UNION EUROPÉENNE

SANCO

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Objet: **Réunion du Code zoosanitaire – novembre/décembre 2002**

Monsieur le Directeur général,

Nous vous prions de bien vouloir trouver en annexe les commentaires de l'Union Européenne sur les rapports du bureau de la Commission du Code zoosanitaire international et du Code sanitaire international pour les maladies des poissons, de l'Office International des Epizooties, en vue de la préparation de la Session générale de 2003.

Nous vous saurions gré de bien vouloir prendre en compte ces commentaires lors de la réunion de la Commission du Code zoosanitaire prévue en novembre/décembre 2002.

En ce qui concerne les chapitres relatifs aux manuels de diagnostic, vous trouverez ci-joint des documents étayant notre position; cependant des commentaires complémentaires vous seront transmis ultérieurement .

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

Preben Willeberg
Chief Veterinary Officer

Robert Coleman
Directeur Général

Annexe: 1

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

ANNEX PART 1

Original: English

July 2002

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

Paris, 1-5 July 2002

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The Bureau of the OIE International Animal Health Code Commission met at OIE Headquarters from 1 to 5 July 2002 and held a joint meeting with the Foot and Mouth Disease and Other Epizootics Commission (the FMD Commission) on 2 and 3 July. The President of the Code Commission met with the Fish Diseases Commission on 25 and 26 June.

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 participants. He referred to the extensive work programme for the Code Commission as a result of discussions at the 70th General Session, and particularly noted the two new areas of responsibility for the Code Commission, those of animal welfare and animal production food safety.

Dr Vallat discussed with the Bureau the importance of making progress with the FMD Commission and the Fish Diseases Commission on the issue of notification of diseases. He urged that development of criteria for the listing of diseases be coordinated among the three Commissions and circulated by Member Countries for comment, in preparation for adoption at the 71th General Session.

Code texts presented by the Code Commission at the 70th General Session and comments received on those texts were examined. The Bureau also examined various draft and revised chapters. The outcome of the Bureau's work is presented as appendices to this report with insertions and amendments to existing and previously circulated drafts being shown as double underlined text, with deleted text in small print and in square brackets.

Member Countries are invited to comment on all aspects of the report. Comments need to reach the OIE Headquarters by 1 November 2002 in order to be considered at the Code Commission meeting to be held in November.

A. TEXTS FOR MEMBER COUNTRY COMMENT

1. Section 1.3. Evaluation of Veterinary Services

As a result of a request from Commonwealth of Independent States (CIS), Baltic and Balkan delegates, the Bureau of the Code Commission reviewed Article 1.3.3.1. regarding the authority of Veterinary Services when establishing or applying animal health measures, particularly when such tasks are conducted by another agency on behalf of the Veterinary Services. Clarification changes were made to the text (Appendix III).

Comments received from Australia and the European Union (EU) on the Guidelines for the Evaluation of Veterinary Services were incorporated into a revised text as appropriate (Appendix IV).

Community comments:
The text proposed at Appendix IV can be supported.

2. Traceability

The Bureau of the Code Commission again reviewed the incorporation of traceability into the *Code*. In this respect, the OIE encourages Member Countries to submit proposals and draft texts which could form the basis of guidelines.

Community comments:
The Community fully supports this initiative.

3. Equivalence

The OIE's lack of progress on this issue has been the subject of criticism in recent meetings of the Committee on the Application of Sanitary and Phytosanitary Measures (SPS Committee) of the World Trade Organization (WTO). The OIE has discussed its approach on the issue of equivalence with other international organisations which are also addressing the issue and, within several months, the Code Commission will produce and circulate a modified text for Member Country comment. Based on the comments received, the text will be revised at the November meeting of the Code Commission, and circulated again in preparation for adoption at the 71st General Session.

Community comments:
The Community fully supports this initiative.

4. Animal welfare

The Bureau of the Code Commission examined the recommendations from Resolution No XIV of the 70th General Session and requested the Director

General to form a Working Group on Animal Welfare as one of the priorities for this year's work programme. The Working Group would initially have the same membership as the *Ad hoc* Group on animal welfare and will meet before November. Priority tasks for the Working Group will include the drafting of guiding principles and the development of a detailed operational plan for the initial 12 months of its work. The Working Group will also recommend experts to address specific animal welfare issues through ad hoc groups.

The Director General of the OIE has commenced discussions with non-governmental organisations having an interest and expertise in the subject and with a broad international base, to determine ways to best utilize their expertise in the OIE's work.

Community comments:
The Community fully supports this initiative. Community experts would be pleased to help in this work.

5. Animal production food safety

The Bureau of the Code Commission examined the tasks at hand and the recommendations from Resolution No XV of the 70th General Session, and requested the Director General to convene a Working Group on Animal Production Food Safety as one of the priorities for this year's work programme. This Group is to meet before the November meeting of the Code Commission to establish work priorities for the Code Commission on the development of recommendations on pre-slaughter animal production food safety. The Group will also review existing *Code* chapters dealing with food safety and zoonoses and recommend necessary changes and additional work in accordance with the overall work programme.

Community comments:
The Community fully supports this initiative. Community experts would be pleased to help in this work.

6. Health certificate for milk and milk products

The Bureau met with representatives from the International Dairy Federation (IDF) to further collaborate on the development of an Export Certificate for Milk and Milk Products by IDF which will include public health as well as animal health recommendations.

The OIE International Trade Department agreed to prepare a summary document listing all chapters in the *Code* making reference to milk and milk products. It was agreed that IDF animal health experts would study the document, identify possible gaps in chapters and suggest areas needing revision. IDF will submit their comments and any concrete suggestions for revised texts to OIE in time for consideration at the November 2002 meeting of the Code Commission.

IDF representatives also agreed to provide the Director General with names of experts the OIE could use in future *Ad hoc* Groups.

Community comments:
The Community fully supports this initiative. Community experts would be pleased to help in this work.

7. Chapter 2.1.1. Foot and mouth disease

The Bureau of the Code Commission addressed comments on FMD received from Australia, Argentina, the EU, Denmark, Japan, the United States of America (USA) and Uruguay.

The Bureau recalled that, in adopting Resolution No XIII, the OIE International Committee had requested the Code and the FMD Commissions to address, prior to the next General Session, some significant issues raised by Member Countries. The Commissions agreed that a three stage approach would be used.

Firstly, the Commissions made some straightforward amendments to the Chapter (Appendix V) in line with comments received.

In addition, in order to address other comments, the Commissions decided during their joint meeting that the FMD Commission will hold an electronic conference with the participation of experts and the members of the Code Commission to deal with the comments received including on the surveillance period required to recover free status, on the singleton reactor issue, on the use of sentinel animals, and on the movement of vaccinated animals into free countries or zones after vaccination has ceased. The outcome of the electronic conference will be discussed by both Commissions during their next meeting in November 2002. Resulting proposed amendments to the chapter will be circulated as part of the Code Commission report of that meeting.

Thirdly, regarding long-term revision of the chapter, the FMD Commission will deal with issues such as carrier animals, questions related to vaccination including efficacy and control procedures, and ways of more effectively

addressing the different risks relating to trade in live animals and commodities.

At the request of Japan, the Commissions examined the consistency of recommendations on the safe use of swill feeding in the chapters on classical swine fever (CSF) and FMD. Both Commissions agreed that the FMD Commission should consult the Reference Laboratory for FMD in Pirbright and the Reference Laboratory for CSF in Hannover on the question of virus inactivation procedures in swill, and provide a draft text for consideration during the next meeting of the two Commissions.

Community comments:
The Community fully supports this initiative. Community experts would be pleased to help in this work.

8. Chapter 2.3.13. Bovine spongiform encephalopathy

The Bureau of the Code Commission addressed comments on the chapter received from the EU, Australia, Canada, Japan and the USA. In revising the chapter (Appendix VI), the Bureau made changes only when scientifically based, for example the recommendations on feed bans are confined to a 'ruminant to ruminant' ban. The broader considerations in Article 2.3.13.2. follow from the need to take all 'risk factors' into account.

Significant comment was received on the cohort issue. For a BSE free country or zone, the recommendation on destruction of cohorts confines itself to progeny born within two years as cases of BSE due to the consumption of contaminated feed in the exporting country would be imported cases. Such cases would not affect the status of the importing country (nor present any risk to animals in that country provided all necessary measures were in place) whereas cases in progeny would be classified as indigenous cases. The Bureau noted that the time of highest risk regarding the consumption of contaminated feed was the first year of life and made no changes to that wording in various articles. Regarding equivalent measures, the Bureau noted the report of the 69th General Session but considered that, as equivalence could be applied to any *Code* recommendations, specific changes to the BSE chapter were not required.

Significant comment was received on the issue of cut-off points for the country/zone risk categories. The Bureau made no changes to the text but will request the Director General to form an *Ad hoc* Group to examine the issues raised. The *Ad hoc* Group will also review the list of 'risk tissues' (including intestines, skulls and liver) and the age groups specified for each.

The Bureau decided that Appendix 3.6.3. would be retained in the *Code* as an assistance to Member Countries wishing to inactivate 'risk tissues' prior to disposal. It will not be referred to in the BSE chapter due to the modifications made to Article 2.3.13.18.

In response to a comment from the USA on the risks presented by various tissues, the Bureau noted that *Code* chapters attempt to address different risks (based on available information and expert opinion) by recommending separate and differing trade restrictions according to the health status of the exporting country and the likelihood of contamination of the commodity by the pathogenic agent.

Comments from the USA on the Guidelines for assessing the BSE risk will be submitted to an expert for review.

Community comments:
The Community can accept the proposed changes provided the comments in Appendix VI are taken into account.

9. Chapter 2.2.6. Paratuberculosis

The proposed draft chapter on paratuberculosis will be discussed with an expert with a view to bringing it into line with the standard *Code* format, in preparation for review at the November meeting of the Code Commission.

Community comments:
The Community supports this initiative and comments will be given when the text is available. Community experts would be pleased to help in this work.

10. Chapter 2.3.7. Bovine anaplasmosis

In order to retain consistency with the approach in the *Code* to the disease status of the importing country, the Bureau of the Code Commission decided

to delete the articles in the chapter on anaplasmosis relating to the importation of animals into infected countries. The revised chapter is in Appendix VII.

Community comments:
The Community does not agree with this approach. The Community considers that the health situation of the importing country should be taken into account and it would be extremely unwise to allow totally naïve animals into such endemic areas. The OIE approach is not consistent with WTO/SPS nor with the suggested new approach for notification of animal diseases to the OIE where more emphasis may be placed on the change in health status of a country with respect to the speed of notification.

11. Chapter 2.3.8. Bovine babesiosis

In order to retain consistency with the approach in the *Code* to the disease status of the importing country, the Bureau of the Code Commission decided to delete the articles in the chapter on babesiosis relating to the importation of animals into infected countries. The revised chapter is in Appendix VIII.

Community comments:
The Community does not agree with this approach. The Community considers that the health situation of the importing country should be taken into account and it would be extremely unwise to allow totally naïve animals into such endemic areas. The OIE approach is not consistent with WTO/SPS nor with the suggested new approach for notification of animal diseases to the OIE where more emphasis may be placed on the change in health status of a country with respect to the speed of notification.

12. Chapter 2.3.11. Theileriosis

The Bureau of the Code Commission decided to modify the chapeau of the chapter on theileriosis in order to retain consistency with the relevant chapter in the *Manual* (Appendix IX).

Community comments:
The Community can accept the proposed changes provided the comments in Appendix IX are taken into account and if it is not the intention to delete the reference to the health situation of the importing country. From the text it is not clear whether this is to be deleted or not. The Community believes that this should be taken into account and it would be extremely unwise to allow totally naïve animals into such endemic areas. The OIE approach is not consistent with WTO/SPS nor with the suggested new approach for notification of animal diseases to the OIE where more emphasis may be placed on the change in health status of a country with respect to the speed of notification..

13. Chapter 2.1.13. Classical swine fever

Based on comments received from the EU, New Zealand, Japan and Australia, the Bureau of the Code Commission made changes to the chapter on classical swine fever (CSF) (Appendix X).

Community comments:
The Community can agree the proposal in Appendix X.

The applicability of compartmentalisation to this disease was questioned and the Bureau decided to ask an expert to clarify and expand on the requirements in Article 2.1.13.5. regarding 'biosecurity measures' and 'clinical and laboratory monitoring'. The recommendations in Articles 2.1.13.10., 2.1.13.14., 2.1.13.17. and 2.1.13.20. are also relevant to this issue. The expert would also be asked to comment on the current time period for recovery of free status.

Regarding Article 2.1.13.4., the Bureau considered that, if residual virus was present after stamping out, then clinical signs would be seen within the six-month period; the Bureau also considered that serological surveillance would be more effective in pigs 6-12 months of age, as seroconversion in pigs of this age would more accurately reflect the presence of virus (see also Article 2.1.13.7.). Point h) of Article 2.1.13.4. was modified to give additional confidence regarding the absence of infection in wild pigs.

Regarding Article 2.1.13.6., the Bureau considered that there was no scientific reason to recommend the slaughter of vaccinated pigs as it considered that the recommendations regarding surveillance provided adequate protection.

The Bureau revised Appendix 3.6.4. incorporating suggestions received from the USA and an expert from the EU (Appendix XI) and comments from Member Countries are invited.

Community comments:
The Community can accept the proposed changes provided the comments in Appendix XI are taken into account.

14. Porcine reproductive and respiratory syndrome

Following a request from Canada, the Bureau of the Code Commission will request the Director General to ask a Canadian expert to write a supporting document and develop a draft chapter on porcine reproductive and respiratory syndrome (PRRS).

Community comments:
Comments will be given when the text is available.

15. Chapter 2.5.1. Contagious equine metritis

The USA suggested that additional testing for contagious equine metritis was required in the case of stallions. The Bureau of the Code Commission will request the USA to provide information supporting such a request.

Community comments:
The Community does not agree with this initiative. The Community considers there is no need for a modification of Chapter 2.5.1. of the Animal Health Code.

However, the Community can agree to a review of Chapter 2.5.1. of the Manual of Standards for Diagnostic Tests and Vaccines, 4th Edition, 2000, in particular with regard to the incubation period required for the identification of the agent..

16. Chapter 2.4.8. Scrapie

Based on comments received from the EU, Australia and New Zealand, the Bureau of the Code Commission made changes to Article 2.4.8.1. The revised chapter (Appendix XII) is presented for Member Country comment.

The Bureau of the Code Commission decided that comments received from New Zealand regarding the recognition of historical freedom from scrapie could not be considered until work on the issue had been advanced by the Working Group on Epidemiology. The Working Group will be asked to continue its work on historical freedom.

In the absence of any proposals from Member Countries on guidelines of surveillance and monitoring for scrapie, the Bureau of the Code Commission decided to request the Director General to ask an expert to develop a draft.

Community comments:
The Community can accept the proposed change to the chapter. Some additional comments are mentioned in Appendix XII.

17. Chapter 2.4.8. Ovine pulmonary adenomatosis

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

Community comments:
The Community supports this initiative and comments will be given when the text is available. Community experts would be pleased to help in this work.

18. Chapters 2.1.14. and 2.1.15. Newcastle disease and highly pathogenic avian influenza

The Bureau of the Code Commission requested the Director General to form an *Ad hoc* Group to examine the current chapters on Newcastle disease and highly pathogenic avian influenza, and to recommend appropriate changes. The *Ad hoc* Group will also be asked to review the risks presented by low pathogenic strains of avian influenza.

Members of the *Ad hoc* Group will be asked to consider, during their discussions, how the concept of compartmentalisation may be incorporated into the two chapters.

Community comments:
The Community supports this initiative and comments will be given when the text is available. Community experts would be pleased to help in this work.

19. Diseases of bees

Due to a lack of response from Member Countries to date, the Bureau of the Code Commission is again circulating draft chapters on six bee diseases and an appendix for comment (Appendices XIII to XIX). The Code Commission intends to submit drafts for adoption at the 71st General Session.

Community comments:
The Community can only accept the proposed change to the chapter provided the comments in Appendixes XIII to XIX are taken into account.

20. Semen related matters

The Bureau of the Code Commission received comments on various issues relating to the collection of semen, including on enzootic bovine leucosis. It also reviewed comments received on the *Code* Appendix on porcine semen prior to the 70th General Session. It decided that it would discuss the issues raised with several experts. The views of the experts would be reviewed at the November meeting of the Code Commission.

Community comments:
The Community supports this initiative and comments will be given when the text is available. Community experts would be pleased to help in this work.

21. Chapter 2.1.8. Rift Valley fever

An OIE *Ad hoc* Group drafted a chapter on Rift Valley fever in February 2002. The draft chapter was circulated as part of the report of the FMD Commission. This draft (Appendix XX) is again circulated for Member Country comment.

Community comments:
The Community can accept the proposed change to the chapter provided the comments in Appendixes XIII to XIX are taken into account.

22. Animal disease notification

The President of the Code Commission met with the Fish Diseases Commission to co-ordinate work on revising current recommendations on notification of terrestrial and aquatic animal diseases. The Bureau of the Code Commission and the FMD Commission met and agreed on the following amendments to the current system for terrestrial animal diseases:

- A single OIE list of diseases for terrestrial animals will be created; initially, it will comprise all existing List A and list B diseases.

- The urgency with which Member Countries are to notify the occurrence of diseases to the OIE will be dependant on epidemiological events; changes based on the above discussions were incorporated in a revision of Article 1.1.3.3. in the Chapter on Notification, and Article 1.2.1.3. in the Chapter on General Obligations (Appendix XXI).

In order to allow time for Member Countries to adapt their operating procedures and for the OIE to make the necessary changes to its disease reporting systems, the Code Commission proposes that changes to Article 1.1.3.3, if adopted at the 71st General Session, would not become operational until 1 January 2005. If these amendments are adopted, the Code Commission would make the necessary text changes throughout the *Code*, reflecting the existence of a single OIE list of terrestrial animal diseases, to meet that deadline.

As to decisions regarding changes to the above OIE list, the Commissions propose that a system could be established whereby the International Committee use the following methodology to determine whether a disease should be deleted from or be added to the above OIE list: either the disease or pathogenic agent has a significant impact on production (morbidity and mortality) or the environment, within a country or group of countries, or it has zoonotic potential; as well, it has a potential for international spread, and freedom or impending freedom from the disease or pathogenic agent is recognised for several countries; or it is an emerging disease with insufficient information available to address the above criteria.

Community comments:
The Community supports this initiative and agrees with the comments given above. It is important that the speed of notification of diseases is linked, inter alia, to the health situation of the reporting country. Any listed disease must be reported urgently if a new outbreak occurs in a previously "free" country or zone. This will ensure that importing countries with a "free" status can take appropriate measures and that any measures taken will reflect the health situation in the importing country in accordance with WTO/SPS principles. Community experts would be pleased to help in this work.

