circulation being the only element to consider for the recognition of a free status of a country or zone (Information given by the surveillance programme) the absence of vaccination during the last 12 months is not a relevant parameter for this recognition. Also it is important that countries notify the findings of sero-conversions for bluetongue and therefore any positive sero-conversions must be notifiable.

Lastly the results of the forthcoming conference on bluetongue should be taken into account.

20.1.2. 1. Purpose of the document

This document describes guidelines for surveillance and monitoring to establish the bluetongue virus (BTV) status of a country or zone, in the absence of clinical signs of bluetongue.

20.1.3. 2. Introduction

The global BTV distribution historically has been shown to be between latitudes of approximately 40°N and 35°S.

Within these latitudes, the BTV status of a country or zone, in the absence of clinical signs of bluetongue, must be substantiated. Demonstration of BTV status requires an adequate knowledge of the epidemiology of BTV in the country or zone being assessed. Such knowledge should include consideration of the natural history of BTVs and their vectors, climate, geography, livestock demographics, vaccination history, animal husbandry practices and relevant historical information.

The composition and mix of a surveillance and monitoring system for any country or zone will be influenced by its location. Within a country or zone where clinical disease is not present, the emphasis will be on surveillance; in infected countries or zones, the emphasis will tend to be on monitoring. Results from surveillance within the supposedly free country or zone will assist in supporting a case for freedom. Results from monitoring in infected countries or zones can further clarify the epidemiology of BTV infection and vector distribution in that country or zone.

20.1.4. 3. Components of a surveillance and monitoring system for bluetongue

a) Clinical surveillance

Clinical bluetongue disease must be notifiable and a system must be in place for reporting suspect clinical bluetongue disease. Suspicion of disease within a free country or zone should be followed by appropriate official control measures. Access to suitable laboratories to screen for and confirm a clinical diagnosis of bluetongue is essential.

b) Serological surveillance and monitoring

An active programme of surveillance and monitoring of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or zone, in the absence of clinical signs. Serological testing of ruminants has shown to be one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV, and the species available, in the local area. Cattle are usually the most sensitive, appropriate and available indicator species.

Surveillance and monitoring may include serological surveys, for example abattoir surveys, the use of sentinel animals, or a combination of methods.

Interpretation of serological data should take into account the sensitivity and specificity of any tests used.

Serological surveillance in a free zone should target those areas that are at highest risk of BTV transmission, based on the results of previous surveillance and other information. This will usually be toward the boundary of the free zone. In view of the epidemiology of BTV, either random or purposive sampling is suitable to select herds and/or animals for testing. For sentinel herds, animals selected to detect BTV transmission should be seronegative at the commencement of the period of study. For serological surveys, only animals that have a complete life history and have not been in an infected area should be sampled. This allows the interpretation of serological results with reference to location, which assists in clarifying the location of the boundary of the free zone.

A surveillance zone within a free country or zone should separate it from a potentially infected country or zone. Serological surveillance in a free country or zone should be carried out over a distance of at least 100 kilometres from the border with a potentially infected country or zone.

Serological monitoring in the infected zone should be weighted towards those areas near the boundary of the free country or zone, based on previous serological surveillance, and monitoring and other information. In view of the epidemiology of BTV, either random or purposive sampling is suitable to select herds to give an appropriate geographical spread and provide animals of suitable age and history for testing. Sentinel animals bled at regular intervals during the potential season of BTV activity provide the best method of detecting evidence of transmission because this approach provides information on the time that any transmission occurs. For sentinel herds, animals selected to detect transmission of BTV should be seronegative at the commencement of the period of study. For serological surveys, only animals that have a complete life history should be sampled. This allows the interpretation of serological results with reference to location, which assists in clarifying the location of the boundary of the free zone.

c) Virological surveillance and monitoring

Isolation and genetic analysis of samples of BTV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

d) Vector surveillance and monitoring

Vector surveillance and monitoring are desirable to obtain a sound understanding of the epidemiology of BTV in the area under study. Vector trapping should take account of the biology and behavioural characteristics of the vectors responsible for transmission in that environment. Vectors should be sorted to species and counted.

For transmission of BTV to occur, both BTV and sufficient competent vectors need to be present. Interpretation of results depends on vector competency, the number of vectors trapped, and the trapping method. Because *Culicoides* spp. can be transported long distances by wind, it is possible for very low numbers of vectors to be detected occasionally in a BTV free country or zone. Such an occurrence may not necessarily change the status of the free country or zone, and the significance of such detections needs to be interpreted in light of serological surveillance and monitoring data and other factors that influence BTV distribution.

e) Climate knowledge

Relevant climatic factors include rainfall, temperature, humidity, wind, and seasonal patterns. Although *Culicoides* spp. vectors are known to breed and survive only in warm, moist conditions, various species differ in their ability to survive and reproduce in different climates. The influence of climate should be considered in light of the ecology of the vector(s) operating in the area under study. Monitoring for evidence of climatic variations may also provide an early warning of potential spread of BTV from infected to free country or zones.