Appendix I

MEETING OF THE BUREAU OF THE

OIE INTERNATIONAL ANIMAL HEALTH CODE COMMISSION

Paris, 1-5 July 2002

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List of Participants

MEMBERS OF THE BUREAU OF THE CODE COMMISSION

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

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

Appendix II

MEETING OF THE BUREAU OF THE

OIE INTERNATIONAL ANIMAL HEALTH CODE COMMISSION

Paris, 1-5 July 2002

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Agenda

1. **Evaluation of Veterinary Services**
2. **Traceability**
3. **Equivalence**
4. **Animal welfare**
5. **Animal production food safety**
6. **Health certificate for milk and milk products**
7. **Foot and mouth disease**
8. **Bovine spongiform encephalopathy**
9. **Paratuberculosis**
10. **Bovine anaplasmosis**
11. **Bovine babesiosis**
12. **Theileriosis**

13. **Classical swine fever**

14. **Porcine reproductive and respiratory syndrome**

15. **Contagious equine metritis**

16. **Scrapie**

17. **Ovine pulmonary adenomatosis**

18. **Newcastle disease and highly pathogenic avian influenza**

19. **Diseases of bees**

20. **Semen related matters**

21. **Rift Valley fever**

22. **Animal disease notification**

Appendix III

CHAPTER 1.3.3.

EVALUATION OF VETERINARY SERVICES

Community comments:

The Community supports this proposal.

Article 1.3.3.1.

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

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

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

These fundamental principles are presented in Article 1.3.3.2. The remaining factors of quality are described in Part 1 (notification, principles of certification, etc.) and in Chapter 1.3.4. of this *Code*.

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

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. 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 *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:

- programming and management of activities, including international veterinary certification activities;

- prevention and control of disease *outbreaks*;
- epidemiological surveillance and zoning;
- inspection and sampling techniques;
- diagnostic tests for animal diseases;
- preparation, production and control of biological products for use in the diagnosis or prevention of diseases;
- *disinfection* and *disinsectisation*;

Community comment
Community proposes to replace "*disinsectisation*" by *"disinfestation"*

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

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.

Article 1.3.3.3.

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

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE Guidelines for the evaluation of *Veterinary Services*.

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

Article 1.3.3.4.

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

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

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

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

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.4.

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Appendix IV

CHAPTER 1.3.4.

GUIDELINES FOR THE EVALUATION OF VETERINARY SERVICES

Community comments:
The text proposed can be supported provided the comments given below are taken into account. However the Community is concerned about the use and the frequency of completing and updating such evaluations.

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 this *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. This document is intended to cover all of these purposes.

   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 formally-based 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.

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, [and] 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.

Community comments:
In addition the following should be included:
- animal health and public health rules and controls including import controls
– the organisation and implementation of measures to prevent and control infectious or contagious diseases including contingency plans.

2. Article 1.3.4.13. outlines appropriate information requirements for:

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

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

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

Article 1.3.4.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

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

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

Community comments:
In addition ", and training" should be included after the word 'certification' ('and' before inspection should therefore be omitted)

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

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

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

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

Article 1.3.4.4.

Evaluation criteria for quality systems

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

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

Community comments:
The Community believes resource and infrastructure components are very important aspects. It believes that it is not always appropriate to place greater emphasis on the outcome of evaluation of these quality systems than on the resource and infrastructure components of the services. The Community proposes that this paragraph should be deleted.

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. It should also include other qualified professional officers, administrative officials and technical support staff. This does not exclude the possibility of employing, in addition, part-time veterinary and para-veterinary staff and private sector veterinarians. 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.

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 veterinary and animal health technical assistants 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 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 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 document. For example, a large field staff (veterinarians and 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 1.3.4.6.

Evaluation criteria for material resources

1. Financial

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

2. Administrative

a) Accommodation

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

b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

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

c) Transport Systems

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

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and

for the performance of animal and animal product inspection in outlying production or processing establishments.

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

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

Community comments:
The Community believes that it is not necessary to restrict to labs accredited by the veterinary services and that the words "by the *Veterinary Services* " **should be deleted.**

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. These laboratories must be approved and designated by the *Veterinary Services* for such purposes, and regular audits carried out.

c) Research

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

Community comment:

The Community believes that this is not a good criterion and it could be detrimental to developing countries.

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, 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. 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.

Community comment:

The Community believes that information on the legislation concerning the registration of holdings, animal identification and traceabilty is of fundamental importance and reference to this should be included. Similarly, animal welfare rules and their implementation, should also be available for assessment

It would also seem appropriate to include the products of animals as well as live animals that need to be destroyed as a potential control measure. This is not properly covered by the words "or contaminated material". Therefore the Community proposes the following new wording:

"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* and their products or other contaminated materials, controls over the use of veterinary medicines, etc. The scope of the animal health and welfare 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".

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 *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.

Article 1.3.4.8.

Animal health controls

1. Animal health status

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

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

2. Animal health control

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

Community comments:

Control programmes can also be applied on a herd level depending on the infectious agent involved and the way the disease spreads, therefore it might for some diseases be interesting to include information on how free herds are separated from infected herds and not only how free zones or countries are separated from infected zones countries.

The Community proposes the following new wording:

"…, physical and other barriers between the free country/zone and those infected, programmes applicable on herd level including a description of the barriers between free herds and infected herds,…"

3. National animal disease reporting systems

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

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

Community comments:
The Community believes that a disease reporting system should cover all parts of a country.

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.

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, [they should provide appropriate help to obtain the relevant information for assessment.] 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 registration, supply and use of veterinary medicines, biologicals and diagnostic reagents. 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.

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

Article 1.3.4.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

Community comments:
The Community believes that there are other important factors which should also be taken into account in such a list e.g. lack of resources and poor infrastructure. The Community proposes the following sentence to replace the above:
"Matters which can adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification and lack of resources and poor infrastructure".

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

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

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

4. Veterinary Services administration

a) Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such

reports should be available to counterpart Services in other countries, especially trade partners.

b) Reports of government review bodies

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

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

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

d) In-service training and development programme for staff

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

e) Publications

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

Community comments:
The Community believes that this individual criterion is not relevant to the question of evaluating the institutional efficiency of veterinary services.

f) Formal linkages with sources of independent scientific expertise

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

Community comments:
The Community believes that this formal criterion is not relevant to the question of evaluating the institutional efficiency of veterinary services.

g) Trade performance history

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

Article 1.3.4.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a Member Country to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary/zoosanitary status for evaluation purposes.

Article 1.3.4.12.

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

2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a risk analysis process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from disease or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.

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

Article 1.3.4.13.

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

1. <u>Organisation and structure of Veterinary Services</u>

   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. <u>National information on human resources</u>

   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]*.

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 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 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-veterinarian)

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 employed by the Veterinary Services

i) Animal health:

- 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 details.

ii) Veterinary public health:

- Numbers 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 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

3. <u>Financial management information</u>

a) Total budgetary allocations to the *Veterinary Services* for the current and past two fiscal years:

i) for the national *Veterinary Services*;

ii) for each of any sub-national veterinary authorities;

iii) for other relevant government-funded institutions.

b) Sources of the budgetary allocations and amount:

i) government budget;

ii) sub-national authorities;

iii) taxes and fines;

i) grants;

v) private services.

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

Community comments:
The Community proposes that the following indent "d) provisional compensation allocations for animal owners affected by disease control measures" is added. This is important to ensure prompt payment to farmers whose animals are affected by disease and which have to be killed and provides an incentive to report suspicionof disease.

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

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

4. Administration details

a) Accommodation

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

b) Communications

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

c) Transport

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

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

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

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

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

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

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

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

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

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

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

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

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

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

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

b) Research laboratories (laboratories engaged primarily in research)

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

- government operated laboratories;

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

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

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research laboratories.

6. Functional capabilities and legislative support

a) Animal health and veterinary public health

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

- animal and veterinary public health controls at national frontiers;

- control of endemic animal diseases, including zoonoses;

Community comments:
Although the OIE has tried to take on board the comments suggested by the Community, the wording is still not acceptable as a zoonosis may not be endemic. Therefore the Community proposes that the word "endemic" is deleted.

- emergency powers for control of exotic disease outbreaks;

- inspection and registration of facilities;

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

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

- registration and use of veterinary pharmaceutical products including vaccines.

Community comments:
The Community proposes that the following indent "compensation provisions for animal owners affected by disease control measures" should be re-instated as requested last time as this is important to ensure farmers fully report all suspicious signs of disease. . However it proposes that this could perhaps be better added in 3 c as indicted therein.

However the following indent must be added above "animal identification including movement controls and traceability"

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

b) Export/import inspection

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

- veterinary public health controls of the production, processing, storage and transportation of meat for export;
- veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
- animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
- animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
- animal health controls of importation of veterinary biological products including vaccines;
- administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
- documentation and compliance.

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

7. <u>Animal health and veterinary public health controls</u>

a) Animal health

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

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

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

- epidemiological surveillance or monitoring programmes;
- officially approved industry-administered control or eradication programmes for specific diseases.

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

v) Recent history of animal disease status:

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

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

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

- emerging diseases in the last ten years;

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

b) Veterinary public health

i) Food hygiene

- Annual national slaughter statistics for the past three years according to official data per animal species (bovine, ovine, porcine, caprine, poultry, equine, other).

Community comments:
The Community believes that farmed and wild game should be included separately in the above as follows:
"Annual national slaughter statistics for the past three years according to official data per animal species (bovine, ovine, porcine, caprine, poultry, farmed game, wild game, equine and other)".

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

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

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

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

  . slaughterhouses (indicate species of *animals*);

  . cutting/packing plants (indicate meat type);

  . meat processing establishments (indicate meat type);

  . cold stores.

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

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

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

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

ii) Zoonoses

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

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

iii) Chemical residue testing programmes

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

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

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

iv) Veterinary medicines

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

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

8. Quality Systems

a) Accreditation

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

b) Quality manuals

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

c) Audit

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

9. Performance Assessment and audit programmes

a) Strategic plans and review

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

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

b) Compliance

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

c) Annual reports of the national Veterinary Services

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

d) Other reports

i) Copies of reports of official reviews into the function or role of the Veterinary Services which have been conducted within the past 3 years.

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

Community comments:
The Community still believes that this is not relevant to the question of evaluating veterinary services.

g) Sources of independent scientific expertise

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

Community comments:
The Community still believes that this is not relevant to the question of evaluating veterinary services.

10. Membership of the OIE

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

11. Other assessment criteria

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[ ] deleted

Appendix V

CHAPTER 2.1.1.

FOOT AND MOUTH DISEASE

Community comments:
The Community supports this proposal provided the comments below are taken into account.

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 the presence of FMD virus (FMDV) infection.

For the purpose 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.

Community comments:

Paragraph (3) to be replaced with:

"3) Seroconversion, or rising titres detected in paired samples, for antibodies to structural or non-structural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals with 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*.

Community comments:
The Community proposes the following wording to replace the above to ensure that any vaccine

used actually complies with OIE Standards as laid down in the *Manual*:
"For the purpose of this chapter, standards for diagnostic tests are described in the *Manual*. Where vaccination is practised, the vaccine used complies at least with the standards as laid down in the OIE *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 [an effective system of] surveillance for both FMD and FMDV infection in accordance with Appendix XXX is in operation and that regulatory measures for the prevention and control of FMD have been implemented;

Community comments:

Last paragraph to be replaced with:

"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;"

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.

Community comments (also mentioned in Paris May 2002)

Last paragraph to be replaced with:

"The country will be included in the existing list of FMD free countries immediately after the submitted evidence has been accepted by the OIE. Acceptance should be based on an assessment and evaluation carried out without undue delay following the receipt of the submitted evidence, thus allowing the freedom to come into effect immediately."

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:

Community comments:
The Community proposes that the word "existing" is inserted before the word 'list' to avoid the need for those countries already on the list to re-apply for inclusion.

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) [an effective system of] surveillance for FMD in accordance with Appendix XXX is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

Community comments:

Paragraph (a) to be replaced with:

"a) Surveillance for FMD in accordance with Appendix XXX (under study) 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*.

Community comments:
The Community proposes that this paragraph is moved to the first Article as it is a general point and therefore the above paragraph is deleted.

The country will be included in the list only after the submitted evidence has been accepted by the OIE.

Community comments (also mentioned in Paris May 2002)

Last paragraph to be replaced with:

"The country will be included in the existing list of FMD free countries where vaccination is practised immediately after the submitted evidence has been accepted by the OIE. Acceptance should be based on an assessment and evaluation carried out without undue delay following the receipt of the submitted evidence, thus allowing the free country where vaccination is not practised to come into effect immediately."

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.;

Community comments:

Paragraph (d) to be replaced with:

"d) without prejudice to Article 2.1.1.7. (1) (c), 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 [an effective system of] surveillance for both FMD and FMDV infection in accordance with Appendix XXX is in operation in the FMD free zone where vaccination is not practised;

Community comments:

Paragraph (3) to be replaced with:

"3) supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix XXX (under study) 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*,

Community comments:

Paragraph (b) to be replaced with:

"b) the boundaries and where relevant the physical or geographical barriers 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.

Community comments:

Last paragraph to be replaced with:

"The free zone will be included in the existing list of FMD free zones where vaccination is practised immediately after the submitted evidence has been accepted by the OIE. Acceptance should be based on an assessment and evaluation carried out without undue delay following the receipt of the submitted evidence, thus allowing the free zone where vaccination is not practised to come into effect immediately."

Article 2.1.1.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in a 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;

3) supply documented evidence that the vaccine used complies with the standards described in the *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,

Community comments:

Paragraph (b) to be replaced with:

"b) the boundaries and where relevant the physical or geographical barriers 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.

Community comments:

The last paragraph to be replaced with:

"The free zone will be included in the existing list of FMD free zones where vaccination is practised immediately after the submitted evidence has been accepted by the OIE. Acceptance should be based on an assessment and evaluation carried out without undue delay following the receipt of the submitted evidence, thus allowing the free zone where vaccination is not practised to come into effect immediately."

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, the country should wait for 12 months after vaccination has ceased and provide evidence showing that FMDV infection has not occurred in the said zone during that period. **REPLACE WITH EU COMMENT**

Community comments:
The last paragraph to be replaced with:

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

After the recognition of the changeover in status in accordance with resolution XVII of the OIE International Committee, vaccinated animals can leave the previous vaccination zone and can be moved into the zone free of FMD without vaccination established in accordance with Article 2.1.1.4."

The words "REPLACE WITH EU COMMENT" should be deleted.

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, or

Community comments:

Paragraph (a) to be replaced with:

"a) 3 months after the last *case* where a *stamping-out policy* and serological surveillance in accordance with Annex XXX (under study) are applied, or"

   b) 3 months after the slaughter of the last vaccinated animal where a *stamping-out policy*, emergency vaccination and serological surveillance are applied, or

Community comments:

Paragraph (b) to be replaced with:

"b) 3 months after the slaughter of the last vaccinated animal where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Annex XXX (under study) are applied, 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, 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.

Community comments:

Paragraph (c) to be replaced with:

"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 in accordance with Annex XXX (under study) are applied, 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.

After the re-establishment of the FMD and FMDV infection free status in accordance with this paragraph, vaccinated animals may be moved within the country or zone free of FMD where vaccination is not practised."

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*, serological surveillance and emergency vaccination are applied, provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection, or

Community comments:

Paragraph (a) to be replaced with:

"a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Annex XXX (under study) are applied, provided that a serological survey 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 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 occurrence of the first FMD *outbreak* or the first detection of FMDV infection, 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 animal of a susceptible species 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;

6) all products obtained from the animals must be considered infected and treated in such a way as to destroy any residual virus; 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 taken to a *quarantine station* under the supervision of the *Veterinary Authority*. Freedom of infection of these animals must be established by appropriate tests.] 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.

Community comments:

The last paragraph to be replaced with:

" 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 2.1.1.12."

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*;

Community comments:

Paragraphs (6) and (7) to be replaced with:

6) *products of animal origin intended for human consumption*, *for use in animal feeding* or *for agricultural or industrial use*; derived from animals of susceptible species,

7) *products of animal origin intended for pharmaceutical or surgical use*; derived from animals of susceptible species,

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*.

Article 2.1.1.10.

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.

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.

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 infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 2.1.1.13.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

<u>for fresh semen of domestic ruminants and pigs</u>

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. or Appendix 3.2.3.

Article 2.1.1.14.

When importing from FMD free countries or zones where vaccination is not practised, *Veterinary Administrations* should require:

<u>for frozen semen of domestic ruminants and pigs</u>

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.

Article 2.1.1.15.

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, with negative results, to tests for antibodies against FMD virus; or

Community comments:

Paragraph (1) (c) (i) to be replaced with:

"i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus carried out on samples taken not earlier than 21 days after the collection of the semen; 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.

Community comments:

The following paragraph to be added:

"c) In the case of semen collected form donor animals 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 results.

Article 2.1.1.16.

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, with negative results, to tests for antibodies against FMD virus; or

Community comments:

Paragraph (1) (c) to be replaced with:

"c) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus carried out on samples taken not earlier than 21 days after the collection of the semen; 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 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.

Article 2.1.1.17.

When importing from FMD free countries or zones (where vaccination either is or is not practised), *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* 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., as relevant.

Community comments:

Paragraph (2) to be replaced with:

"2) insemination was carried out 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. or Appendix 3.3.9., 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.

Community comments:

Paragraph (2) to be replaced with:

"2) insemination was carried out 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 for at least 30 days in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.9., as relevant."

Article 2.1.1.19.

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. or Appendix 3.3.9., as relevant.

Article 2.1.1.20.

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;

   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. or Appendix 3.3.9., as relevant.

Community comments:

Paragraph (4) to be replaced with:

"4) the embryos were collected, processed and stored for at least 30 days in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.9., as relevant."

Article 2.1.1.21.

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:

1) which have been kept in the FMD free country or zone where vaccination is not practised since birth, or that have been imported from an FMD free country or zone where vaccination is not practised;

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.

Article 2.1.1.22.

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:

1) comes from animals which:

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

   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;

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.

Article 2.1.1.23.

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:

1) which have been kept in the country or zone since birth, or have been imported from a country or zone free from FMD (where vaccination either is or is not practised);

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.

Article 2.1.1.24.

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;

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

[Note: Article 2.1.1.24. should also apply when meat is to be imported from an infected country into another infected country, in order to prevent the introduction of new strains of FMD virus.]

Article 2.1.1.25.

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

for *meat products* of domestic ruminants and pigs

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

1) the entire consignment of *meat* comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;

2) the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.1.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 2.1.1.26.

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).

Article 2.1.1.27.

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

for milk and cream

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.

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.

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.

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.

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.

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.

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.]*

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Appendix VI

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Community comments :

The proposed changes can in general be supported provided our comments are taken into account. As a general comment the EU considers that the code should be based on a mammalian to ruminant rather than ruminant to ruminant feed ban. Experience within the Community shows that this is the very minimum requirement for a feed ban that can be effectively controlled. The Community would also request that its views on specified risk materials be taken into account by the proposed ad hoc group.

The EU Commission has started the examination of dossiers in relation to the classification of countries according to their BSE status. Based on some case studies it appears that some of the criteria have a decisive impact resulting in a BSE status not sufficiently linked to the initial risk identified. This may result in trade conditions, which are either inadequate from a consumer protection point of view or unnecessarily strict.

By making certain modifications to the criteria, the classification could be better aligned to the actual BSE risk in a country. To this end, the Community proposes the following amendments:

1. **The required seven years compliance with the surveillance criteria laid down in Appendix 3.8.4. prevent most countries from being classified as a BSE free country. This seems unnecessarily stringent as on the one hand the risk assessment already demonstrates that the presence of BSE is unlikely and on the other hand the surveillance standard would probably not lead to the detection of BSE should it occur at a low level. The Community proposes putting the emphasis on the risk assessment and deleting the requirement for the seven years surveillance in BSE free countries or regions. This proposal would allow most countries with a negligible BSE risk to be classified as a BSE free country.**

2. **Countries with a certain BSE risk or where BSE has already been detected should introduce active monitoring. At the same time, the cut-off limits in categories 3, 4 and 5 should be doubled.**

3. **The risk assessment can be replaced by a conclusive statistical survey of the epidemiological situation regarding BSE. As BSE may occur at very low levels in particular in the initial phase, and as this possibility would predominantly be used by countries with a certain risk of BSE, it is important that the design of the survey and sample size are sufficient to allow the detection of BSE at very low levels. The active monitoring programme in the EU has already provided a large amount of information, which should be used as a basis for determining the rules for such statistical surveys. The cut-off limits for determining the sample size should be sufficiently low in order not to compromise consumer safety (eg. 1 per 100 million in BSE free countries and 1 per 10 million in provisionally free countries)**

Article 2.3.13.1.

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

Article 2.3.13.2.

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

1) the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:

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

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

    c) importation of animals or embryos/oocytes potentially infected with a TSE;

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

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

    f) the origin 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;

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

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

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

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

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

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, 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, the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years and the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years.

Community comments:
In view of the comments in the introduction of the Chapter 2.3.13. , the Community suggests replacing:

Article 2.3.13.3 point 1 with:

"1): A risk assessment as described in point 1) of Article 2.3.13.2., has been conducted which demonstrates that the presence of BSE is highly unlikely"

Article 2.3.13.3 point 2), a), i) with:

" 2), a), i): the criteria in point 2), 3) and 5) of Article 2.3.13.2. have been complied with for at least seven years and the criteria in point 4) are being complied with"

Article 2.3.13.3 point 2), b), i) with:

" 2), b), i): the criteria in point 2), 3) and 5) of Article 2.3.13.2. have been complied with for at least seven years and the criteria in point 4) are being complied with"

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to add the following part as an alternative option for points 1) and 2) to be recognised as BSE free country:

"Or

II. A country or region where a conclusive statistical survey of the epidemiological situation regarding BSE has been carried out which demonstrates that the presence of BSE is highly unlikely,

And

1. Either no BSE cases have been reported, and,

(i) the criteria in point 2), 3) and 5) of Article 2.3.13.2. have been complied with for at least seven years and the criteria in point 4) are being complied with and

(ii) an active monitoring programme is in place.

2. Or 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, 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,

(i) the criteria in point 2), 3) and 5) of Article 2.3.13.2. have been complied with for at least seven years and the criteria in point 4) are being complied with and

(ii) an active monitoring programme is in place.

3. Or where the last indigenous case of BSE was reported more than seven years ago,

And,

(i) the criteria in point 2) to 5) of Article 2.3.13.2. have been complied with for at least seven 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 eight years, and

(iii) an active monitoring programme is in place."

Article 2.3.13.4.

BSE provisionally free country or zone

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

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

2) either:

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

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

      ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or greaves have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;

   OR

   b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

if alive in the country or zone, have been slaughtered and completely destroyed; and either:

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

ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or greaves have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years.

Community comments:
In view of the comments in the introduction of the Chapter 2.3.13. , the Community suggests replacing Article 2.3.13.4 point 1) with :

"1) A risk assessment as described in point 1) of Article 2.3.13.2., has been conducted, or a conclusive statistical survey of the epidemiological situation regarding BSE has been carried out, which demonstrates that the presence of BSE is unlikely, but not excluded,";

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to add the following points:

" 2) a) iii): "And an active monitoring is in place"

" 2) b) iii): " And an active monitoring is in place"

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to add the following point:

" Or

c) the last indigenous case of BSE was reported more than seven years ago, the criteria in point 2) to 5) of Article 2.3.13.2. have been complied with for at least seven years, 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 eight years, and an active monitoring programme is in place"

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to add the following paragraph as an alternative to points 1 and 2:

"A risk assessment as described in point 1) of Article 2.3.13.2. has been conducted, or a conclusive statistical survey of the epidemiological situation regarding BSE has been carried out, which demonstrates that the presence of BSE is highly unlikely, but where the conditions to be considered as BSE free are not complied with."

Article 2.3.13.5.

Country or zone with a minimal BSE risk

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

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

2) EITHER:

a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with *meat-and-bone meal* and greaves derived from ruminants is effectively enforced, but:

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

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

OR

b) the last indigenous *case* of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*, and:

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

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

iii) the affected cattle as well as:

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

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

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

In view of the comments in the introduction of the Chapter 2.3.13. , the Community suggests replacing:

Article 2.3.13.5 point 1 with :

"1) A risk assessment as described in point 1) of Article 2.3.13.2. , has been conducted which demonstrates that the presence of BSE is likely but not confirmed or confirmed at a lower level, or a conclusive statistical survey of the epidemiological situation regarding BSE has been carried out which demonstrates that the presence of BSE is below 2 cases per million in the cattle population over 24 months of age, ";

Article 2.3.13.5 point 2), a) with :

" 2), a) No BSE cases have been reported or the last indigenous case was reported more than seven years ago, the criteria in points 2), 3) and 5) of Article 2.3.13.2 are complied with and an active monitoring has been in place for at least 12 months, and the ban on feeding ruminants with meal-and-bone meal and greaves derived from ruminants is effectively enforced."

Article 2.3.13.5 point 2), b) with :

" 2), b) the last indigenous case of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous cases, has been less than two cases per million during each of the last four consecutive 12-months period within the cattle population over 24 months of age in the country or zone (Note: for countries with a population of less than 500,000 adult cattle, the maximum allowed incidence should be expressed in cattle-years), and :"

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to add the following point :

" 2), b) iv) an active monitoring programme, covering at least all bovine animals above 24 months of age which die on the farm or are slaughtered as emergencies, has been in place for at least 12 months"

Article 2.3.13.6.

Country or zone with a moderate BSE risk

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

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

2) the BSE incidence rate, calculated over the past 12 months, has been:

   a) greater than, or equal to, one indigenous *case* per million and less than, or equal to, one hundred cases per million within the cattle population over 24 months of age in the country or zone; or

   b) less than one indigenous *case* per million for less than four consecutive 12-month periods *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*;

3) the affected cattle as well as:

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

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

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

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

Community comments:
In view of the comments in the introduction of the Chapter 2.3.13. , the Community suggests replacing Article 2.3.13.6 point 2 with:

" 2) the BSE incidence rate has been:

a) greater than or equal to two indigenous cases per million and less than or equal to two hundred indigenous cases per million within the cattle population over 24 months of age within the country or zone, calculated over the last 12 months; or

b) less than two indigenous cases per million for less than four consecutive 12 month periods. (Note: for countries with a population of less than 500,000 adult cattle, the maximum allowed incidence should be expressed in cattle-years);"

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to add the following point :

" 4) an active monitoring programme, covering at least all bovine animals above 24 months of age which die on the farm or are slaughtered as emergencies, has been in place for at least 12 months"

In view of the comments in the introduction of the Chapter 2.3.13. , it is suggested to replace the last paragraph with:

" Countries and zones where the BSE incidence rate, calculated over the past 12 months, has been less than two indigenous cases per million within the cattle population over 24 months of age in the country or region, but where the conditions to be considered as provisionally free from BSE or as presenting a minimal risk are not complied with, shall be considered as countries with a moderate risk."

Article 2.3.13.7.

Country or zone with a high BSE risk

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

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, the other criteria listed in Article 2.3.13.2. are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than one hundred cases per million within the cattle population over 24 months of age in the country or zone; or

the BSE incidence rate, calculated over the past 12 months, has been greater than, or equal to, one case per million and less than, or equal to, one hundred cases per million within the cattle population over 24 months of age in the country or zone, but at least one of the other requirements to be considered as presenting a moderate BSE risk is not complied with.

Community comments:
In view of the comments in the introduction of the Chapter 2.3.13. , the Community suggests replacing

Article 2.3.13.7 point 1 with:

" 1) A risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, the other criteria listed in Article 2.3.13.2. are complied with, and the BSE incidence rate, calculated over the past 12 months has been greater than two hundred cases per million within the cattle population over 24 months of age in the country or zone and an active monitoring programme, covering at least all bovine animals above 24 months of age which die on the farm or are slaughtered as emergencies, has been in place for at least 12 months ; or"

Article 2.3.13.7 point 2 with:

" 2) The BSE incidence rate, calculated over the past 12 , has been greater than, or equal to, two cases per million and less than, or equal to, two hundred cases per million within the cattle

population over 24 months of age in the country or zone, but at least one of the other requirements to be considered as presenting a minimal or moderate BSE risk is not complied with."

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 embryos;

Community comments:
The Community suggests that if semen and embryos are considered risk free, then logically so should oocytes. It is suggested to replace subparagraph 2) with "semen, embryos and oocytes;"

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

Community comments:
The Community has posed a number of questions to the Scientific Steering Committee on the sourcing of raw materials for tallow and the treatment processes required to ensure safety. It reserves its position on tallow pending the response of the Committee.

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

Community comments:

The Community suggests that Dicalcium Phosphate should be removed from the list of products which are authorised without restriction. It refers to the 26 June 1998 Opinion of the Scientific Steering Committee on the safety of Dicalcium Phosphate which casts doubt on whether current production processes can produce Dicalcium Phosphate free of protein or fat and which recommends risk-related sourcing and production parameters.

5) hides and skins;

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

Article 2.3.13.9.

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

for all *commodities* from cattle not listed in Article 2.3.13.8.

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

Article 2.3.13.10.

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

for cattle

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

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

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

Article 2.3.13.11.

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

for cattle

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

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

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

3) cattle selected for export:

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

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

Article 2.3.13.12.

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

for cattle

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

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

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

3) cattle selected for export:

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

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

Article 2.3.13.13.

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

for cattle

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

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

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

3) the affected cattle as well as:

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

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

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

4) cattle selected for export:

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

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

Article 2.3.13.14.

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

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

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

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

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

Community comments:
The Community feels it is approporiate that in a provisionally free country there should be removal of specified risk material which reflects this level of risk. It follows from this that pithing, and stunning methods involving the injection of air, should also be prohibited to exclude dissemination of brain material to other tissues. Harvesting of mechanically recovered meat from skull or vertebral column of cattle should also be prohibited; for control reasons this prohibition should apply to animals of any age.

The Community reserves its position on the age limit for the inclusion of vertebral column in the list of specified risk materials, pending internal discussions.

Therefore it is suggested to add the following points:

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

4) The fresh meat and meat products destined for export do not contain the skull including the brain and eyes, the tonsils and the spinal cord from cattle over 30 months of age, nor intestine and mesentery of bovine animals of any age, all of which have been removed in a hygienic manner. Neither do they contain mechanically recovered meat from skull or vertebral column of bovine animals."

Article 2.3.13.15.

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

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

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

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

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

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

4) the *fresh meat* and *meat products* destined for export [have neither been contaminated by, nor] do not contain [either] brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been removed in a hygienic manner.

Community comments:

In their opinion of 9 December 1997 (re-edited January 1998) on Specified Risk Materials the SSC state that "an extremely cautious limit for the CNS as a highly infective tissue could be set at 12 months and provide considerable reassurance of non-infectivity. In cattle greater reassurance would be derived by limiting the use of CNS to less than 6 months. This might only be deemed necessary if animals are derived from high risk areas." In the same opinion and in their opinion of 27-28 November 2000 they recommend that the intestine of bovine animals of all ages should be removed as specified risk material whenever it is not highly unlikely that the slaughtered animals are infected.

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

The Community reserves its position on the age limit for inclusion of vertebral column pending internal discussions.

In view of this the Community suggest replacing article 2.3.13.15 point 4 with:

"4) 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 2.3.13.16.

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

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

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

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

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

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

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

5) the *fresh meat* and *meat products* destined for export [have neither been contaminated by, nor] do not contain brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age, all of which have been removed in a hygienic manner.

Community comments:

In their opinion of 9 December 1997 (re-edited January 1998) on Specified Risk Materials the SSC state that "an extremely cautious limit for the CNS as a highly infective tissue could be set at 12 months and provide considerable reassurance of non-infectivity. In cattle greater reassurance would be derived by limiting the use of CNS to less than 6 months. This might only be deemed necessary if animals are derived from high risk areas." In the same opinion and in their opinion of 27-28 November 2000 they recommend that the intestine of bovine animals of all ages should be removed as specified risk material whenever it is not highly unlikely that the slaughtered animals are infected.

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 2.3.13.17.

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

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

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

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

2) the *meat* destined for export [, if obtained from animals over 9 months of age, has been deboned and have neither been contaminated by, nor contains] does not contain the tissues listed in point 1) of Article 2.3.13.19. [nor nervous and lymphatic tissues exposed during a deboning process], all of which have been removed in a hygienic manner;

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

4) the *meat products* destined for export are derived from deboned meat and [have neither been contaminated by, nor] do not contain the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been removed in a hygienic manner;

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

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

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

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

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

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

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

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

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

9) the affected cattle as well as:

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

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

contaminated feed as that which the affected cattle consumed during the first year of their life,

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

Article 2.3.13.18.

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

Article 2.3.13.19.

1) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column, and protein products derived therefrom, from cattle over 6 months of age originating from countries with a high BSE risk. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:

   a) brains, eyes, spinal cord, distal ileum, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter aged over 6 months;

   b) brains, eyes and spinal cord, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a minimal BSE risk has been reported, that were at the time of slaughter aged over 30 months.

   Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using the commodities listed in points a) and b) above should also not be traded.

Community comments:

In their opinion of 9 December 1997 (re-edited January 1998) on Specified Risk Materials the SSC state that "an extremely cautious limit for the CNS as a highly infective tissue could be set at 12 months and provide considerable reassurance of non-infectivity. In cattle greater reassurance would be derived by limiting the use of CNS to less than 6 months. This might only be deemed necessary if animals are derived from high risk areas." In the same opinion and in their opinion of 27-28 November 2000 they recommend that the intestine of bovine animals of all ages should be removed as specified risk material whenever it is not highly unlikely that the slaughtered animals are infected.

The Community reserves its position on the age limit for the inclusion of vertebral column, pending internal discussions.

In view of this the Community suggest replacing article 2.3.13.19 paragraph 2 with:

"2) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:

a) skull, brain, eyes, tonsils or spinal cord of bovine animals over 12 months, or intestine of bovine animals of any age, or protein products derived

therefrom, originating from a country or zone with a moderate or minimal BSE risk.

b) skull, brain, eyes, tonsils or spinal cord of bovine animals over 30 months, or intestine of bovine animals of any age, or protein products derived therefrom, originating from a BSE provisionally free country or zone

Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded."

Article 2.3.13.20.

Veterinary Administrations of *importing countries* should require:

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

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

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

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

   a) skulls and vertebrae (excluding tail vertebrae) have been excluded;

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

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

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

      or to an equivalent process in terms of infectivity reduction.

Community comments:

The Community has posed a number of questions to the Scientific Steering Committee on the sourcing of raw materials for gelatine and the treatment processes required to ensure safety. It reserves its position on gelatine pending the response of the Committee.

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

   a) if prepared by fat melting, 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)b) of Article 2.3.13.19.;

   b) if prepared by rendering, (under study); or

3) a country or zone with a moderate BSE risk; and

   a) if prepared by fat melting, 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)a) of Article 2.3.13.19.;

   b) if prepared by defatting of bones:

      i) skulls and vertebral columns from cattle over 6 months of age have been excluded; or

      ii) it has been processed using a method that reduces the infectivity by at least 5 $\log_{10}$ LD_{50}/g (processes under study);

   c) if prepared by rendering, (under study).

Community comments:

The Community has posed a number of questions to the Scientific Steering Committee on the sourcing of raw materials for tallow and the treatment processes required to ensure safety. It reserves its position on tallow pending the response of the Committee.

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 VII

CHAPTER 2.3.7.

BOVINE ANAPLASMOSIS

Community comments:
The Community does not agree with the approach taken by the OIE to delete the requirements for imports into an affected country. This is not consistent with the approach under the WTO/SPS agreement. In addition there may be differences in strains between one country to another. This movement may therefore compromise both the health of the native population in countries receiving imported animals and the imported animals themselves and runs counter to good veterinary practise.. The Community therefore proposes that the suggesteddeletion is re-instated.

Article 2.3.7.1.

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

Article 2.3.7.2.

When importing from countries considered infected with bovine anaplasmosis, *Veterinary Administrations* of free countries should require:

for cattle

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

1) showed no clinical sign of bovine anaplasmosis on the day of shipment; and

2) were, since birth, kept in a zone known to be free of bovine anaplasmosis for the previous 2 years;

OR

3) showed no clinical sign of bovine anaplasmosis on the day of shipment; and

4) were subjected to a diagnostic test for bovine anaplasmosis with negative results during 30 days prior to shipment; and

5) were treated with an effective drug such as oxytetracycline for 5 consecutive days at a dose of 22 mg/kg (under study);

AND

in either of the above cases:

6) were treated with an acaricide and, if necessary, a repellant against biting insects prior to shipment and were completely free of ticks.

[Article 2.3.7.3.

When importing from countries considered infected with bovine anaplasmosis, *Veterinary Administrations* of infected countries should require:

for cattle

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

1) showed no clinical sign of bovine anaplasmosis on the day of shipment; and

2) were, since birth, kept in a zone known to be free of bovine anaplasmosis for the previous 2 years;

OR

3) showed no clinical sign of bovine anaplasmosis on the day of shipment; and

4) were subjected to a diagnostic test for bovine anaplasmosis with negative results during 30 days prior to shipment, or immediately before pre-shipment vaccination if administered; or

5) were treated with an effective drug such as oxytetracycline for 5 consecutive days at a dose of 22 mg/kg (under study);

AND

in either of the above cases:

6) if destined for bovine anaplasmosis endemic areas, were vaccinated at least 30 days prior to shipment; and

7) were treated with acaricides and, if necessary, a repellant against biting insects prior to shipment and were completely free of ticks.