In addition, BTV transmission is seasonal in most areas and such knowledge allows the design of more effective surveillance and monitoring systems. For example, it is useful to allocate most effort to sentinel herd surveillance and monitoring during the BTV transmission season.

A clear understanding of the role of climate in the epidemiology of BTV is also required if a country or zone wishes to be considered as seasonally free.

f) Geography

Geographical features such as deserts, mountain ranges, and large bodies of water can serve as barriers to BTV vectors. Factors related to geography also include vegetation and soil type.

The degree of variability of geographical features in the free country or zone and the adjoining country or zone should be considered. The level of variability influences the likelihood of the survival of isolated foci of vector populations in suitable ecological niches in a country or zone.

g) Livestock demographics and movements

The surveillance programme needs to be tailored appropriately to the number, type and concentration of various ruminant species in a country or zone as these determine the availability of susceptible hosts.

The movement of potentially infected animals within a country or zone should be considered if there is an uneven distribution of vector populations that could support the transmission of BTV.

h) Historical considerations

Relevant historical data (including climatic data and reports of outbreaks) over many years may be used to help design the surveillance programme.

CHAPTER 2.1.9.

BLUETONGUE

Community comments:
The Community can support this proposal but a further strategy could be added namely: "-vector protection of the vehicle itself". This has been achieved in certain countries with special seals and ventilation systems.

. . .

Article 2.1.9.16.

Protecting animals from Culicoides attack

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

Potential risk management strategies include:

= treating animals with chemical repellents prior to and during transportation;

= loading, transporting and unloading animals during daylight hours, avoiding dawn and dusk;

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

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

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

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

— text deleted

CHAPTER 2.1.14.

AVIAN INFLUENZA

Community comments:
The Community can only support this proposal if the comments in Annex 3 are taken on board.

Article 2.1.14.1.

For the purposes of this *Code*, avian influenza (AI) is defined as 'an infection of poultry caused either by any influenza A virus which has an IVPI in 6-week-old chickens greater than 1.2 or by an influenza A virus of H5 or H7 subtype'.

Poultry is defined as 'all birds reared or kept in captivity 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'.

For the purpose of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by AI virus, but also with the presence of infection with AI virus in the absence of clinical signs. Articles dealing with trade in *commodities* recommend different sanitary measures, depending on the presence or absence of clinical signs.

The following defines the occurrence of AI virus infection:

1) AI virus has been isolated and identified as such from poultry or a product derived from poultry, or

2) viral antigen or viral RNA specific to H5 or H7 subtype of AI virus has been identified in samples from poultry or a product derived from poultry, or

3) antibodies to H5 or H7 subtype of AI virus that are not a consequence of vaccination have been detected in poultry.

For the purposes of this *Code*, the *incubation period* for AI shall be 28 days.

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

Any vaccine used should comply with the standards described in the *Manual.*

Article 2.1.14.1 bis

The AI status of a country or zone can be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for AI occurrence and their historic perspective;

2) that AI is notifiable in the whole country, an on-going AI awareness programme is in place, and all notified suspect occurrences of AI 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 AI surveillance programme in accordance with this chapter and Chapter 1.3.6.

Article 2.1.14.2.

AI free country or compartment

A country or compartment may be considered free from AI when it has been shown that AI infection has not been present for the past 12 months. If a *stamping out policy* is applied ~~infected poultry are slaughtered~~, this period shall be 6 months after the slaughter of the last infected poultry.

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of AI infection of 20%. In the case of a enterprise in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of AI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. ~~Additional security should be provided by~~ The use of relevant serological tests in identifiable sentinel birds will help to identify field infections in vaccinated flocks.

Article 2.1.14.3.

When importing from an AI free country or compartment, *Veterinary Administrations* should require:

for live poultry

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

1) showed no clinical sign of AI on the day of shipment;

2) were kept in an AI free country or compartment since they were hatched or for the past 28 days.

[Note: If the poultry were vaccinated against AI, the nature of the vaccine used and the date of vaccination should be stated in the certificate.]

Article 2.1.14.4.

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of live birds other than poultry:

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

1) showed no clinical sign of AI on the day of shipment;

2) were kept in isolation ~~*a quarantine station*~~ since they were hatched or for the 28 days prior to shipment and showed no clinical sign of AI during the isolation ~~quarantine~~ period;

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from AI.