(Note: Where both treatment and pre-shipment vaccination are applied, vaccination must be administered not later than 21 days before treatment [under study] or not earlier than 21 days after treatment [under study].)]

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[ ] deleted

CHAPTER 2.3.8.

BOVINE BABESIOSIS

Community comments:
The Community does not agree with the approach taken by the OIE to delete the requirements for imports into an affected country. This is not consistent with the approach under the WTO/SPS agreement. In addition there may be differences in strains between one country to another. This movement may therefore compromise both the health of the native population in countries receiving imported animals and the imported animals themselves and runs counter to good veterinary practise. The Community therefore proposes that the suggested deletion is re-instated.

Article 2.3.8.1.

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

Article 2.3.8.2.

When importing from countries considered infected with bovine babesiosis, *Veterinary Administrations* of free countries should require:

for cattle

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

1) showed no clinical sign of bovine babesiosis on the day of shipment; and

2) were, since birth, resident in a zone known to be free of bovine babesiosis for the previous 2 years;

OR

3) showed no clinical sign of bovine babesiosis on the day of shipment; and

4) were subjected to a diagnostic test for bovine babesiosis with negative results during 30 days prior to shipment; and

5) were treated with an effective drug such as imidocarb as a single dose injection at 2 mg/kg or amicarbalide at 10 mg/kg (under study);

AND

in either of the above cases:

6) were treated with acaricides prior to shipment and were completely free of ticks.

Community position:
The animals should be protected against vectors after sampling and after imidocarb or amicarbide treatment. The Community proposes that a further indent be included as follows:

"6) were treated with acaricides prior to shipment, were completely free of ticks and were protected against re-infestation".

[Article 2.3.8.3.

When importing from countries considered infected with bovine babesiosis, *Veterinary Administrations* of infected countries should require:

for cattle

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

1) showed no clinical sign of bovine babesiosis on the day of shipment; and

2) were, since birth, resident in a zone known to be free of bovine babesiosis for the previous 2 years;

OR

3) showed no clinical sign of bovine babesiosis on the day of shipment; and

4) were subjected to a diagnostic test for bovine babesiosis with negative results during 30 days prior to shipment, or immediately before pre-shipment vaccination if administered; or

5) were treated with an effective drug such as imidocarb as a single dose injection at 2 mg/kg or amicarbalide at 10 mg/kg (under study);

AND

in either of the above cases:

6) if destined for bovine babesiosis endemic areas, were vaccinated at least 30 days prior to shipment; and

7) were treated with acaricides prior to shipment and were completely free of ticks.

(Note: Where both treatment and pre-shipment vaccination are applied, vaccination must be administered not later than 10 days before treatment [under study] or not earlier than 35 days after treatment [under study].)]

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[ ] deleted

Appendix IX

CHAPTER 2.3.11.

THEILERIOSIS

Community comments:
The Community presumes that it is the intention to delete the last Article (as is proposed above) and if this is the case then the Community does not agree with the approach taken by the OIE to delete the requirements for imports into an affected country. [NB It appears that the first bracket for the deletion is missing from the text.] This is not consistent with the approach under the WTO/SPS agreement. In addition there may be differences betweenstrains from one country to another This movement may therefore compromise both the health of the native population in countries receiving imported animals and the imported animals themselves and runs counter to good veterinary practise. The Community therefore proposes that the suggested deletion is re-instated. .
The Community agrees with the proposed change to Article 2.3.11.1.

Article 2.3.11.1.

For the purposes of this *Code*, theileriosis is defined as a highly fatal disease in cattle and buffaloes caused by *Theileria parva* and *Theileria annulata.*

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

Article 2.3.11.2.

When importing from countries considered infected with theileriosis, *Veterinary Administrations* of free countries should require:

for cattle

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

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

2) were, since birth, kept in a zone known to be free of theileriosis for the previous 2 years;

OR

3) showed no clinical sign of theileriosis on the day of shipment; and

4) were subjected to a diagnostic test for theileriosis with negative results during the 30 days prior to shipment (under study); and

5) showed negative results from microscopic examination of blood smears;

AND

in either of the above cases:

6) were treated with acaricides (under study) prior to shipment and were completely free of ticks.

Article 2.3.11.3.

When importing from countries considered infected with theileriosis, *Veterinary Administrations* of infected countries should require:

for cattle

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

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

2) were, since birth, kept in a zone known to be free of theileriosis for the previous 2 years;

OR

3) showed no clinical sign of theileriosis on the day of shipment; and

4) were subjected to a diagnostic test for theileriosis with negative results during the 30 days prior to shipment (under study); and

5) showed negative results from microscopic examination of blood smears;

AND

in either of the above cases:

6) were treated with acaricides (under study) prior to shipment and were completely free of ticks; and

7) if destined for theileriosis endemic areas, were vaccinated at least 30 days prior to shipment.

Appendix X

CHAPTER 2.1.13.

CLASSICAL SWINE FEVER

Community comments:
The Community can agree with the proposed changes.

Article 2.1.13.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pigs includes all varieties of *Sus scrofa*, both domestic breeds and wild boar. A distinction is made between farmed and permanently captive pigs, and free-living pigs. Farmed and permanently captive pigs of any breed will hereafter be referred to as domestic pigs. Free-living pigs of any breed will hereafter be referred to as wild pigs. Extensively kept pigs may fall into either of these categories or may alternate between the two.

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of disease. Pigs exposed postnatally have an *incubation period* of 7-10 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections.

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

Article 2.1.13.2.

The CSF status of a country or zone can only be determined after considering the following criteria both in domestic and wild pigs:

1) a risk assessment has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;

2) CSF should be notifiable in the whole country and all clinical signs suggestive of CSF should be subjected to field and/or laboratory investigations;

3) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of CSF;

4) the *Veterinary Administration* should have current knowledge of, and authority over, all *establishments* containing pigs in the whole country;

5) the *Veterinary Administration* should have current knowledge about the population and habitat of wild pigs in the whole country.

Article 2.1.13.3.

For the purposes of this *Code*:

'CSF infected establishment' means a domestic pig holding in which the presence of the infection has been confirmed by field and/or laboratory investigations.

'Country or zone with CSF infection in domestic pigs' means a country or zone containing a CSF infected *establishment*.

The size and limits of a CSF domestic pig control area must be based on the control measures used and the presence of natural and administrative boundaries, as well as an assessment of the risks for disease spread.

Article 2.1.13.4.

Country or zone free of CSF in domestic and wild pigs

1. Historically free status

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

2. Free status as a result of an eradication programme

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

   a) it is a notifiable disease;

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

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

   d) animal health regulations to control the movement of *commodities* listed in Article 2.1.13.8. 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;

   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; if vaccination has occurred in the last 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 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; if vaccination has occurred in the last 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.

Article 2.1.13.5.

Country or zone free of CSF in domestic pigs but with infection in the wild pig population

Requirements in point 2) of Article 2.1.13.4., as relevant, are complied with, but CSF infection is known to occur in wild pigs. Additional conditions for the free status are that in the country or zone:

1) a programme for the management of CSF in wild pigs is in place, and CSF wild pig control areas are delineated around every CSF *case* reported in wild pigs, taking into account the measures in place to manage the disease in the wild pig population, the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risk of disease spread;

2) biosecurity measures are applied to prevent transmission from wild pigs to domestic pigs;

3) clinical and laboratory monitoring (under study) is carried out in the domestic pig population, with negative results.

Article 2.1.13.6.

Recovery of free status

Should a CSF *outbreak* occur in an *establishment* of a free country or zone (free in domestic and wild pigs, or free in domestic pigs only), the status of the country or zone may be restored at least 30 days after completion of a *stamping-out policy* which should include the following measures:

1) a CSF domestic pig control area (including an inner protection area of at least 3 kilometres radius and an outer surveillance area of at least 10 kilometres radius) should be delineated around the *outbreak*, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;

2) all the pigs have been killed and their carcasses destroyed, and *disinfection* has been applied within the *establishment*;

3) in the protection area around a CSF *outbreak*:

    a) a risk assessment should be carried out to determine the likelihood of CSF infection in neighbouring *establishments*; when a significant risk is indicated, a *stamping-out policy* of all domestic pigs within a radius of at least 0.5 kilometre may be applied;

    b) an immediate clinical examination of all pigs in all pig *establishments* situated within the protection area has been carried out;

4) in the surveillance area around a CSF *outbreak*, all sick pigs should be subjected to laboratory tests for CSF;

5) an epidemiological examination including clinical examination, and/or serological and/or virological testing has been carried out in all pig *establishments* that have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within the CSF domestic pig control area, demonstrating that these *establishments* are not infected;

6) measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, *vehicles*, etc. have been implemented.

If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status can not occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.1.13.7.

Country or zone free of CSF in wild pigs

A country or zone may be considered free from CSF in wild pigs when:

1) the domestic pig population in the country or zone is free from CSF infection;

2) a monitoring system (under study) has been in place to determine the CSF status of the wild pig population in the country, and in the country or zone:

   a) there has been no clinical, nor virological evidence of CSF in wild pigs during the last 12 months;

   b) no seropositive wild pigs have been detected in the age class 6-12 months during the last 12 months;

3) there has been no vaccination in wild pigs for at least 12 months;

4) the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present in conformity with one of the procedures referred to in Article 3.6.4.1 (under study);

5) imported wild pigs comply with the relevant requirements set forth in the present chapter.

A zoning approach can only be adopted if there is a wild pig population that is isolated from other wild pigs.

Article 2.1.13.8.

Veterinary Administrations should examine whether they run a risk of introducing CSF by accepting the importation or transit through their territory, directly or indirectly from other countries or zones, of the following *commodities*:

1) live pigs;

2) semen of pigs;

3) embryos/ova of pigs;

4) *fresh meat* of pigs;

5) *meat products* of pigs;

6) *products of animal origin* (from pigs) *intended for use in animal feeding* or *for agricultural or industrial use*;

7) *products of animal origin* (from pigs) *intended for pharmaceutical or surgical use*;

8) *pathological material* and biological products (see Chapter 1.4.6. and Section 1.5.);

9) trophies derived from wild pigs.

Article 2.1.13.9.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for domestic pigs

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

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

2) were kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;

3) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows.

Article 2.1.13.10.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for domestic pigs

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

1) were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;

2) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows;

3) come from an *establishment* which is not located in a CSF wild pig control area as defined in Article 2.1.13.5., and has been regularly monitored to verify absence of CSF;

4) have had no contact with pigs introduced into the *establishment* during the past 40 days;

5) showed no clinical sign of CSF on the day of shipment.

Article 2.1.13.11.

When importing from countries or zones with CSF infection in domestic pigs, *Veterinary Administrations* should require:

for domestic pigs

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

1) have not been vaccinated against CSF (in the case of piglets, the mother sows have not been vaccinated against CSF);

2) were kept since birth, or for the past 3 months, in an *establishment* not situated in a CSF domestic or wild pig control area as defined in Articles 2.1.13.5. and 2.1.13.6.;

3) were isolated in a *quarantine station* for at least 40 days;

4) were subjected during that period of quarantine to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;

5) showed no clinical sign of CSF on the day of shipment.

Article 2.1.13.12.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for wild pigs

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

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

2) have been captured in a country or zone free from CSF in domestic and wild pigs;

3) have not been vaccinated against the disease;

and, if the zone where the animal has been captured is adjacent to a zone with infection in wild pigs:

4) were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.

Article 2.1.13.13.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

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

1) the donor animals:

   a) were kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;

   b) showed no clinical sign of CSF on the day of collection of the semen;

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.1.13.14.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

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

1) the donor animals:

   a) have been kept in an *artificial insemination centre* which is not located in a CSF wild pig control area and is regularly monitored to verify absence of CSF;

   b) were isolated in the *artificial insemination centre* for at least 40 days prior to collection;

   c) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.1.13.15.

When importing from countries or zones considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

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

1) the donor animals:

   a) showed no clinical sign of CSF on the day of collection of the semen and for the following 3 months;

   b) have not been vaccinated against CSF, and were subjected to a serological test performed at least 21 days after collection, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.1.13.16.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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

1) the donor females showed no clinical sign of CSF on the day of collection of the embryos;

2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.4.

Article 2.1.13.17.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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

1) the donor females:

   a) were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;

   b) showed no clinical sign of CSF on the day of collection of the embryos;

2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.4.

Article 2.1.13.18.

When importing from countries considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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

1) the donor females:

   a) were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;

   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 21 days;

   c) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection;

2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.4.

Article 2.1.13.19.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *fresh meat* of domestic pigs

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

1) have been kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;

2) have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.1.13.20.

When importing from countries or zones free of CSF in domestic pigs but with infection in wild pigs, *Veterinary Administrations* should require:

for *fresh meat* of domestic pigs

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

1) were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;

2) were kept in an *establishment* which was not located in a CSF wild pig control area and had been regularly monitored to verify absence of CSF;

3) have been slaughtered in an *approved abattoir* not located in a CSF control area, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.1.13.21.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *fresh meat* of wild pigs

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

1) the entire consignment of meat comes from animals which:

   a) have been killed in a country or zone free of CSF in domestic and wild pigs;

   b) have been subjected to post-mortem inspection in an approved examination centre, and have been found free of any sign suggestive of CSF;

and, if the zone where the animal has been killed is adjacent to a zone with infection in wild pigs:

2) a sample has been collected from every animal shot, and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 2.1.13.22.

Veterinary Administrations of *importing countries* should require:

for *meat products* of pigs (either domestic or wild), or for *products of animal origin* (from *fresh meat* of pigs) *intended for use in animal feeding*, *for agricultural or industrial use*, or *for pharmaceutical or surgical use*, or for trophies derived from wild pigs

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

1) have been prepared:

   a) exclusively from *fresh meat* meeting the conditions laid down in Articles 2.1.13.19., 2.1.13.20. or 2.1.13.21., as relevant;

   b) in a processing establishment:

      i) approved by the *Veterinary Administration* for export purposes;

      ii) regularly inspected by the *Veterinary Authority*;

      iii) not situated in a CSF control area;

      iv) processing only meat meeting the conditions laid down in Articles 2.1.13.19., 2.1.13.20. or 2.1.13.21., as relevant;

OR

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2. (under study).

Article 2.1.13.23.

Veterinary Administrations of *importing countries* should require:

for *products of animal origin* (from pigs, but not derived from *fresh meat*) *intended for use in animal feeding* and *for agricultural or industrial use*

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

1) have been prepared:

   a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.1.13.19., 2.1.13.20. or 2.1.13.21., as relevant;

   b) in a processing establishment:

i) approved by the *Veterinary Administration* for export purposes;

ii) regularly inspected by the *Veterinary Authority*;

iii) not situated in a CSF control area;

iv) processing only products meeting the conditions laid down in point a) above;

OR

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2. (under study).

Article 2.1.13.24.

Veterinary Administrations of *importing countries* should require:

for bristles (from pigs)

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

1) come from a country or zone free of CSF in domestic and wild pigs; or

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

Article 2.1.13.25.

Veterinary Administrations of *importing countries* should require:

for litter and manure (from pigs)

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

1) come from a country or zone free of CSF in domestic and wild pigs; or

2) come from *establishments* situated in a country or zone free of CSF in domestic pigs but with infection in wild pigs, but not located in a CSF control area; or

3) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

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APPENDIX 3.6.4.

CLASSICAL SWINE FEVER VIRUS DESTRUCTION PROCEDURES

Community comments:
The Community can agree with the proposed changes only if the amendments indicted for the treatments below are included.

Article 3.6.4.1.

Swill

(under study)

Article 3.6.4.2.

Meat

For the destruction of viruses present in meat, one of the following procedures should be used:

1. Heat treatment

   Meat shall be subjected to one of the following treatments:

   a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

   b) heat treatment at a minimum temperature of 70°C, which must be reached throughout the meat. [;]

   [c) heat treatment in a hermetically sealed container at a temperature of at least 60°C for a minimum of 4 hours, during which the core temperature must reach at least 70°C for 30 minutes.]

2. Natural fermentation and maturation

   The meat should be subjected to a treatment consisting of [in] natural fermentation and maturation [of not less than 9 months and] having the following characteristics:

   a) an aw value of not more than 0.93, or

   b) a pH value of not more than 6.0.

   Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

[*NOTE: Other pig meat processing, such as salami processing, may be effective for the destruction of the classical swine fever virus. However, given the variability of the processing protocols, the effectiveness of each specific processing must be demonstrated.*]

3. Dry cured pork meat

a) Italian style hams with bone in should be cured with salt and dried for a minimum of 313 days.

Community comments:
The Community believes that the period for Italian style hams is much to long for the inactivation of CSF virus. According to the Scientific review of the OIE 16 (1), 65-78 the inactivation times for CSF virus is as follows:
189 days in Parma ham
Therefore the Community proposes that the sentence above be replaced by:
"a) Italian style hams with bone in should be cured with salt and dried for a minimum of 190 days

b) Spanish style pork meat with bone in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

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[ ] deleted

CHAPTER 2.4.8.

SCRAPIE

Community position:
The Community can support the proposed change to the chapter. The Community refers to the comments it made on other parts of the chapter last year and in particular the references to surveillance and monitoring and to historical freedom. We welcome the initiative by the Code Commission to ask an expert to develop a draft appendix on surveillance and monitoring. It is important that this appendix should contain a significant reference to active surveillance. The Community has recently embarked on an extensive active surveillance programme in small ruminants – we would be happy to make available the results and experience gained from this programme.

Article 2.4.8.1.

Scrapie is a neurodegenerative disease of [the transmissible spongiform encephalopathy (TSE) group most commonly reported affecting adult] sheep and goats. The main mode of transmission is from mother to offspring immediately after birth. [It is traditionally recognised that the agent is transmitted horizontally and maternally.] A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the disease is variable, however it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

The recommendations in the present chapter are not intended**,** or sufficient**,** to manage the risks associated with the potential presence of the bovine spongiform encephalopathy agent in small ruminants.

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

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Appendix XIII

CHAPTER 2.9.1.

ACARAPISOSIS OF HONEY BEES

(Tracheal mite infestation of honey bees)

Community comments:

The Community can in general support this Chapter but only if the comment provided is taken into account. It is excessive to sample every hive for disease control purposes and unless the statistical survey is amended on the lines suggested no trade will be able to take place. In addition not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration* in the text as appropriate.

Article 2.9.1.1.

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

Article 2.9.1.2.

Country or zone with an official control programme for acarapisosis

To be considered as a country or zone with an official control programme for acarapisosis, a country or zone should meet the following requirements:

1) the *Veterinary Administration* has current knowledge of, and authority over, all beehives existing in the country or zone;

2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;

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

4) a sample of the bee population of each hive in the country or zone should be collected at least every year and subjected to a diagnostic test for acarapisosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a within hive prevalence rate exceeding 5%;

Community comments:

It is excessive to sample every hive so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for acarapisosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

5) all infected hives should be either treated with appropriate acaricides or destroyed.

Article 2.9.1.3.