...

Article 2.1.14.9.

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of semen of birds other than poultry.

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

1) were kept in isolation ~~*quarantine*~~ for the 28 days prior to semen collection;

2) showed no clinical sign of AI during the isolation ~~quarantine~~ period;

3) were tested between 7 and 14 days prior to semen collection and shown to be free of AI.

Article 2.1.14.10.

When importing from AI free country or compartment, *Veterinary Administrations* should require:

for *fresh meat* and processed meat of poultry, and poultry viscera

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

1) which have been kept in an AI free country or compartment since they were hatched or for the past 28 days;

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

~~Article 2.1.14.11.~~

~~When importing from AI free country or compartment, *Veterinary Administrations* should require:~~

~~for poultry viscera~~

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

~~1) which have been kept in an AI free country or compartment since they were hatched or for the past 28 days;~~

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

Article 2.1.14.12.

When importing from a country or compartment not considered free from AI, *Veterinary Administrations* should require:

for *fresh meat* of poultry

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

1) which have been kept in an *establishment* free from AI for at least 28 days and regularly inspected by the *Official Veterinarian*;

2) which have been tested to give a 95% probability of detecting a 5% prevalence of AI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, with negative results;

3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with AI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for AI with favourable results.

Article 2.1.14.12 bis

When importing from a country or compartment free from clinical signs of AI but not considered free from AI infection, *Veterinary Administrations* should require:

for *fresh meat* of poultry

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

1) which have been kept in a country or compartment free from clinical signs of AI but not considered free from AI infection since they were hatched or for the past 28 days;

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

. . .

— text deleted

ANNEX 2

Appendix XVII-SANCO/10557/2003-Rev.1

CHAPTER 2.1.14.

AVIAN INFLUENZA

Community comments:

The Community can only support this proposal if the comments below are taken on board.

The EC welcomes the exhaustive review of this chapter and the uptake of recent experiences gained in Europe and other countries on the control of this disease, including vaccination.

The proposed chapter is to a large extent in line with the recommendations given in the Community Scientific Report on the definition of avian influenza and the use of vaccination against avian influenza of 27 June 2000.

However it is clear that the adoption of the Chapter as proposed would have profound consequences on trade following of detection of low pathogenic avian influenza viruses (LPAI). It is important to ensure that trade restrictions are proportionate to the risk posed by such viruses.

The Community further highly appreciates that the OIE has decided to carry out further work on:

1) the zoonotic aspects of AI;

2) the influence of different disease control strategies, including vaccination, on virus circulation;

3) the development of guidelines for the practical application of compartmentalisation within the Chapter on the 'General Definitions'.

4) the development of guidelines on AI surveillance and suitable tests;

5) rules for trade which are proportionate to the risk presented by the different commodities and the disease status of countries or zones of origin; and

6) inactivation procedures for AI viruses in different commodities.

The Community suggests that the following two issues should be given the highest priority and possibly dealt with before the general session in May 2004:

1) the development of guidelines on AI surveillance and suitable tests;

The EC welcomes the O.I.E.'s readiness to develop guidelines for NAI surveillance. The EC will be able to give a further contribution to this work once the results of the surveillance programme currently under way in the EC are available at the end of this year.

2) the development of guidelines for the practical application of compartmentalisation within the Chapter on the 'General Definitions'.

The EC in principle favours this approach but has some reservations, particularly with respect to the difficulty of ensuring effective bio-security measures and its application to densely populated poultry areas; it will therefore be necessary to draw up such guidelines specifically for the poultry sector in relation to AI, so that eventually these two matters could be dealt with jointly.

Article 2.1.14.1.

For the purposes of this *Code*, avian influenza (AI) is defined as 'an infection of poultry caused either by any influenza A virus which has an IVPI in 6-week-old chickens greater than 1.2 or by an influenza A virus of H5 or H7 subtype'.

Community comment:

Highly pathogenic avian influenza (HPAI) viruses cause severe disease and high mortality in susceptible bird species with high economic losses.

LPAI viruses of the H5 and H7 subtypes do not induce serious disease in poultry and economic losses are not as dramatic as for HPAI. However, the circulation of H5 and H7 LPAI viruses in domestic bird populations can give rise to the potential emergence of HPAI virus strains. Surveillance and trade requirements should be proportionate to the risk posed by the two categories of viruses and take into account the current scientific knowledge on the pathogenesis of infection in different species.