Country or zone free from acarapisosis

To be considered free from acarapisosis, a country or zone should fulfil the following requirements:

1) an official control programme for acarapisosis has existed in the country or zone for at least 3 years, and no *outbreak* of acarapisosis has been reported during this period;

2) then, annual surveys, with negative results, are carried out on a representative sample of all the beehives in the country or zone to provide a confidence level of at least 99% of detecting acarapisosis if at least 0.2% of the hives were infected at a within hive prevalence rate of at least 5%;

3) the importation of the *commodities* listed in Article 2.9.1.4. into the country or zone is carried out in conformity with the import conditions contained in the relevant Articles of the present Chapter.

Article 2.9.1.4.

Veterinary Administrations of countries shall consider whether there is a risk with regard to acarapisosis in accepting importation or transit through their territory, from other countries, of bees (queen honey bees, worker bees and drones).

Other *commodities* (honey bee semen, honey bee eggs, used equipments associated with beekeeping, honey, honey bee-collected pollen, propolis or royal gelly) should be considered as not having the potential to spread acarapisosis when they are the subject of *international trade*.

Article 2.9.1.5.

Veterinary Administrations of *importing countries* should require:

<u>for queen honey bees, accompanying bees (worker bees) and drones with or without associated brood combs</u>

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

1) come from a country or zone free from acarapisosis; or

2) come from:

   a) a country or zone with an official control programme for acarapisosis;

Community comments:
It is excessive to require an official control programme for the whole country or zone so the Community proposes the following wording to replace the above:
"a) a site containing hives which are under official control and which have been free of infestation for at least 12 months and all neighbouring sites where hives are present within a radius of 10 kms."

   b) hives which were subjected to sampling for acarapisosis in accordance with point 4 of Article 2.9.1.2. on two occasions with negative results, the first sample being collected at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to shipment.

CHAPTER 2.9.2.

AMERICAN FOULBROOD

Community comments:

The Community can in general support this Chapter but only if the comment provided is taken into account. It is excessive to sample every hive for disease control purposes and unless the statistical survey is amended on the lines suggested no trade will be able to take place. In addition not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration* in the text as appropriate.

Article 2.9.2.1.

For the purposes of this *Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

Article 2.9.2.2.

Country or zone with an official control programme for American foulbrood

To be considered as a country or zone with an official control programme for American foulbrood, a country or zone should fulfil the following requirements:

1) the *Veterinary Administration* has current knowledge of, and authority over, all beehives existing in the country or zone;

2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;

3) American foulbrood is notifiable in the whole country, and any clinical cases suggestive of American foulbrood are subjected to field and laboratory investigations;

4) inspection of each hive in the country or zone should be conducted at least every year to provide a confidence level of at least 99% of detecting the disease in honey bee larvae or pupae if it is present at a within brood prevalence rate exceeding 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for American foulbrood; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

5) all infected hives should be either treated with appropriate antibiotics or destroyed.

Article 2.9.2.3.

Country or zone free from American foulbrood

To be considered free from American foulbrood, a country or zone should fulfil the following requirements:

1) an official control programme for American foulbrood has existed in the country or zone for at least 3 years, and no *outbreak* of the disease has been reported during this period;

2) then, annual surveys, with negative results, are carried out on a representative sample of all the beehives in the country or zone to provide a confidence level of at least 99% of detecting the disease if at least 0.2% of the hives were infected at a within brood prevalence rate of at least 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for American foulbrood; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

3) the importation of the *commodities* listed in Article 2.9.2.4. into the country or zone is carried out in conformity with the import conditions contained in the relevant Articles of the present Chapter.

Article 2.9.2.4.

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

1) queen honey bees and accompanying bees (worker bees);

2) used equipment associated with beekeeping;

3) honey, honey bee-collected pollen, propolis and royal gelly.

Other *commodities* (honey bee semen and eggs) should be considered as not having the potential to spread American foulbrood when they are the subject of *international trade*.

Community comments:
There may be potential risk with eggs if they are cut out of the comb and transfer with any comb material. The Community would propose that this point be clarified with the expert and proposes that the words "provided no extraneous material from the hive is included and all necessary steps have been taken to ensure no possible risk of transmission has been taken" are inserted at the end of the sentence.

In addition point 3 should be replaced by the following wording "honey, honey bee-collected pollen, propolis and royal jelly only when intended for use in apiculture." If this is not done then all honey for human consumption will need a veterinary certificate and this is excessive.

Article 2.9.2.5.

Veterinary Administrations of *importing countries* should require:

for queen honey bees, accompanying bees (worker bees) and drones with or without associated brood combs

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

1) come from a country or zone free from American foulbrood; or

2) come from:

   a) a country or zone with an official control programme for American foulbrood;

Community comments:
It is excessive to require an official control programme for the whole country or zone so the Community proposes the following wording to replace the above:
"a) a site containing hives which are under official control and which have been free of infestation for at least 12 months and all neighbouring sites where hives are present within a radius of 10 kms."

   b) an apiary in which no clinical sign of American foulbrood was reported during the 45 days prior to shipment (not including the wintering period which may vary according to the country);

   c) hives that were subjected to inspection for American foulbrood in accordance with point 4 of Article 2.9.2.2. on two occasions with negative results, the first inspection being carried out at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to shipment.

Article 2.9.2.6.

Veterinary Administrations of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes, or gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or exposure to ethylene oxide at greater than 450 mg/litre of air for greater than 8 hours at a temperature greater than 38°C and a relative humidity greater than 80%.

Article 2.9.2.7.

Veterinary Administrations of *importing countries* should require:

for honey, honey bee-collected pollen, propolis and royal gelly

Community comments:
The wording above should be replaced by the following wording "honey, honey bee-collected pollen, propolis and royal jelly only when intended for use in apiculture." If this is not done then all honey for human consumption will need a veterinary certificate and this is excessive.

the presentation of an *international veterinary certificate* attesting that these products were collected in:

1) a country or zone free from American foulbrood; or

2) apiaries:

   a) located in a country or zone with an official control programme for American foulbrood;

   b) in that no clinical sign of American foulbrood was reported during the 45 days prior to collection (not including the wintering period which may vary according to the country);

   c) in that hives were subjected to inspection for American foulbrood in accordance with point 4 of Article 2.9.2.2. on two occasions with negative results, the first inspection being carried out at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to collection.

CHAPTER 2.9.3.

EUROPEAN FOULBROOD

Community comments:

The Community can in general support this Chapter but only if the comment provided is taken into account. It is excessive to sample every hive for disease control purposes and unless the statistical survey is amended on the lines suggested no trade will be able to take place. In addition not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration* in the text as appropriate.

Article 2.9.3.1.

For the purposes of this *Code*, the incubation period for European foulbrood shall be 4 days (not including the wintering period which may vary according to country).

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

Article 2.9.3.2.

Country or zone with an official control programme for European foulbrood

To be considered as a country or zone with an official control programme for European foulbrood, a country or zone should fulfil the following requirements:

1) the *Veterinary Administration* has current knowledge of, and authority over, all beehives existing in the country or zone;

2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;

3) European foulbrood is notifiable in the whole country, and any clinical cases suggestive of European foulbrood are subjected to field and laboratory investigations;

4) inspection of each hive in the country or zone should be conducted at least every year to provide a confidence level of at least 99% of detecting the disease in honey bee larvae or pupae if it is present at a within brood prevalence rate exceeding 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for European foulbrood; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place

5) all infected hives should be either treated with appropriate antibiotics or destroyed.

Article 2.9.3.3.

Country or zone free from European foulbrood

To be considered free from European foulbrood, a country or zone should fulfil the following requirements:

1) an official control programme for European foulbrood has existed in the country or zone for at least 3 years, and no *outbreak* of the disease has been reported during this period;

2) then, annual surveys, with negative results, are carried out on a representative sample of all the beehives in the country or zone to provide a confidence level of at least 99% of detecting the disease if at least 0.2% of the hives were infected at a within brood prevalence rate of at least 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"2) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for European foulbrood; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place

3) the importation of the *commodities* listed in Article 2.9.3.4. into the country or zone is carried out in conformity with the import conditions contained in the relevant Articles of the present Chapter.

Article 2.9.3.4.

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

1) queen honey bees and accompanying bees (worker bees);

2) used equipment associated with beekeeping;

3) honey, honey bee-collected pollen, propolis and royal gelly.

Community comments:
The wording above should be replaced by the following wording "honey, honey bee-collected pollen, propolis and royal jelly only when intended for use in apiculture." If this is not done then all honey for human consumption will need a veterinary certificate and this is excessive.

Other *commodities* (honey bee semen and eggs) should be considered as not having the potential to spread European foulbrood when they are the subject of *international trade*.

Community comments:
There may be potential risk with eggs if they are cut out of the comb and transfer with any

comb material. The Community would propose that this point be clarified with the expert and proposes that the words "provided no extraneous material from the hive is included and all necessary steps have been taken to ensure no possible risk of transmission has been taken" are inserted at the end of the sentence.

Article 2.9.3.5.

Veterinary Administrations of *importing countries* should require:

for queen honey bees and accompanying bees (worker bees)

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

1) come from a country or zone free from European foulbrood; or

2) come from:

   a) a country or zone with an official control programme for European foulbrood;

Community comments:
It is excessive to require an official control programme for the whole country or zone so the Community proposes the following wording to replace the above:
"a) a site containing hives which are under official control and which have been free of infestation for at least 12 months and all neighbouring sites where hives are present within a radius of 10 kms."

   b) an apiary in that no clinical sign of European foulbrood was reported during the 12 days prior to shipment (not including the wintering period which may vary according to the country);

   c) hives that were subjected to inspection for American foulbrood in accordance with point 4 of Article 2.9.3.2. on two occasions with negative results, the first inspection being carried out at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to shipment.

Article 2.9.3.6.

Veterinary Administrations of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy.

Article 2.9.3.7.

Veterinary Administrations of *importing countries* should require:

for honey, honey bee-collected pollen, propolis and royal gelly

Community comments:
The wording above should be replaced by the following wording "honey, honey bee-collected pollen, propolis and royal jelly only when intended for use in apiculture." If this is not done then all honey for human consumption will need a veterinary certificate and this is excessive.

the presentation of an *international veterinary certificate* attesting that these products were collected in:

1) a country or zone free from European foulbrood; or

2) apiaries:

   a) located in a country or zone with an official control programme for European foulbrood;

Community comments:
It is excessive to require an official control programme for the whole country or zone so the Community proposes the following wording to replace the above:
"a) a site containing hives which are under official control and which have been free of infestation for at least 12 months and all neighbouring sites where hives are present within a radius of 10 kms."

   b) in that no clinical sign of European foulbrood was reported during the 12 days prior to collection (not including the wintering period which may vary according to the country);

   c) in that hives were subjected to inspection for American foulbrood in accordance with point 4 of Article 2.9.3.2. on two occasions with negative results, the first inspection being carried out at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to collection.

CHAPTER 2.9.4.

NOSEMOSIS OF HONEY BEES

Community comments:

The Community can in general support this Chapter but only if the comment provided is taken into account. It is excessive to sample every hive for disease control purposes and unless the statistical survey is amended on the lines suggested no trade will be able to take place. In addition not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration* in the text as appropriate.

Article 2.9.4.1.

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

Article 2.9.4.2.

Country or zone with an official control programme for nosemosis

To be considered as a country or zone with an official control programme for nosemosis, a country or zone should fulfil the following requirements:

1) the *Veterinary Administration* has current knowledge of, and authority over, all beehives existing in the country or zone;

2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;

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

4) a sample of the bee population of each hive in the country or zone should be collected at least every year and subjected to a diagnostic test for nosemosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a within hive prevalence rate exceeding 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for Nosemosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

5) all infected hives should be either treated with appropriate antibiotics or destroyed.

Article 2.9.4.3.

Country or zone free from nosemosis

To be considered free from nosemosis, a country or zone should fulfil the following requirements:

1) an official control programme for nosemosis has existed in the country or zone for at least 3 years, and no *outbreak* of nosemosis has been reported during this period;

2) then, annual surveys, with negative results, are carried out on a representative sample of all the beehives in the country or zone to provide a confidence level of at least 99% of detecting nosemosis if at least 0.2% of the hives were infected at a within hive prevalence rate of at least 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"2) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for Nosemosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

3) the importation of the *commodities* listed in Article 2.9.4.4. into the country or zone is carried out in conformity with the import conditions contained in the relevant Articles of the present Chapter.

Article 2.9.4.4.

Veterinary Administrations of countries shall consider whether there is a risk with regard to nosemosis in accepting importation or transit through their territory, from other countries, of bees (queen honey bees, worker bees and drones).

Other *commodities* (honey bee semen, honey bee eggs, honey, honey bee-collected pollen, propolis or royal jelly) should be considered as not having the potential to spread nosemosis when they are the subject of *international trade*.

Community comments:
There may be potential risk with eggs if they are cut out of the comb and transfer with any comb material. The Community would propose that this point be clarified with the expert and proposes that the words "provided no extraneous material from the hive is included and all necessary steps have been taken to ensure no possible risk of transmission has been taken" are inserted at the end of the sentence.

Article 2.9.4.5.

Veterinary Administrations of *importing countries* should require:

<u>for queen honey bees, accompanying bees (worker bees) and drones with or without associated brood combs</u>

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

1) come from a country or zone free from nosemosis; or

2) come from:

a) a country or zone with an official control programme for nosemosis;

Community comments:
It is excessive to require an official control programme for the whole country or zone so the Community proposes the following wording to replace the above:
"a) a site containing hives which are under official control and which have been free of nosemosis for at least 12 months and all neighbouring sites where hives are present within a radius of 10 kms."

b) hives that were subjected to sampling for nosemosis in accordance with point 4 of Article 2.9.4.2. on two occasions with negative results, the first sample being collected at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to shipment.

Article 2.9.4.6.

Veterinary Administrations of *importing countries* should require:

<u>for used equipment associated with beekeeping</u>

the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or exposure to ethylene oxide at greater than 600 mg/litre of air for greater than 8 hours at a temperature greater than 38°C and a relative humidity greater than 80%, or fumigation with a 60% dilution of acetic acid used at a dose of 2 ml/litre of confined space containing the equipment for 7 days, or heat treatment at a temperature of at least 49°C for at least 24 hours.

CHAPTER 2.9.5.

VARROOSIS OF HONEY BEES

Community comments:

The Community can in general support this Chapter but only if the comment provided is taken into account. It is excessive to sample every hive for disease control purposes and unless the statistical survey is amended on the lines suggested no trade will be able to take place. In addition not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration* in the text as appropriate.

Article 2.9.5.1.

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

Article 2.9.5.2.

Country or zone with an official control programme for varroosis

To be considered as a country or zone with an official control programme for varroosis, a country or zone should fulfil the following requirements:

1) the *Veterinary Administration* has current knowledge of, and authority over, all beehives existing in the country or zone;

2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;

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

4) each hive in the country or zone should be subjected to a diagnostic test for varroosis at least every year; the sampling method used should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5% in the bee population of each hive;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for varroosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

5) all infected hives should be either treated with appropriate acaricides or destroyed.

Article 2.9.5.3.

Country or zone free from varroosis

To be considered free from varroosis, a country or zone should fulfil the following requirements:

1) an official control programme for varroosis has existed in the country or zone for at least 3 years, and no *outbreak* of varroosis has been reported during this period;

2) then, annual surveys, with negative results, are carried out on a representative sample of all the beehives in the country or zone to provide a confidence level of at least 99% of detecting varroosis if at least 0.2% of the hives were infected at a within hive prevalence rate of at least 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"2) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test forVarroosis; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

3) the importation of the *commodities* listed in Article 2.9.5.4. into the country or zone is carried out in conformity with the import conditions contained in the relevant Articles of the present Chapter.

Article 2.9.5.4.

Veterinary Administrations of countries shall consider whether there is a risk with regard to varroosis in accepting importation or transit through their territory, from other countries, of bees (queen honey bees, worker bees and drones).

Other *commodities* (honey bee semen, honey bee eggs, extracted honey, or royal gelly) should be considered as not having the potential to spread varroosis when they are the subject of *international trade*.

Community comments:
There may be potential risk with eggs if they are cut out of the comb and transfer with any comb material. The Community would propose that this point be clarified with the expert and proposes that the words "provided no extraneous material from the hive is included and all necessary steps have been taken to ensure no possible risk of transmission has been taken" are inserted at the end of the sentence.

Article 2.9.5.5.

Veterinary Administrations of *importing countries* should require:

<u>for queen honey bees, accompanying bees (worker bees) and drones with or without associated brood combs</u>

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

1) come from a country or zone free from varroosis; or

2) come from:

a) a country or zone with an official control programme for varroosis;

Community comments:
It is excessive to require an official control programme for the whole country or zone so the Community proposes the following wording to replace the above:
"a) a site containing hives which are under official control and which have been free of varroosis for at least 12 months and all neighbouring sites, where hives are present, within a radius of 10 kms."

b) hives which were subjected to sampling for varroosis in accordance with point 4 of Article 2.9.5.2. on two occasions with negative results, the first sample being collected at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to shipment.

Article 2.9.5.6.

Veterinary Administrations of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment come from:

1) a country or zone free from varroosis; or

2) a country or zone with an official control programme for varroosis, and:

a) contains no live honey bees or bee brood;

b) has been held away from contact with live honey bees for more than 7 days prior to shipment.

Community comments:
It is excessive to require an official control programme for the whole country or zone as well as the requirements in a) and b) so the Community requests the OIE to review this Article. It should be possible to lay down methods of disinfestation as has been done for the other bee diseases.

Article 2.9.5.7.

Veterinary Administrations of *importing countries* should require:

for honey-bee collected pollen, comb honey and propolis

the presentation of an *international veterinary certificate* attesting that these products come from:

1) a country or zone free from varroosis; or

2) a country or zone with an official control programme for varroosis, and have been held away from contact with live honey bees for more than 7 days prior to shipment.

Appendix XVIII

CHAPTER 2.9.6.

TROPILAELAPS INFESTATION OF HONEY BEES

Community comments:

The Community can in general support this Chapter but only if the comment provided is taken into account. It is excessive to sample every hive for disease control purposes and unless the statistical survey is amended on the lines suggested no trade would be able to take place. In addition not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration* in the text as appropriate.

Article 2.9.6.1.

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

Article 2.9.6.2.

Country or zone with an official control programme for *Tropilaelaps* infestation

To be considered as a country or zone with an official control programme for *Tropilaelaps* infestation, a country or zone should fulfil the following requirements:

1) the *Veterinary Administration* has current knowledge of, and authority over, all beehives existing in the country or zone;

2) the control programme complies with the general provisions of Appendix 3.4.2., and is supervised by the *Veterinary Administration*;

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

4) each hive in the country or zone should be subjected to a diagnostic test for at least every year (outside the wintering period which may vary to country); the sampling method used should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5% in the bee population of each hive;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"4) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for *Tropilaelaps* infestation**; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."**

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

5) all infected hives should be either treated with appropriate acaricides or destroyed.