Taking into account that the words "Avian Influenza" are used by the scientific community to indicate any infection of birds with Influenza viruses H1-H15 of avian origin, including H5 and H7, the Community deems that trade standards should be based on the following definition:

"Notifiable avian Influenza (NAI) is an infection of poultry caused by any Influenza A virus of the H5 or H7 subtypes or by any AI virus with an IVPI greater than 1.2. Notifiable avian Influenza viruses can be divided into "Notifiable Highly Pathogenic Avian Influenza" (NHPAI) and "Notifiable Low Pathogenicity Avian Influenza (NLPAI)". NHPAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or multiple basic amino acids at the cleavage site of the haemagglutinin molecule. NLPAI are all Influenza A viruses of H5 and H7 subtype that are not NHPAI viruses"

The acronyms NAI, NHPAI and NLPAI will be therefore used throughout.

The Community understands that the OIE has already addressed this issue to a certain extent by applying different trade rules in the case of AI disease or AI infection. However, the Community believes that this could leave open space for misinterpretation and therefore insists on keeping the differentiation into LPAI and HPAI.

Poultry is defined as 'all birds reared or kept in captivity 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'.

For the purpose of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by AI virus, but also with the presence of infection with AI virus in the absence of clinical signs. Articles dealing with trade in *commodities* recommend different sanitary measures, depending on the presence or absence of clinical signs.

For the purpose of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by [AI] NHPAI virus, but also with the presence of [infection with AI] NLPAI virus in the absence of clinical signs. **(same comment as above)**

The following defines the occurrence of AI virus infection:

1) AI virus has been isolated and identified as such from poultry or a product derived from poultry, or

2) viral antigen or viral RNA specific to H5 or H7 subtype of AI virus has been identified in samples from poultry or a product derived from poultry, or

3) antibodies to H5 or H7 subtype of AI virus that are not a consequence of vaccination have been detected in poultry.

Community Comment:

The Community believes that there is an urgent need to clarify the 'occurrence of AI virus infection' in relation to serological findings; in particular with regard to a clearly defined cut-off point for the interpretation of positive results and 'singleton reactors' for example.

For the purposes of this *Code*, the *incubation period* for AI shall be 28 days.

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

Any vaccine used should comply with the standards described in the *Manual*.

Article 2.1.14.1 bis

The AI status of a country or zone can be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for AI occurrence and their historic perspective;

2) that AI is notifiable in the whole country, an on-going AI awareness programme is in place, and all notified suspect occurrences of AI are subjected to field and, where applicable, laboratory investigations;

The Community welcomes that the O.I.E. has introduced by this Article criteria to determine the NAI status of a country, zone or compartment by addressing the following issues:

1) the performance of a risk assessment to identify all potential factors for NAI occurrence and their historic perspective;

2) compulsory notification of NAI in the whole country, an on-going NAI awareness programme with all notified suspect occurrences of NAI subjected to field and, where applicable, laboratory investigations;

3) an on-going surveillance programme to demonstrate absence of NLPAI infection in the country or zone, focused on areas and poultry establishments in the country which present a higher risk of introduction of NAI viruses originating from wild birds, which may vary geographically and in time, the prevalence of infection in certain categories (e.g. broilers versus turkeys) and the testing difficulties in different species. Therefore a risk -based approach must be sought for surveillance. The provisions of existing guidelines according to Chapter 1.3.6. should be taken into account.

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 AI surveillance programme in accordance with this chapter and Chapter 1.3.6.

However, the Community wants to clarify the following in relation to paragraph 3):

Reference is made to *"birds other than poultry"*, which are within the Community not considered as wild (free-living) birds but as captive or pet birds. Compulsory surveillance in this category of birds for defining the status of a country seems not appropriate, because:

a) the risk posed by these birds for commercial poultry is negligible.

b) the practical implementation would be problematic and costly without adding additional safety to international trade.

New Articles

Community proposal:
Following a country's evaluation according to the criteria laid down in Article 2.1.14.1. the Community proposes to introduce the following categories below for the status of a country, zone or compartment:

New Article I:

A country, zone may be considered free from NHPAI with the absence of NLPAI demonstrated, without vaccination ("NAI category 1"), if the following conditions are met:

a) in addition to the general surveillance referred to in 1.3 above an on-going surveillance programme is implemented in all establishments of the country or zone..... .

b).....

c).....

New Article II

A country or zone may be considered free from NHPAI with the absence of NLPAI demonstrated, with vaccination ("NAI category 2"), if the following conditions are met:

a) in addition to the general surveillance referred to in 1.3 above an on-going surveillance programme is implemented in all establishments of the country or zone..... .....

b).....

c).....

New Article III

A country or zone may be considered free from HPAI with absence of LPAI not demonstrated, without vaccination ("NAI category 3"), if the following conditions are met:

a) the general surveillance referred to in article 1.3 above is implemented .....

b).....

c).....