Article 2.9.6.3.

Country or zone free from *Tropilaelaps* infestation

To be considered free from *Tropilaelaps* infestation, a country or zone should fulfil the following requirements:

1) an official control programme for *Tropilaelaps* infestation has existed in the country or zone for at least 3 years, and no *outbreak* of *Tropilaelaps* infestation has been reported during this period;

2) then, annual surveys, with negative results, are carried out on a representative sample of all the beehives in the country or zone (outside the wintering period which may vary to country) to provide a confidence level of at least 99% of detecting *Tropilaelaps* infestation if at least 0.2% of the hives were infected at a within hive prevalence rate of at least 5%;

Community comments:

It is excessive to sample every hive and for example each sheep farm is not sampled for disease control purposes so the Community proposes the following wording to replace the above:
"2) a random number of sites where there is/are hives with a bee population in the country or zone should be sampled at least every year and subjected to a diagnostic test for *Tropilaelaps* infestation**; the sample size should be sufficient to provide at least 99% confidence of detecting the disease if it is present at a prevalence rate exceeding 5%. If infected hives are found the survey must be extended to all neighbouring sites where hives are present."**

Unless the statistical survey is amended on the lines suggested no trade will be able to take place.

3) the importation of the *commodities* listed in Article 2.9.6.4. into the country or zone is carried out in conformity with the import conditions contained in the relevant Articles of the present Chapter.

Article 2.9.6.4.

Veterinary Administrations of countries shall consider whether there is a risk with regard to *Tropilaelaps* infestation in accepting importation or transit through their territory, from other countries, of bees (queen honey bees, worker bees and drones).

Other *commodities* (honey bee semen, honey bee eggs, extracted honey, or royal gelly) should be considered as not having the potential to spread *Tropilaelaps* infestation when they are the subject of *international trade*.

Community comments:
There may be potential risk with eggs if they are cut out of the comb and transfer with any comb material. The Community would propose that this point be clarified with the expert and proposes that the words "provided no extraneous material from the hive is included and all necessary steps have been taken to ensure no possible risk of transmission has been taken" are inserted at the end of the sentence.

Article 2.9.6.5.

Veterinary Administrations of *importing countries* should require:

for queen honey bees, accompanying bees (worker bees) and drones with or without associated brood combs

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

1) come from a country or zone free from *Tropilaelaps* infestation; or

2) come from:

   a) a country or zone with an official control programme for *Tropilaelaps* infestation;

Community comments:
It is excessive to require an official control programme for the whole country or zone as well as the requirements in a) and b) so the Community requests the OIE to review this Article. It should be possible to lay down methods of disinfestation as has been done for the other bee diseases.

   b) hives that were subjected to sampling for *Tropilaelaps* infestation in accordance with point 4 of Article 2.9.6.2. on two occasions with negative results, the first sample being collected at least 4 months and no more than 12 months, and the second sample no more than 7 days, prior to shipment.

Article 2.9.6.6.

Veterinary Administrations of *importing countries* should require:

for used equipment associated with beekeeping

the presentation of an *international veterinary certificate* attesting that the equipment come from:

1) a country or zone free from *Tropilaelaps* infestation; or

2) a country or zone with an official control programme for *Tropilaelaps* infestation, and:

   a) contains no live honey bees or bee brood;

   b) has been held away from contact with live honey bees for more than 7 days prior to shipment.

Community comments:
It is excessive to require an official control programme for the whole country or zone as well as the requirements in a) and b) so the Community requests the OIE to review this Article. Methods of disinfestion should be possible to lay down as has been done for the other bee diseases.

Article 2.9.6.7.

Veterinary Administrations of *importing countries* should require:

for honey-bee collected pollen, comb honey and propolis

the presentation of an *international veterinary certificate* attesting that these products come from:

1) a country or zone free from *Tropilaelaps* infestation; or

2) a country or zone with an official control programme for *Tropilaelaps* infestation, and have been held away from contact with live honey bees for more than 7 days prior to shipment.

Appendix XIX

APPENDIX 3.4.2.

OFFICIAL PROGRAMMES FOR THE CONTROL OF HONEY BEE DISEASES

Community comments:
The Community can support this proposal provided the comments given below and in the text are taken into account.
Not all veterinary services are responsible for this area of work and it is proposed that this is reflected by including "or other competent authorities" after *Veterinary Administration or Veterinary Authority* in the text as appropriate.

Article 3.4.2.1.

Countries wishing to implement an official programme for the control of any of the honey bee diseases mentioned in the *Code* should include in the programme the following:

a) an organisation for permanent health surveillance;

b) an official laboratory for diagnosis of the disease;

c) notification of the disease or any suspicion thereof;

d) *Veterinary Authority* responsability for all beehives located in the country;

e) annual random surveys to detect the potential presence of the disease within the honey bee population;

f) a requirement for periodic inspection of all beehives for the disease;

g) a requirement to either treat or destroy any beehives found to be infected with the disease;

h) controls, as relevant according to the disease, over the movement of, and international trade in, honey bees, drones, brood combs, used equipment associated with beekeeping, honey, honey bee-collected pollen, propolis and royal gelly;

Community comments:
A requirement for a contingency plan when disease is diagnosed should also be introduced so as to ensure proper controls and follow-up in particular in the neighbouring sites where hives are in use is carried out. Following disease confirmation. The word 'gelly' throughout should be replaced by "jelly".

i) measures for cleaning, *disinfection* and *disinsectisation* of apicultural equipment;

Community comment
Community proposes to replace "*disinsectisation*" by *"disinfestation"*

j) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 3.4.2.2.

Organisation for permanent official sanitary surveillance of apiaries

Permanent official sanitary surveillance of apiaries should be under the authority of the *Veterinary Administration* and should be performed either by representatives of the *Veterinary Authority* or by representatives of an approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.

The official surveillance service thus established should be entrusted with the following tasks:

1. visit apiaries:

    a) annual visits during the most appropriate periods to detect the disease;

    b) unexpected visits to apiaries where breeding or transport operations are carried out for trade or transfer to other zones within the country or to *importing countries*, or any other purpose whereby the disease could be spread, as well as to apiaries located in the vicinity;

    c) special visits for sanitary surveillance to sectors where apiaries are producing stock or products for export purposes;

2. collect the samples required for the diagnosis of the disease and despatch of them to an official laboratory; the laboratory should have the mandatory obligation to communicate the results of its examinations within the shortest delay to the *Veterinary Authority*;

3. apply sanitary measures, comprising, in particular, treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of infected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any *outbreak* of a the disease.

Article 3.4.2.3.

Obligations of beekeepers

Bee-keepers should be required to:

1. immediately notify the *Veterinary Authority* of any suspicion of the disease of bees in the apiary and in other apiaries in the vicinity;

2. not introduce into the apiary any bee (including larval stages) or apicultural material or product originating from another apiary unless health control has been previously performed by the *Veterinary Authority*;

3. apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen honey bees and accompanying bees;

4. collect and send to the official laboratory, at the times specified by the legislation applicable to the disease, samples from breeding material, brood-combs, queen-bees and bees (including possibly separately raised accompanying bees), as relevant.

Article 3.4.2.4.

Recommendations concerning sanitation and disinfection of apicultural equipment

Veterinary Administrations should regulate the use of products and means for sanitation and *disinfection* of apicultural equipment, taking into account the following guidelines.

1. Any apicultural equipment which has been recognised as being infected by the disease should be subjected to sanitary measures ensuring the elimination of pathogens.

2. In all cases, these measures comprise the initial cleaning and scraping of the equipment, followed by sanitation or *disinfection* according to the disease concerned.

3. The kind of equipment (hives, small hives, combs, extractor, small equipment, appliances for handling or storage) shall also be taken into account in the choice of procedures to be applied.

4. Infected or contaminated equipment which cannot be subjected to the above-mentioned measures must be destroyed, preferably by burning.

5. The products and means used for sanitation and *disinfection* shall be recognised as being effective by the *Veterinary Administration* and should be used in such a manner as to exclude any risk of soiling the equipment which could eventually affect the health of honey bees or adulterate the products of the hive.

6. When these procedures are not performed, the products shall be kept away from the bees and sheltered from any contact with apicultural equipment and products.

7. Waste water from the cleaning, sanitation and *disinfection* of apicultural equipment shall be kept away from the bees at all times and disposed of in a sewer or in an unused well.

Article 3.4.2.5.

Preparation of international veterinary certificates for export

International veterinary certificates relating to honey bees, drones, brood combs, used equipment associated with beekeeping, honey, honey bee-collected pollen, propolis and royal gelly should be prepared in accordance with the principles of certification provided for in Chapter 1.2.2.

Community comments:
The wording above should be added to by the following wording "….honey, honey bee-collected pollen, propolis and royal jelly only when intended for use in apiculture….." If this is not done then all honey for human consumption will need a veterinary certificate and this is excessive.

Model *international veterinary certificates* are presented in Part 4 of the *Code*.Appendix XX

CHAPTER 2.1.8

RIFT VALLEY FEVER

Community comments:

The Community supports this proposal but would like the comments below to be taken on board.

Article 2.1.8.1.

For the purposes of this *Code*, the *infective period* for Rift Valley fever (RVF) shall be 30 days.

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

The historic distribution of RVF is the African continent, Madagascar and the Arabian Peninsula.

Countries or zones within the historic distribution of RVF or adjacent to those that are historically infected should be subjected to surveillance.

Epidemics of RVF may occur in infected areas after flooding. They are separated by inter-epizootic periods that may last for several decades in arid areas. During inter-epidemic periods the prevalence of infection in humans, animals and mosquitoes can be difficult to detect.

In the absence of clinical disease, the RVF status of a country or zone within the historically infected regions of the world should be determined by a surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or zone at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epizootics have recently occurred.

Article 2.1.8.2.

RVF infection-free country or zone

A country or a zone may be considered free from RVF infection when the disease is notifiable in humans and animals throughout the country and either:

1) the country or zone lies outside the historically infected regions, or countries or zones adjacent to historically infected regions, or

2) a surveillance and monitoring programme as described in Article 2.1.8.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or zone during the past 10 years.

The provisions of the last paragraph of Article 2.1.8.1. may need to be complied with on a continuous basis in order to maintain freedom from infection, depending on the geographical location of the country or zone.

A RVF infection-free country or zone in which surveillance and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of permanently marked seropositive animals or those destined for direct slaughter.

Article 2.1.8.3

RVF infected country/zone free of disease

A RVF disease-free country or zone is a country/zone that is not infection-free (2.1.8.2) but in which disease has not occurred in man or animals in the last six months.

Community comments:
The period of 6 months seems rather short and there is no relation to climatic changes during this period. This can be compared to article 2.1.8.8. 2) where consideration to the climatic changes during the period is taken into account. The Community proposes the following new wording:

"A RVF disease-free country or zone is a country/zone that is not infection free (2.1.8.2) but in which disease has not occurred in man or in animals the last six months provided that climatic changes predisposing to *outbreaks* of RFV have not occurred during this time."

Article 2.1.8.4

RVF infected country/zone with disease

A RVF infected country/zone with disease is one in which clinical disease in humans or animals has occurred within the last 6 months.

Article 2.1.8.5

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

1) live ruminants and other RVF susceptible animal species;

Community comments:
For clarity it should be specified exactly what are the other RVF susceptible animals

2) meat and meat products of domestic and wild ruminants.

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

Article 2.1.8.6.

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

for ruminants and other RVF susceptible animals

Community comments:
For clarity it should be specified exactly what are the other RVF susceptible animals

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

1) were kept in a RVF free country or zone since birth or for at least 30 days prior to shipment, and

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

Article 2.1.8.7.

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

for meat and meat products of domestic and wild ruminants

the presentation of an *international veterinary certificate* attesting that the products are derived from animals which remained in the RVF infection free country/zone since birth or for the last 30 days

Article 2.1.8.8.

When importing from RVF infected country/zone free of disease, *Veterinary Administrations* should require:

for ruminants and other RVF susceptible herbivores

Community comments:
For clarity it should be specified exactly what are the other RVF susceptible herbivores and in the previous articles animals are are referred to. Consisitency in this wording is also required.

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

1) showed no evidence of RVF on the day of shipment;

2) were kept in a RVF infected country/zone free of disease since birth or for the last 6 months providing that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time;

OR

3) were vaccinated against RVF at least 21 days prior to shipment with modified live virus vaccine

OR

4) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquitoes between quarantine and *place of shipment*

Community comments:
The Community is concerned that this requirement is difficult to ensure in practice and would like some guidelines to be drawn up concerning mosquito proofing and protection from mosquitoes between quarantine and place of shipment. The Community would like to remind the OIE that this point has been raised during the reviews of the Bluetongue Chapter.

AND

5) did not transit through an infected zone with disease during transportation to the *place of shipment*.

Article 2.1.8.9

When importing from RVF infected countries or zones without disease, *Veterinary Administrations* should require:

for meat and meat products of domestic and wild ruminants

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

1) the products are derived from animals which:

   a) remained in the RVF disease free country/zone since birth or for the last 30 days

   b) were slaughtered in an *approved abattoir* and were subjected to ante-mortem and post-mortem inspections for RVF with favourable results

2) the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter.

Community comments:
The Community wonders if a maximum temperature should also be included for hygiene purposes such as below +10°C.

Article 2.1.8.10.

When importing from a RVF infected country/zone with disease, *Veterinary Administrations* should require:

for ruminants and other RVF susceptible herbivores

Community comments:
For clarity it should be specified exactly what are the other RVF susceptible herbivores and in the previous articles animals are are referred to. Therefore consisitency in this wording is also required.

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

1) showed no evidence of RVF on the day of shipment;

2) were vaccinated against RVF at least 21 days prior to shipment with modified live virus vaccine

OR

3) held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquito attack between quarantine and *place of shipment*

Community comments:
The Community is concerned that this requirement is difficult to ensure in practice and would like some guidelines to be drawn up concerning mosquito proofing and protection from mosquitoes between quarantine and place of shipment. The Community would like to remind the OIE that this point has been raised during the reviews of the Bluetongue Chapter. In addition the word "were" needs to be inserted before 'held in a mosquito-proof….'

Article 2.1.8.11

When importing from a RVF infected country/zone with disease, *Veterinary Administrations* should require:

for meat and meat products of domestic and wild ruminants

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

1. are from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for RVF with favourable results; and

2. have been fully eviscerated and submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter.

Community comments:
The Community wonders if a maximum temperature should also be included for hygiene purposes such as below +10°C.

CHAPTER 1.1.3.

NOTIFICATION AND EPIDEMIOLOGICAL INFORMATION

Community comments:

The text proposed can be supported but it would like the comments given in the text below taken on board.
The Community fully agrees that it is important that the speed of notification of diseases is linked, inter alia, to the health situation of the reporting country. Any listed disease must be reported urgently if a new outbreak occurs in a previously "free" country or zone. This will ensure that importing countries with a "free" status can take appropriate measures and that such measures taken will reflect the health situation in the importing country in accordance with WTO/SPS principles.
It is important that this notification procure must come into effect at the same tome as the establishment of a new single list

Article 1.1.3.1.

For the purposes of the *Code* and in terms of Articles 5, 9 and 10 of the Statutes, every Member Country of the OIE shall recognise the right of the *Central Bureau* to communicate directly with the *Veterinary Administration* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Administration* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Administration* shall be regarded as having been sent by the country concerned.

Article 1.1.3.2.

1. Countries shall make available to other countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases and to assist in achieving better worldwide control of these diseases.

2. To achieve this, countries shall comply with the *notification* requirements specified in Article 1.1.3.3.

3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the format given in *Animal Health Status Reports* 1 to 3.

4. Recognising that scientific knowledge concerning the relationship between disease agents and diseases is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of a disease, countries shall ensure through their reports that they comply with the spirit and intention of paragraph 1 above.

5. In addition to notifying new findings in accordance with Article 1.1.3.3., countries shall also provide information on the measures taken to prevent the spread of diseases; including quarantine measures and restrictions on the movement of *animals*, animal products and biological products and other miscellaneous objects which could by their nature be responsible for transmission of disease. In the case of diseases transmitted by vectors, the measures taken against such vectors shall also be specified.

Article 1.1.3.3.

Veterinary Administrations shall send to the OIE:

1. *notification* by telegram, fax or e-mail, within 24 hours, of any of the following events:

   a) for [*List A*] diseases listed by the OIE, the suspicion or confirmation of the first occurrence or re-occurrence of a disease, if the country or zone of the country was previously considered to be free from that particular disease;

   [b) for *List A* diseases, important new findings which are of epidemiological significance to other countries;]

   b) for [*List A*] diseases listed by the OIE, [a provisional diagnosis] evidence of changes in the characteristics of a disease (including host range, pathogenicity, strain) if this represents important new information of epidemiological significance to other countries, in particular if a disease may have a zoonotic impact;

Community comments:
The Community would like clarification on what exactly is meant by 'evidence of changes in the characteristics'.

   c) for diseases not listed by the OIE [in *List A*], if there [are new findings which are of] is information of exceptional epidemiological significance to other countries, in particular if a disease may have a zoonotic impact;

   in deciding whether findings justify immediate *notification*, countries must ensure that they comply with the obligations of Section 1.2. (especially Article 1.2.1.3.) of the *Code*, to report developments which may have implications for *international trade*;

2. weekly reports by telegram, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the disease has been eradicated or the situation has become sufficiently stable that monthly reporting under point 3 will satisfy the obligation of the country to the OIE;

3. monthly reports on the absence or presence, and evolution of diseases listed by the OIE [in *List A*,] and [findings] information of epidemiological significance [importance] to other countries [with respect to diseases which are not in *List A*];

4. annual reports on all diseases listed by the OIE [in *List A* and *List B*] and any other [diseases considered to be of socio-economic importance or of major veterinary interest] information of epidemiological significance to other countries.

Community comments:
Paragraphs 3 and 4 appear to require the same reports, monthly and yearly, respectively. It might be clearer if the 4th paragraph stated that the monthly reports referred to in paragraph 3 should be summarised in yearly reports at a certain date each year. It is clear that the annual report should contain additional information and in order to clarify exactly what is required a reference to the format of the annual report should be made.

Article 1.1.3.4.

1. The *Veterinary Administration* of a territory in which an *infected zone* was located shall inform the *Central Bureau* when this zone is free from the disease.

2. An *infected zone* for a particular disease shall be considered as such until a period exceeding the *infective period* specified in the *Code* has elapsed after the last reported *case*,

and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the disease. These measures will be found in detail in the various chapters of Section 2.1. of this *Code*.

3. A country may be considered to regain freedom from a specific disease when all conditions given in the corresponding chapters of Section 2.1. of this *Code* have been fulfilled.

4. The *Veterinary Administration* of a country which sets up one or several *free zones* shall inform the OIE giving necessary particulars and indicating clearly the location of the zones on a map of the country.