New Article IV

A country or zone may be considered free from HPAI with the absence of LPAI not demonstrated, with vaccination ("NAI category 4"), if the following conditions are met:

a) the general surveillance referred to in article 1.3 above is implemented.....

b).....

c).....

New Article V

An HPAI infected country or zone is a country or zone that does not fulfil the requirements of any of the *New Articles II -V* ("NAI category 5").

New Article VI

Rules and time periods for recovery of free status must be specific to the status sought, the disease control measures and the surveillance applied, as appropriate. The periods of 12 or 6 months indicated in the text proposed is far too long, taking into account:

- the incubation period of disease (28 days), and

- that, after appropriate measures are adopted to eliminate any infected poultry, effective surveillance can be rather rapidly carried out to exclude any further presence of NAI virus in the country or zone.

The EC therefore proposes new Articles as follows, the requirements to be set by an ad hoc group.

Recovery of country or zone status

1) When NAI infection occurs in a country or zone free from NHPAI with the absence of NLPAI demonstrated, without vaccination, the status of the country or zone may be recovered on the following basis:

a) .....

b).....

c).....

2) When NAI infection occurs in a country or zone free from NHPAI with the absence of NLPAI demonstrated, with vaccination, the status of the country or zone may be recovered on the following basis:

a).....

b).....

c).....

3) When a NHPAI outbreak occurs in a country or zone free from NHPAI with the absence of NLPAI not demonstrated, without vaccination, the status of the country or zone may be recovered on the following basis:

a).....

b).....

c).....

4) When a NHPAI outbreak occurs in a country or zone free from NHPAI with the absence of NLPAI not demonstrated with vaccination, the status of the country or zone may be recovered on the following basis:

a).....

b).....

c).....

Article 2.1.14.2.

AI free country, zone or compartment

A country, zone or compartment may be considered free from AI when it has been shown that AI infection has not been present for the past 12 months. If a *stamping out policy* is applied ~~infected poultry are slaughtered~~, this period shall be 6 months after the slaughter of the last infected poultry.

Community comment:
The Community feels that 6 months is too long a period and therefore proposes 2 months (approx. double incubation period of 56 days). The shortening of the period should be linked to appropriate intensified surveillance in relation to the outbreak.

Community comment on compartmentalisation:

During the recent NHPAI and NLPAI epidemics in the EC Member States, it has been proven that the infection spread rapidly not only between poultry farms belonging to one integrated system, but also between holdings located in close proximity (neighbourhood spread) without any apparent functional connection. This means that for the establishment of a "compartment" both geography and management should be considered when necessary depending on the situation. It appears appropriate that at least under certain circumstances a buffer zone should be established around the enterprises of the compartment.

Until guidelines are available, the Community deems that the compartmentalisation concept cannot be successfully applied. The Chapter proposed does not address the possible different risks presented by countries or zones with respect to NAI. As regards the specific requirements for international trade the lower risk of transmission of NLPAI should result in a distinction between

countries or zones affected by NLPAI and NHPAI, taking into account that if NHPAI occurs it would be rapidly detected by passive surveillance. In addition the use of vaccination for disease control should be reflected in rules for trade. To apply these principles the EC proposes new Articles as follows, the requirements to be set by an ad hoc group. The words "country or zone" below should read "country, zone or compartment" once the concept of compartment has been clarified.

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of AI infection of 20%. In the case of a enterprise in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of AI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. ~~Additional security should be provided by~~ The use of relevant serological tests in identifiable sentinel birds will help to identify field infections in vaccinated flocks.

Community comments on specific surveillance:

Please see comments made on surveillance in the introduction and in relation to the assessment of a country's status.

Trade requirements

Community proposal:

New requirements should be developed on the basis of a risk assessment and be proportionate to the risks posed by the two categories of virus.

The current scientific knowledge on the pathogenesis of infection and the characteristics of each commodity should be taken into account. The molecular basis of pathogenicity suggests that NLPAI viruses do not produce systemic but only localised infection. This affects not only the expression of disease, and therefore economic losses, but also the virus amount in internal organs and meat, and the possibility to spread the infection via poultry products. As a consequence there should be Articles giving requirements for commodities from each country or zone as appropriate to their status. Trade requirements for all commodities should not be more restrictive than necessary.

It may be concluded that the requirements may be the same for some commodities originating from countries or zones with different NAI status, provided that in this way the same level of protection is achieved.

When the risk mitigation provided by the country or zone status and/or the nature of the commodity is not sufficient, additional requirements at the level of the flock of origin may be needed to permit trade.

The EC therefore proposes the code to be structured in the following way. The draft articles as previously proposed for the review of the whole Chapter have been included where applicable.