Community comments:
The term 'necessary particulars' needs to be further specified, for example criteria for the freedom status and requirements for maintaining the status etc.

Article 1.1.3.5.

Veterinary Administrations shall communicate to the OIE the provisions of their quarantine regulations and importation and exportation animal health regulations.

They shall also communicate any amendments to their regulations as soon as they are made and, at the latest, before the annual General Session of the OIE International Committee.

Community comments:
Under WTO/SPS rules there is a requirement to notify changes as soon as possible and therefore the words 'and, at the latest before ….' weaken this requirement. The Community proposes that these words be deleted.

Article 1.1.3.6.

1. The *Central Bureau* shall send by telegram, fax, e-mail or *Disease Information* to the *Veterinary Administrations* concerned, all *notifications* received as provided in Articles 1.1.3.2. to 1.1.3.4.

2. The *Central Bureau* shall despatch by the OIE *Bulletin* the number of new *outbreaks* of listed [*List A*] diseases.

3. The *Central Bureau*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of the *Code* and its effects on *international trade*.

Community comments:
It should be stated that some sort of recognition of receipt of the notfication shall be ensured, otherwise communication of a disease report only by e-mail might lead to reports getting lost in cyberspace. The method of communication by '*Disease Information*' needs to be explained, as no definition is offered in this chapter. In addition the word dispatch is misspelled and the words "information on" should be inserted before the phrase '…number of new outbreaks..'

Article 1.1.3.7.

All telegrams or faxes sent by *Veterinary Administrations* in pursuance of Articles 1.1.3.3. and 1.1.3.6. shall receive priority in accordance with the circumstances. Communications by telephone, telegram or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic disease, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

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CHAPTER 1.2.1.

GENERAL OBLIGATIONS

Community comments:
The text proposed can be supported but the Community.

Article 1.2.1.1.

International trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable risks to human and animal health.

Because of the likely variations in animal health situations, various options are offered by the *Code*. The animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements which have to be met for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Administrations* of Member Countries should base their import requirements on the OIE standards, guidelines and recommendations.

These requirements should be included in the model certificates approved by the OIE which form Part 4 of this *Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Administrations* of *importing* and *exporting countries* is useful and may be necessary. It enables the setting out of the exact requirements so that the signing veterinarian can, if necessary, be given a note of guidance explaining the understanding between the *Veterinary Administrations* involved.

When Members of a *Veterinary Administration* wish to visit another country for matters of professional interest to the *Veterinary Administration* of the other country, the latter should be informed.

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 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*.

Article 1.2.1.3.

Responsibilities of the exporting country

1. An *exporting country* should be prepared to supply the following information to *importing countries* on request:

   a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *free zones* of listed [*List A* or *List B*] diseases, including the regulations and procedures in force to maintain its free status;

   b) regular and prompt information on the occurrence of transmissible diseases;

   c) details of the country's ability to apply measures to control and prevent the relevant listed diseases [*List A* diseases and, where appropriate, *List B* diseases];

   d) information on the structure of the *Veterinary Services* and the authority which they exercise;

   e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.

2. *Veterinary Administrations* of *exporting countries* should:

   a) have official procedures for authorisation of certifying veterinarians, defining their functions and duties as well as conditions covering possible suspension and termination of the appointment;

   b) ensure that the relevant instructions and training are provided to certifying veterinarians;

   c) monitor the activities of the certifying veterinarians to verify their integrity and impartiality.

3. The Head of the *Veterinary Service* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 1.2.1.4.

Responsibilities in case of an incident occurring after importation

International trade involves a continuing ethical responsibility. Therefore, if within the recognised *incubation periods* of the various diseases subsequent to an export taking place, the *Veterinary Administration* becomes aware of the appearance or reappearance of a disease which has been specifically included in the *international veterinary certificate*, there is an obligation for the Administration to notify the *importing country*, so that the imported stock

may be inspected or tested and appropriate action be taken to limit the spread of the disease should it have been inadvertently introduced.

Equally, if a disease condition appears in imported stock within a time period after importation consistent with the recognised *incubation period* of the disease, the *Veterinary Administration* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the disease in a previously free herd. The *Veterinary Administration* of the *importing country* should be informed of the result of the investigation since the source of infection may not be in the *exporting country*.

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[ ] deleted

ANNEX Part 2

FISH DISEASES COMMISSION

Appendix I

MEETING OF THE OIE FISH DISEASES COMMISSION

Paris, 24–28 June 2002

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Agenda

1. Member Country comments on the report of the previous FDC meeting (January 2002)

2. *International Aquatic Animal Health Code*

2.1. Amendments to the *International Aquatic Animal Health Code*

3. *Diagnostic Manual for Aquatic Animal diseases*

3.1. Schedule for the preparation of the fourth edition of the *Manual*

3.2. Amendments to the *Diagnostic Manual for Aquatic Animal Diseases*

4. Joint meeting with the International Animal Health Code Commission

4.1. Disease notification

4.2. Development of mechanisms for OIE official recognition of 'free country' or 'free zone'

5. The role and activities of the OIE in the field of aquatic animals

5.1. Publications

6. OIE Reference Laboratories – role and functions

6.1. Guidelines for applicants for Reference Laboratory status

6.2. New applications for Reference Laboratory status/Reference Expert changes

7. Any other business

7.1. Cooperation and partnership with other international organisations and regional organisations

7.2. Status of FDC Internet activities – FDC Web site

7.3. Collaborating Centre – status of new version of disease database

7.4. Amphibian disease issues

7.5. Ad hoc Group on Risk Analysis

7.6. Report of the meeting of the Presidents of the OIE Specialist Commissions

7.7. Animal Welfare Mandate of the OIE (Resolution No. XIV)

7.8. Date of next meeting: 6–14 January 2003

Appendix II

MEETING OF THE OIE FISH DISEASES COMMISSION

Paris, 24–28 June 2002

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1.1. List of participants

MEMBERS

Prof Tore Hästein *(President)*

National Veterinary Institute, Ullevålsveien 68,
P.O. Box 8156 Dep., 0033 Oslo

NORWAY

Tel.: (47-23) 21.61.50

Fax: (47-23) 21.60.01

email: tore.hastein@vetinst.no

Dr Eva-Maria Bernoth

Office of the Chief Veterinary Officer, Agriculture, Fisheries and Forestry – Australia, GPO Box 858, Canberra ACT 2601, AUSTRALIA

Tel.: (61-2) 62.72.43.28

Fax: (61-2) 62.73.52.37

email: eva-maria.bernoth@affa.gov.au

Dr Christian Michel *(Vice-President)*

Laboratoire de Virologie et d'Immunologie moléculaires, Centre de Recherches de Jouy-en-Josas, Domaine de Vilvert, 78352 Jouy en Josas Cedex

FRANCE

Tel.: (33-1) 34.65.25.86

Fax: (33-1) 34.65.22.73

email: michel@jouy.inra.fr

2. PROF. DONALD V. LIGHTNER

Aquaculture Pathology Section, Department of Veterinary Science, University of Arizona, Building 90, Room 202, Pharmacy/Microbiology, Tucson, AZ 85721, USA

Tel.: (1.520) 621.84.14

Fax: (1-520) 621.48.99
email: dvl@u.arizona.edu

Prof. Barry Hill *(Secretary General)*

CEFAS – Weymouth Laboratory

Barrack Road, The Nothe

Weymouth, Dorset DT4 8UB

UNITED KINGDOM

Tel.: (44-1305) 20.66.26

Fax: (44-1305) 20.66.27

email: b.j.hill@cefas.co.uk

OTHER PARTICIPANT

Dr Franck

Berthe

IFREMER, Laboratoire Génétique et Pathologie

BP 133, 17390 La Tremblade

FRANCE

Tel.: (33-5) 46.36.98.43

Fax: (33-5) 46.36.37.51

email:fberthe@ifremer.fr

OIE CENTRAL BUREAU

Dr Bernard Vallat

Director General

12 rue de Prony, 75017 Paris

FRANCE

Tel.: (33-1) 44.15.18.88

Fax: (33-1) 42.67.09.87

email: oie@oie.int

Dr James Pearson

Head, Scientific & Technical Dept

email: je.pearson@oie.int

Dr Alejandro Schudel

Head, Scientific & Technical Dept

email: a.schudel@oie.int

Dr Dewan Sibartie

Deputy Head, Scientific & Technical Dept
email: d.sibartie@oie.int

Ms Sara Linnane

Scientific editor

email: s.linnane@oie.int

GUEST Participant

Dr Andrew Cunningham

Head of Wildlife Epidemiology, ZSL Institute of Zoology

Regent's Park, London NW1 4RY, UNITED KINGDOM

Tel.: (44.207) 449.66.74

Fax: (44.207) 586.14.57

email: andrew.cunningham@ioz.ac.uk

SECTION 1.3.

[VETERINARY] OBLIGATIONS AND ETHICS [AND CERTIFICATION FOR] IN INTERNATIONAL TRADE

Community comments:

The Community supports the text proposed in this Appendix, provided that the general remarks below and the specific comments included in the text are taken into account.

The Community questions the justification for the use of "Competent Authority" and "Veterinary Administration" in the text and proposes that only "Veterinary Administration" is used through out the AAHC. The term "Competent Authority" should in that case be covered by the definition of "Veterinary Administration". This appears to be the case in the AAHC as it stands today and consistency with the AHC is preferable.

The same question is raised as regards "certifying veterinarian" and "(other) certifying officials". Preferably, only the term "certifying official" should be used and all different categories of qualified personal should be covered by its definition.

In general, the Community would like the FDC to review the whole text in order to ensure a consistent use of terminology and simplify the text where possible.

CHAPTER 1.3.1
GENERAL [REQUIREMENTS] OBLIGATIONS

Article 1.3.1.1.

International trade in *aquatic animals* and *aquatic animal products depends* on a combination of health factors that should be taken into account to ensure unimpeded trade, without incurring unacceptable *risks* to human and aquatic animal health.

Because of the likely variations in [sanitary] aquatic animal health situations, various options are offered by the *Code* [to importing countries and only by considering]. The [sanitary] aquatic animal health situation in the *exporting* [and] *country, in* the *transit country* or *countries* [can the importing country precisely state the requirements that are to be met for imports] and in the *importing country* should be considered before determining the requirements that have to be met for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Competent Authorities* of Member Countries should base their import requirements on the OIE standards, guidelines and recommendations.

These requirements [are mentioned] should be included in the model *international aquatic animal health* certificates approved by the OIE, which form Part 6 of this *Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Competent Authorities* of *importing* and *exporting countries* is useful and may be necessary. [This makes it possible to set] It enables the setting out of the exact requirements so that the signing veterinarian or other *certifying official* can, if necessary, be given a note of guidance explaining the understanding between the *Competent Authorities* involved.

When Members of [the] a *Competent Authority* [of a country] wish to visit another country for matters of professional interest to the *Competent Authority* of the other country, the latter should be informed.

Article 1.3.1.2.

Responsibilities of the importing country

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

2. The *international aquatic animal health certificate* should not include requirements for the exclusion of pathogens or *aquatic animal diseases* that 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. [If the Competent Authority tranmits] The transmission by the *Competent Authority* or *Veterinary Administration* of certificates or [communicates] the communication of import [permit] requirements to persons other than the *Competent Authority* or *Veterinary Administration* of another country[, then] necessitates that copies of these documents [must] be also sent to the *Competent Authority* or Veterinary Administration [of that country].

   This [essential requirement] important procedure avoids delays and difficulties that may arise between traders and *Competent Authorities*/*Veterinary Administrations* when the authenticity of the certificates or permits is not established.

   This information is usually the responsibility of *Veterinary Administrations* or other *Competent Authorities* [i.e. those having authority at a national level]. However, it can be the responsibility of [a local competent body directly responsible for the application of aquatic animal health measures] Veterinary Authorities or other *Competent Authorities* at the place of origin of the *aquatic animals* when it is agreed that the issue of certificates does not require the approval of the *Veterinary Administration* or other *Competent Authorities*.

Article 1.3.1.3.

Responsibilities of the exporting country

1. An *exporting country* should be prepared to supply the following information to *importing countries* on request:

a) information on the aquatic animal health [status] situation and national aquatic animal health information systems to determine whether that country is free or has *zones* that are free from *diseases notifiable to the OIE* or *other significant diseases*, including the regulations and procedures in force to maintain its free status;

b) regular and prompt information on the occurrence of transmissible *diseases;*

c) details of the country's ability to apply measures to control and prevent *diseases notifiable to the OIE* and, where appropriate, *other significant diseases;*

d) information on the structure of the *Competent Authority* and the authority that they exercise;

e) technical information, particularly on biological tests and vaccines applied in all or part of the national *territory*.

Community comments:

In 1.3.1.3, 1.f) (below) it is unclear what is meant with "details". The requirements should be specified further.

f) details of the country or location of harvest or production of the product being exported.

2. *Competent Authorities* of *exporting countries* should:

a) have official procedures for the authorisation of *certifying officials,* defining their functions and duties as well as conditions covering possible suspension and termination of their appointment;

b) ensure that the relevant instructions and training are provided to *certifying officials;*

c) monitor the activities of the *certifying officials* to verify their integrity and impartiality.

The Head of the *Competent Authority* of the *exporting country* is ultimately accountable for the *certifying official* used in *international trade*.

Article 1.3.1.4.

Responsibilities in case of an incident occurring after importation

Community comments:
In Article 1.3.1.4, it should also be required that information about appearance of other diseases of significant importance (as emerging diseases) is exchanged between the Competent Authorities concerned.

[Additional responsibilities of exporting and importing countries]

International trade involves a continuing ethical responsibility. Therefore, if within the [normal] recognised *infective periods* of the various *diseases* subsequent to an export taking place, the *Competent Authority* becomes aware of the appearance or reappearance of a *disease* [in an aquatic animal population] that has been specifically included in the *international aquatic animal health certificate*, [or in bilateral agreements,] there is an obligation for the *Authority* to notify [this fact to] the *importing country*, so that the imported *aquatic animals* may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.

Equally, if a disease condition appears in imported [stocks of] *aquatic animals* within a time period after importation consistent with the recognised *incubation period* of the disease, the *Competent Authority* of the *exporting country* should be informed so as to enable an investigation to be made, because this may be the first available information on the occurrence of the *disease* in a previously free aquatic animal population. The *Competent Authority* of the *importing country* [is entitled to] should be informed of the result of the investigation because the source of infection may not be in the *exporting country*.

[ ] deleted

CHAPTER 1.3.2.

[PRINCIPLES OF] CERTIFICATION PROCEDURES

Article 1.3.2.1.

Protection of the professional integrity of the certifying veterinarian or other certifying officials

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the *certifying official* or other certifying veterinarian must be respected and safeguarded.

It is essential not to include in the requirements additional specific matters that cannot be accurately and honestly signed by a *certifying official* or other veterinarian. For example, these requirements should not include certification of an area as being free from [non-notifiable] *diseases* that are not notifiable in that country, the occurrence of which the signing *certifying official* or other veterinarian is not necessarily informed about. Equally, to [require] ask for certification for events that will take place after the document is signed is unacceptable when these events are not under the direct control and supervision of the signing *certifying official* or other veterinarian.

Certification of freedom from *diseases* based on purely clinical freedom and aquatic animal population history [may be] is of limited value. This is also true of *diseases* for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The purpose of the note of guidance referred to in [paragraph 2 above] Article 1.3.1.1. is not only to inform the signing *certifying official* or other veterinarian but also to safeguard [his/her] professional integrity.

Article 1.3.2.2.

Procedures for the preparation of international aquatic animal health certificates

[Certification procedures]

Certificates should be drawn up in accordance with the following principles:

1. Paper certificates should be pre-printed, if possible on one sheet of paper, serially numbered, and issued by the *Competent Authority* on officially headed notepaper and, if possible, printed using techniques that prevent forgery. Electronic certification procedures should include equivalent safeguards.

2. They should be written in terms that are as simple, unambiguous and easy to understand as possible, without losing their legal meaning.

3. If so required, they should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the *certifying official*.

4. They should require appropriate identification of [shipments of] *aquatic animals* and *aquatic animal products* except where this is impractical (e.g. *eyed eggs*).

5. They should not require a *certifying official* to certify matters that are outside his/her knowledge or that he/she cannot ascertain and verify.

6. Where appropriate, they should be accompanied, when presented to the *certifying official*, by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

7. Their text should not be amended except by deletions that must be signed and stamped by the *certifying official*. The signature and stamp must be in a colour different to that of the printing of the certificate.

8. Only original certificates are acceptable.

Article 1.3.2.3.

Certifying officials

Certifying officials should:

1. be authorised by the *Competent Authority* of the *exporting country* to sign *international aquatic animal health certificates*;

2. [sign certificates only at the appropriate time; in particular, they should not sign blank or incomplete certificates, or certificates relating to *aquatic animals* or *aquatic animal products* that they have not inspected or that have passed out of their control] only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;

3. sign only at the appropriate time [ensure before signing that] certificates that have been completed fully and correctly; where a certificate is signed on the basis of [another support certificate or attestation] supporting documentation, the *certifying official* should be in possession of that documentation before signing;

4. have no [financial] conflict of interest in the commercial aspects of the *aquatic animals* or *aquatic animal products* being certified and [not be in the direct employment of the owner of the *aquatic animals* or *aquatic animal products*] be independent from the commercial parties.

Article 1.3.2.4.

Electronic certification

1. [International aquatic animal health certificates] Certification may be provided by electronic documentation sent directly from the *Competent Authority* of the *exporting country* to the *Competent Authority* of the *importing country*. Normally such systems also provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The *certifying official* must have access to all information such as laboratory results and aquatic animal identification data.

2. Electronic certificates should carry the same information as conventional certificates.

3. [Electronic certificates must be secure] The *Competent Authority* must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4. The *certifying official* must be officially responsible for the [security] secure use of his/her electronic signature. This may be by a personal identification number or a similar secure mechanism.

[Article 1.3.2.4.

Community comments:

The Community questions the exclusion of Article 1.3.2.4.

Harmonisation of methods

In as much as the OIE has approved or agreed standards concerning:

a) tests for the diagnosis of *diseases* of *aquatic animals;*

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

c) *disinfection;*

d) treatments intended to destroy viruses, bacteria or spores in *aquatic animal products* coming from countries considered to be infected with certain *diseases;*

these standards (included in the *Manual* or in this *Code* as Appendices) should be adopted by *Competent Authorities* with respect to *international trade* in *aquatic animals* and *aquatic animal products*.]

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[ ] deleted

Appendix IV

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Article 1.1.1.1.

Community comments:

The Community supports that new general definitions are laid down as needed, yet it proposes the definition of *"Emerging disease"* to read as follows:

"Emerging disease means a newly recognised significant *disease*, the cause of which may or may not yet be established, that has the potential to spread within and between populations - for example by way of trade in *aquatic animals* and/or *aquatic animal products* or by *passive transmission*".

For the purposes of this *Code:*

. . .