Part 1

Requirements applicable regardless of the NAI status of the country or zone of origin

1.1.

for the importation of live birds other than poultry, **which are not kept permanently in captivity**:

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

1) showed no clinical sign of NAI on the day of shipment;

2) were kept in **isolation approved by the Veterinary authority** since they were hatched or for the 28 days prior to shipment and showed no clinical sign of NAI during the **isolation period**;

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from NAI.

1.2.

for semen of birds other than poultry, **which are not kept permanently in captivity:**

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

1) were kept in **isolation approved by the Veterinary authority** for the 28 days prior to semen collection;

2) showed no clinical sign of NAI during the **isolation period**;

3) were tested between 7 and 14 days prior to semen collection and shown to be free of AI.

Other commodities may be included in this section on the basis of a risk assessment that shows that the NAI status of the country or zone of origin does not contribute to risk mitigation.

Part 2

When importing from countries or zones of origin with "NAI category 1", *Veterinary Administrations* should require:

2.1.

for live poultry and other birds kept permanently in captivity the presentation of an *international veterinary certificate* attesting that the poultry:

1) showed no clinical sign of NAI on the day of shipment;

2) were kept in an NAI free country or zone [compartment] since they were hatched or for the past 28 days.

3) **have not been vaccinated against any AI virus.**

[Note: If the poultry were vaccinated against AI, the nature of the vaccine used and the date of vaccination should be stated in the certificate.]

2.2.

for day-old live poultry

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

1) showed no clinical sign of NAI on the day of shipment;

2) were kept in an NAI free country or zone [compartment] since they were hatched;

3) **come from establishments or hatcheries which are regularly inspected by the *Veterinary Administration*;**

4) **and the parents of the poultry have not been vaccinated against any AI virus.**

[Note: If the day-old poultry or the parents of the poultry were vaccinated against AI, the nature of the vaccine used and the date of vaccination should be stated in the certificate.]

2.3.

for *hatching eggs [or eggs for consumption]*

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

1) [the eggs] come from an NAI free country or zone [compartment.];

2) **have been disinfected in conformity with the procedures referred to in Appendix 3.4.1.**

3) **come from establishments or hatcheries which are regularly inspected by the *Veterinary Administration.***

2.4.

for eggs for consumption

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

come from an NAI free country or zone.

2.5.

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 or zone [compartment].

2.6.

for poultry semen

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

1) showed no clinical sign of NAI on the day of semen collection;

2) were kept in an NAI free country or zone [compartment] for the 28 days prior to semen collection.

2.7.

for *fresh meat, viscera* and processed meat of poultry *(draft Articles 2.1.14.10 & 11 combined)*:

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

1) which have been kept in an NAI free country or zone since they were hatched or for the past 28 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.

2.8.

for *products of animal origin* (from poultry) *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 birds which have been kept in an NAI free country or **zone** [compartment] since they were hatched or for the past 28 days.

2.9.

for feathers and down (from poultry)
the presentation of an *international veterinary certificate* attesting that the entire consignment of feathers or down comes from birds which have been kept in an AI free country or **zone** [compartment] since they were hatched or for the past 28 days.

Part 3

When importing from countries or zones of origin with "NAI category 2", *Veterinary Administrations* should require:

Part 4

When importing from countries or zones of origin with "NAI category 3", *Veterinary Administrations* should require:

Part 5

When importing from countries or zones of origin with "NAI category 4", *Veterinary Administrations* should require:

Part 6

When importing from countries or zones of origin with "NAI category 5", *Veterinary Administrations* should require:

Article 2.1.14.3.

When importing from an AI free country or compartment, *Veterinary Administrations* should require:

for live poultry

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

1) showed no clinical sign of AI on the day of shipment;

2) were kept in an AI free country or compartment since they were hatched or for the past 28 days.

[Note: If the poultry were vaccinated against AI, the nature of the vaccine used and the date of vaccination should be stated in the certificate.]

Article 2.1.14.4.

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of live birds other than poultry:

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

1) showed no clinical sign of AI on the day of shipment;

2) were kept in isolation ~~*a quarantine station*~~ since they were hatched or for the 28 days prior to shipment and showed no clinical sign of AI during the isolation ~~quarantine~~ period;

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from AI.

...

Article 2.1.14.9.

Regardless of the AI status of the country of origin, *Veterinary Administrations* should require for the importation of semen of birds other than poultry.

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

1) were kept in isolation ~~*quarantine*~~ for the 28 days prior to semen collection;

2) showed no clinical sign of AI during the isolation ~~quarantine~~ period;

3) were tested between 7 and 14 days prior to semen collection and shown to be free of AI.

Article 2.1.14.10.

When importing from AI free country or compartment, *Veterinary Administrations* should require:

for *fresh meat* and processed meat of poultry, and poultry viscera

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

1) which have been kept in an AI free country or compartment since they were hatched or for the past 28 days;

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

~~Article 2.1.14.11.~~

~~When importing from AI free country or compartment, *Veterinary Administrations* should require:~~

~~for poultry viscera~~

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

~~1) which have been kept in an AI free country or compartment since they were hatched or for the past 28 days;~~

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

Article 2.1.14.12.

When importing from a country or compartment not considered free from AI, *Veterinary Administrations* should require:

for *fresh meat* of poultry

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

1) which have been kept in an *establishment* free from AI for at least 28 days and regularly inspected by the *Official Veterinarian*;

2) which have been tested to give a 95% probability of detecting a 5% prevalence of AI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, with negative results;

3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with AI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for AI with favourable results.

Article 2.1.14.12 bis

When importing from a country or compartment free from clinical signs of AI but not considered free from AI infection, *Veterinary Administrations* should require:

for *fresh meat* of poultry

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

1) which have been kept in a country or compartment free from clinical signs of AI but not considered free from AI infection since they were hatched or for the past 28 days;

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

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ANNEX 3

Note de synthèse sur les relations entre les virus VISNA et CAEV

Michel PEPIN[a], Tim GREENLAND[b], Françoise DION[c], Pierre RUSSO[a] & Christian VITU[a]

[a]*AFSSA Sophia Antipolis, BP111, 06902 Sophia Antipolis*

[b]*UMR INRA 754, Université Claude-bernard Lyon1, 50 avenue Tony Garnier, 69366 Lyon cedex 07*

[c]*France UPRA Sélection (FUS), INAPG, 16 rue Claude Bernard, 75231 Paris cedex 05*

Les virus VISNA et CAEV appartiennent au genre lentivirus dans la famille des RETROVIRUS (tableau 1) et ont été initialement isolés chez le mouton (visna) ou chez la chèvre (CAEV).

Les infections à lentivirus chez les petits ruminants par les virus visna et CAEV partagent de nombreuses caractéristiques sur le plan de la pathogénie [20,21,24,33] :

- infections à évolution lente
- phase de latence plus ou moins longue
- tropisme tissulaire similaire (poumon, mamelle, articulations, cerveau)
- tropisme cellulaire identique : essentiellement les cellules de la lignée monocyte/macrophage, mais également quelques autres types cellulaires comme les cellules épithéliales
- évolution fatale.

Les deux virus ont également en commun d'être fortement variables [2,5,14,15,17,26]. En revanche, contrairement aux autres lentivirus des mammifères tel que le HIV, le SIV, ..., les virus visna et CAEV n'induisent pas d'immunosuppression vraie [6,20].

L'avénement de l'épidémiologie moléculaire a permis de revisiter les relations exactes entre ces deux virus depuis moins de dix ans.

Il faut rappeler que l'étude des relations entre ces deux virus a d'abord reposé sur les séquences de quelques souches prototypes ; pour le visna :

- K1514= souche islandaise [30]
- SA-OMVV= souche sud-africaine [22]
- et EV1= souche britannique [29].

Pour le CAEV, la souche prototype est la souche CAEV-Co (pour CAEV Cork) en provenance des USA [7,28].

Les nouvelles études d'épidémiologie moléculaire ont débuté vers le milieu des années 90 en utilisant sensiblement une seule et même approche : identification de souches à partir d'animaux infectés dans diverses régions géographiques par la technique de PCR puis séquençage de la partie amplifiée. Les études de phylogénie consistent ensuite à aligner les séquences ainsi obtenues et à les comparer avec celles des souches prototypes ou celles publiées par d'autres auteurs et disponibles dans les banques de données (exemple : GenBank) ; pour ce faire, différentes méthodes ont été utilisées basées sur différents algorithmes. Les régions des virus amplifiées étaient très souvent comprises dans trois gènes importants pour les lentivirus : *gag, pol* et *env* codant respectivement pour les protéines de la capside (capside, nucléocapside, matrice), de la réverse transcriptase et de l'enveloppe (Tableau 2).

Des études faites dans différents pays :

- en France : groupes de R. Mamoun [25,31] et de JF. Mornex [3,12,13,16]
- en Suisse : groupe de E. Peterhans [23,34,36]
- aux USA : groupes de W. Cheevers [9,10] et de O. Narayan [4,11]
- en Italie : groupe de S. Rosati [8,26]
- au Canada : groupe de J. Pasik [18,19]

ont conduit globalement à la même conclusion, à savoir que les virus visna et CAEV sont des quasi-espèces avec des variations entre souches selon l'animal hôte et/ou les capacités pathogènes. En fait, selon les études, les auteurs ont tour-à-tour avancé que le visna dérivait du CAEV [11,13] et inversement que le CAEV avait pour ancêtre le visna [3,31] ; en réalité, ces études ont montré qu'il y avait manifestement des passages inter-espèces des lentivirus des petits ruminants, visna et CAEV entre le mouton et la chèvre. Ces études ont montré également qu'il était possible de regrouper les variants en différentes classes ou clades, avec le plus souvent un mélange de variants de visna et CAEV à l'intérieur d'une même clade [25].

Cette parenté entre les virus visna et CAEV a conduit :

- à utiliser indifféremment des antigènes de CAEV pour le diagnostic par IDG ou ELISA du visna/maedi [1] et inversement des antigènes visna pour le diagnostic sérologique du CAEV [19,27,35] ;
- à recommander dans les programmes de lutte contre le visna chez le mouton ou contre le CAEV chez les chèvres de mener une campagne de lutte commune aux deux espèces. Cette dernière recommandation figure très clairement dans le texte de la conférence consensus de l'action COST 834[1] réunissant les représentants de 18 pays européens (Lyon ; septembre 2002) : « ...BUT THERE WAS CONSENSUS THAT SRLV INFECTION ACROSS THE SPECIES BARRIER MUST BE TAKEN INTO ACCOUNT IN CONTROL PROGRAMMES. SPECIFICALLY, THE SAME REGULATIONS SHOULD APPLY TO BOTH MV AND CAE, AND CONTROL PROGRAMMES THAT ONLY TARGET SHEEP OR GOATS ALONE ARE NO LONGER ACCEPTABLE".

En conclusion, les éléments présentés dans cette note montre à l'évidence qu'il est difficile, sinon impossible, d'ignorer, le CAEV lorsque des autorités sanitaires d'un pays ou d'une région sont amenées à proposer des mesures pour lutter contre le visna/maedi chez les ovins. Pour preuve finale (même si la transmission s'est faite du mouton vers la chèvre), il faut rappeler l'épisode suisse qui a vu, lors d'une foire agricole, des troupeaux de chèvres infectés à la suite d'un contact lors de cette foire avec des moutons infectés par le visna [32] ; cet épisode démontre l'importance de considérer les lentivirus des petits ruminants dans leur ensemble et non séparément.

[1] Action COST 834 : Lentiviruses of small ruminants: pathogenesis, diagnosis and prevention

Tableau 1. La sous-famille des lentivirus et des virus apparentés

VIRUS	NATURAL HOST	MAIN TARGET CELL	CLINICAL MANIFESTATIONS
TRUE LENTIVIRUSES			
Maedi-visna virus (MVV)	Sheep	monocyte/macrophage	pneumonia, encephalitis, mastitis, arthritis
Caprine arthritis-encephalitis virus (CAEV)	Goat	monocyte/macrophage	pneumonia, encephalitis, mastitis, arthritis
Equine infectious anaemia virus (EIAV)	Horse	monocyte/macrophage	fever, anaemia, asymptomatic carriers
AIDS virus (HIV)	Man	lymphocyte CD4+, monocyte/macrophage	immune deficiency, encephalopathy, myelopathy, opportunist infections
Feline immunodeficiency virus (FIV)	Cat	CD4+ and CD8+ T lymphocytes, B lymphocyte, monocyte/macrophage	immune deficiency, opportunist infections
Simian immunodeficiency virus (SIV)	Monkey	lymphocyte, monocyte/macrophage	immune deficiency, opportunistic infections
Bovine immunodeficiency virus (BIV)	Cattle	T lymphocyte, B lymphocyte, 00 Tcell, monocyte/macrophage	silent infection, immune deficiency?
RELATED LENTIVIRUSES			
Jembrana disease virus (JDV)	Cattle	?	acute and severe disease: fever, lymphadenopathy, lymphopenia; pathology: intense lymphoproliferative disorder {87}

Tableau 2. Organisation génomique des lentivirus des petits ruminants

Gene	Product	
	Precursor	Final products
gag (group-specific antigen)	$Pr55^{gag}$	matrix (MA): p17
		capsid (CA): p25
		nucleocapsid (NC): p14
pol (polymerase)	gag-pol polyprotein precursor	reverse transcriptase (RT)
		integrase (IN)
		protease (PR)
		Rnase H
		dUTPase
vif (viral infectivity factor)	...	Vif
tat	...	Tat
Rev (regulator of virion protein expression)	...	Rev
env (envelope)	Env: gp160	surface glycoprotein (SU): gp135
		transmembrane glycoprotein (TM): gp44

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