Emerging disease

means a newly recognised significant *disease*, the cause of which may or may not yet be established, that has the potential to be spread by trade in *aquatic animals* and/or *aquatic animal products*.

Infection

means the presence of the infectious agent in the host.

Quarantine

means maintaining a group of *aquatic animals* in isolation with no direct or indirect contact with other *aquatic animals*, in order to undergo observation for a specified length of time and, if appropriate, testing and treatment.

Vertical transmission

means the transovarian transmission of a pathogen from a parent *aquatic animal* to its progeny.

. . .

Community comments:

The Community supports the preparation of this Appendix, provided that the specific comments included in the text are taken into account.

SECTION 1.1.

GENERAL DEFINITIONS

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

Community comments:

The Community supports that the definition of "*fallowing*" is changed as needed, yet proposes the following wording:

***"Fallowing* means for disease management purposes, an operation where an *aquaculture establishment* is emptied of *aquatic animals* susceptible to a *disease* of concern, or known to be capable of acting as carriers of the pathogen. For *aquatic animals* of unknown susceptibility and those agreed not to be capable of acting as carriers of the pathogen of concern, decisions on *fallowing* should be based on a *risk assessment*."**

For the purpose of this *Code:*

. . .

2.1. Fallowing

means for disease management purposes, an operation where an *aquaculture establishment* is emptied of *aquatic animals* susceptible to a *disease* of concern. For these *aquatic animals* likely to be capable of acting as carriers of a *disease* of concern, decisions on *fallowing* should be based on a *risk assessment.*

[means a period during which aquatic animal premises are left empty (for *disease agents* or parasites to die or be killed by *disinfection*)]

. . .

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[ ] deleted

CHAPTER X.X.X.

GUIDELINES FOR FALLOWING IN AQUACULTURE

Community comments:

The Community would propose the following changes to the text of Article X.X.X.1: Second paragraph, last sentence should end as follows: "…be subjected to a required period of fallowing - if necessary synchronised."

Article X.X.X.1.

3. INTRODUCTION

Gaps in aquaculture production at the same location are commonly recognised to be value in resting or restoring the local environment. As part of this strategy, *fallowing* can break re-infection cycles by removing loci of a *disease* from a farm. Consequently, *fallowing* is often carried out as a regular disease management measure in aquaculture, especially prior to the introduction of new populations of *aquatic animals* into a previously used site. In order to promote improved health in aquaculture, the *Competent Authority* responsible for aquatic animal health in a country may encourage the use of *fallowing* as a routine management strategy for many *diseases*. Account should be taken of the likely beneficial effects of *fallowing* in proportion to the economic costs involved. The *Competent Authority* should also consider such factors as the level of risk to the local and national aquaculture operations, previous knowledge of the severity of a disease(s), the *infective period* and distribution of the *disease agent*(s), the socioeconomic conditions, and benefits pertaining to the general aquatic resources.

However, where an official *stamping-out policy* is being carried out for a *disease* of concern, the *Competent Authority* should require that an infected *aquaculture establishment*, and all other *aquaculture establishments* in an officially established *infected zone*, be subjected to a required period of *fallowing*.

Article X.X.X.2.

Community comments:

The Community would propose that the text in Article X.X.X.2, point a) reads as follows:

"Defining the disease circumstances when fallowing or synchronised fallowing is required".

4.

5. LEGAL POWERS

In cases where *fallowing* may be a compulsory measure, for instance in the establishment or restoration of a disease *free zone*, countries should establish a legal framework for the implementation of *fallowing* procedures in *aquaculture establishments*. Legal provisions could include:

a) Defining the disease circumstances when *fallowing* is required.

b) Defining mechanisms based on *risk assessment* where individual disease-specific measures may be determined, including *disinfection* and the length of the *fallowing* period prior to the re-introduction of *susceptible species.*

c) Following permission by the *Competent Authority* to restock with *susceptible species*, defining a period of *surveillance* and *diagnosis* to verify freedom from the specified *disease.*

Article X.X.X.3.

Community comments:

The Community would propose that an additional point (c) is included in Article X.X.X.3, which should read as follows:

"c) As appropriate, removal of other species".

Accordingly, the former point c) is changed to point d) and should read:

"d) equipment and other materials contaminated or otherwise capable of harbouring the pathogen have either…"

Technical parameters for the implementation of a statutory fallowing plan

Fallowing of a farm should start immediately after:

a) removal of all *susceptible species* of *aquatic animals* for the *disease* of concern and

b) removal of all species capable of acting as carriers of the *disease* of concern and

c) equipment and other materials capable of harbouring infection have either been removed or subjected to *disinfection* to standards approved by the *Competent Authority.*

The length of the statutory *fallowing* period should be based on scientific evidence of the likelihood of a *disease agent* remaining infective outside its aquaculture host(s) in the local environment, at a level likely to cause an unacceptable risk of re-infection of the *aquaculture establishment*. Account should be taken of the extent of the *disease outbreak*, local availability of alternative hosts, the survival and infectivity characteristics of the *disease agent* and the local climatological, geographical and hydrographical factors. In

addition, the level of risk to the local aquaculture industry and wider aquatic resources may be included. A *risk assessment* approach should be used to determine the length of the *fallowing* period, using qualitative methods when available data are limited, and quantitative analysis to obtain deeper insight when possible.

Article X.X.X.4.

6. INSTRUCTIONS

Countries establishing *fallowing* procedures should develop a detailed set of instructions for *disinfection* of *aquaculture establishments* prior to *fallowing*. For this purpose, the instructions set out in Section 5.2, Appendices 5.2.2., 5.2.3. and 5.2.4. in this *Code* should be used as guidelines, taking into account current scientific knowledge on the efficacy of the treatments for the *disease agent* of concern.

Article X.X.X.5.

Community comments:

The Community would propose that Article X.X.X. 5, first paragraph, first sentence should read:

"No aquaculture establishment that have been under compulsory fallowing should be restocked until the…"

7.

8. RESTOCKING

All *aquaculture establishments* that have been under compulsory *fallowing* should not be restocked until the *fallowing* period has been completed and permission from the *Competent Authority* has been received. When restocking, care should be taken not to use stocks of *aquatic animals* that would compromise the objectives of the *fallowing* procedure.

To increase confidence in the effectiveness of the *fallowing* procedures, all farms subjected to compulsory *fallowing* should have a period of high level official *surveillance* after *susceptible species* have been restocked. The duration and intensity of the *surveillance* should be appropriate for the *disease* of concern and local conditions.

Appendix VI

CHAPTER 1.5.6.

MEASURES CONCERNING INTERNATIONAL TRANSFER OF AQUATIC ANIMAL PATHOGENS AND PATHOLOGICAL MATERIAL [AND BIOLOGICAL PRODUCTS]

Community comments:

The Community supports the preparation of this Appendix, provided that the specific comments included in the text are taken into account.

Furthermore, the Community would propose that the title Chapter 1.5.6. should read:

" Measures concerning international transport of aquatic animal pathogens and pathological material."

Article 1.5.6.1.

Objective

To prevent the introduction and spread of *aquatic animal diseases* caused by pathogens.

Article 1.5.6.2.

Introduction

The consequences of the introduction into a country of an infectious *disease* or an aquatic animal pathogen or new strain of pathogen from which it is currently free, are potentially very serious. This is because aquatic animal health and trade may all be adversely affected to a greater or a lesser degree. Countries will already have in place a range of measures, such as requirements for pre-import testing and *quarantine*, to prevent such introductions through the importation of live *aquatic animals* or *aquatic animal products*.

However, there is also the *risk* that *disease* may occur as a result of the accidental release of aquatic animal pathogens during international transfer of packaged materials. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied at national borders by prohibiting or controlling the importation of specified pathogens or *pathological material*, which may contain them.

Article 1.5.6.3.

Community comments:

The Community supports the proposal for a risk based import license from the relevant authority of the import country. However, the need for an import license in every case regardless of the risk the transport of pathogens or pathological material poses, may not be necessary. An import licence should be required if the consignment is considered to be a dangerous substance.

Furthermore, the Code should not refer to IATA only, as there are other relevant international transport associations as well. The text should reflect this situation, by inserting e.g. "*or other relevant transport associations*".

Importation of aquatic animal pathogens

The importation of any aquatic animal pathogen, *pathological material* [and biological products that may contain infectious agents causing the *diseases* listed in this *Code* should require specific authorisation by the *Competent Authority* of the *importing country,* with the conditions of importation described] or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the *risk* posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of dangerous goods as outlined in Article 1.5.6.4.

When considering applications to import *pathological material* from other countries, the authorities should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various *diseases* and the animal health situation of the country of origin. It may be advisable to require that material be pretreated before import to minimise the risk of inadvertent introduction of a pathogen.

Any material that does not satisfy [these] the applied conditions should be returned or sterilised together with its packing.

Article 1.5.6.4.

Community comments:

The Community proposes, in accordance with international transport rules, that the responsibility for proper packaging is placed upon the sender of the consignment in article 1.5.6.4.

The first paragraph of Article 1.5.6.4. may thereby read: "The safe transfer of an aquatic animal pathogen, with respect to the pathogen, the handlers and the environment, is primarily dependent on proper packaging, and it is the responsibility of the sender that this is done in accordance with current rules.

Furthermore, in relation to paragraph 5 of Article 1.5.6.4., the Community questions the requirement for the documentation to be taped to the outside of the secondary receptacle, and not to the outer package.

Packaging and documentation for transport

The safe transfer of an aquatic animal pathogen, with respect to the pathogen, the handlers and the environment, is primarily dependent on proper packaging.

8.1. Basic triple packaging system

The system consists of three layers as follows:

1. Primary receptacle: a labelled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage.

2. Secondary receptacle: a second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle. Sufficient additional absorbent material must be used to cushion multiple primary receptacles.

3. Outer shipping package: the secondary receptacle is placed in an outer shipping package, which protects it and its contents from outside influences such as physical damage, temperature fluctuations and water while in transit.

Ice or dry ice when used in a shipment must be placed outside the secondary receptacle. If wet ice is used it should be in a leak-proof container and the outer package must also be leak-proof. The secondary receptacle must be secured within the outer package to prevent damage after the refrigerant has melted or dissipated.

Dry ice must NOT be placed inside the primary or secondary receptacle because of the risk of explosions. The outer package must permit the release of carbon dioxide gas if dry ice is used. IATA Packing Instruction 904 must be observed for packages containing dry ice.

Documentation

Specimen data forms, letters and other types of information that identify or describe the specimen and also identify the shipper and receiver should be taped to the outside of the secondary receptacle, together with a copy of the recipient's import permit.

Article 1.5.6.5.

Any sender of aquatic animal pathogen(s) or *pathological material* must ensure that the proposed receiver has obtained the necessary import licence referred to in Article 1.5.6.3.

Article 1.5.6.6.

1. Every consignment of aquatic animal pathogens or *pathological material* [or biological products] should be notified [by the consigner to the consignee,] in advance by the sender to the intended recipient, giving the following information:

   a) exact nature of the [product] sample and its packaging;

   b) the number of packages sent and the marks and numbers enabling their identification;

c) date of despatch;

d) method of *transport* used for consignment of products (ship, aircraft, railway wagon or road vehicle).

2. The [consignee] recipient should notify the [consigner] sender of the receipt of each consignment of aquatic animal pathogen or *pathological material* [or *biological products*] on its arrival.

3. When a consignment that has been notified by the [consigner] sender fails to arrive by the anticipated date, the [consignee] intended recipient should notify the *Competent Authority* of the receiving country and, at the same time, the [consigner] sender in the country of origin, so that any necessary action can be taken for investigation to be made without delay.

[Article 1.5.6.3.

For the purposes of this *Code,* the sending of *pathological material* and *biological products* should be subject to the special rules concerning packaging stipulated for perishable biological material by the Universal Postal Convention established by the Universal Postal Union.

Article 1.5.6.4.

For the purposes of this *Code,* vaccines containing live attenuated microorganisms, or live attenuated (modified) viruses packaged or in bulk and sent in large quantities that render the conditions described in Article 1.5.6.3 inapplicable in practice, should be packed in such a way that no outside contamination is possible (solid, well-sealed internal containers, solid and securely fastened protective boxes or cases, a sufficient amount of absorbent material, and labels marked: Perishable biological products – Dangerous – Not to be opened during transportation).

Article 1.5.6.5.

1. Each receiving country should only accept vaccines for veterinary use for which a certificate is provided stating that the vaccines were officially controlled in the *exporting country*.

2. Vaccines for which the authorisation described in Article 1.5.6.1 has been made and whose identity and conformity with the certificates of origin have been verified, should be permitted entry.

3. However, if inspection of the consignment shows any change in the vaccines for veterinary use that could endanger the health of humans or *aquatic animals,* the *Competent Authority* of the receiving country should cause these vaccines to be seized and destroyed.]

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Community comments:

The Community supports the preparation of this Appendix, provided that the specific comments included in the text are taken into account.

SECTION 5.1.

BLOOD SAMPLING AND VACCINATION

APPENDIX 5.1.1.

HYGIENIC PRECAUTIONS

Article 5.1.1.1.

The use of needles and syringes in routine [veterinary] aquatic animal health work in *aquaculture establishments* for procedures such as blood sampling and vaccination should be carried out in a highly professional manner, ensuring that appropriate hygienic precautions are observed.

The intraperitoneal use of unsterilised needles or syringes in *aquatic animals* should be professionally unacceptable.

The use of unsterilised or contaminated equipment (needles, syringes, etc.) or products is especially unacceptable between different *aquaculture establishments* and for live *aquatic animals* that are to be exported. It is a requirement, particularly applicable to *aquatic animals* that are to be exported live, that necessary care be taken to ensure the sterility of all the equipment and products [used] associated with the conditions of certification.

These precautions have particular importance for teams of veterinarians and other aquatic animal health specialists, including vaccination service providers.

The range of organisms capable of being transmitted includes viruses, bacteria and protozoa. The list of infectious agents transmissible in the context of this Appendix continues to expand for all species of *aquatic animals*.

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SECTION 5.2.

DESTRUCTION OF PATHOGENS

APPENDIX 5.2.1.

DISINFECTION OF FISH EGGS [WITH IODINE]

Article 5.2.1.1.

Introduction

Although generally effective for decontamination of egg surfaces, the use of [iodophor] *disinfectants*, such as iodophors, cannot be relied upon to prevent vertical transmission of some bacterial (e.g. *Renibacterium salmoninarum*) and viral pathogens (e.g. infectious pancreatic necrosis virus) that may be present within the *egg*.

Article 5.2.1.2.

Community comments:

Article 5.2.1.2, first paragraph: The Community propose that the second sentence should read as follows: "At a pH of 6 or less, the toxicity for *eggs* increases, and at 8 or more, the biocidal activity decreases. "

Article 5.2.1.2, first paragraph: The Community propose that the fourth sentence should read as follows: "It is recommended that the *eggs* be rinsed in fresh water before and after *disinfection,* or that the iodine, after the appropriate contact time, be neutralised with sodium thiosulfate, and that water free from organic matter be used to prepare the iodophor solution. "

Article 5.2.1.2, first paragraph, last sentence: The Community propose that also a minimum contact time is indicated in the text

Article 5.2.1.2, fourth paragraph, last sentence should read: "For the other species, preliminary tests should be conducted to determine at what egg stage and with what type/concentration of disinfectant, disinfection can be carried out safely."

Conditions of use

The pH of the solutions of the iodophor products must be between 6 and 8. At a pH of 6 or less, the toxicity for *eggs* increases, and at 8 or more, the antiseptic efficacy decreases. It is therefore essential to control the pH, and 100 mg/litre of $NaHCO_3$ must be added to water with a low alkalinity value. It is recommended that the *eggs* be rinsed in fresh water before and after *disinfection,* or that the iodine be neutralised with sodium thiosulfate, and that water free from organic matter be used to prepare the

iodophor solution. Generous amounts of this solution should be used and the solution should be replaced when it turns pale yellow and before the colour disappears. One litre of solution at a concentration of 100 mg/litre *disinfectant* will disinfect 2000 salmonid *eggs*. The contact time at this concentration should be no more than 30 minutes.

Finally, in the case of *eggs* that have been transported, the packaging should also be disinfected or, better still, destroyed in a manner that will not pose a contamination or health risk to water and/or other *fish* at the end destination.

Certain precautions must be taken prior to the use of iodophors as products on the market contain a variable quantity of detergents that can give rise to toxic effects. It is therefore recommended that preliminary tests be carried out among the products on the market. It is advisable to build up stocks of the most satisfactory product, but expiry dates must be considered.

Disinfection of *eggs* with iodine can be carried out for the various *fish* species but it is most commonly used for *fish* of the Salmonidae family. For the other species, preliminary tests should be conducted to determine at what egg stage and iodophore concentration [when and at what] disinfection can be carried out safely.

Disinfection of *eggs* of marine species, such as plaice, cod, Atlantic halibut, for which adverse effects have been documented, may be obtained with 400–600 mg/litre glutaraldehyde with a contact time of 5–10 minutes. However, this is not effective against nodaviruses, for which the use of ozone at 1 mg O_3/litre for 30 seconds is recommended. A concentration of ozone of 0.1–0.2 mg O_3/litre for 3 minutes inactivates most pathogenic fish bacteria as well.

Article 5.2.1.3.

Efficacy limits

Disinfection of *eggs* with iodine is ineffective when trying to avoid vertical transmission of infectious pancreatic necrosis, renibacteriosis and even infectious haematopoietic necrosis, for which this method was recommended initially. The ineffectiveness of iodine has been proved by epidemiological surveys and laboratory tests.

Article 5.2.1.4.

Neutralisation of halogens

See Appendix 5.2.2.

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APPENDIX 5.2.2.

DISINFECTION OF FISH FARMS

Article 5.2.2.1.

General principles

The choice of *disinfection* procedures depends on the size, type and nature of the materials and sites to be disinfected. With the exception of the skin of personnel and *eggs,* which must be disinfected with non-corrosive products, the surfaces to be disinfected consist of fabric or woven material (clothes, nets), hard surfaces (plastic, cement) or permeable materials (earth, gravel). *Disinfection* is more difficult for permeable surfaces and requires more time. Table 1 indicates the most common ingredients and the methods to be used on the basis of these criteria.

The use of chemical [methods] products entails the implementation of measures to protect personnel. It is first necessary to protect the skin and eyes from contact with dangerous substances by using impermeable clothing, boots, glasses and a hat. The respiratory tract must be protected by a mask and the operator must not touch any food without having thoroughly washed his/her hands. Finally, the products must be stored in such a way as not to present direct or indirect danger to animal/*fish* or human life.

The material must be thoroughly cleaned before being disinfected.

Ideally, an approval scheme for *disinfection* of products for use in aquaculture should be established. An approval scheme should consider disinfection effect against target pathogens, toxicological and ecotoxicological properties of the products.

Article 5.2.2.2.

Community comments:

The Community proposes that a reference to UV-C (254 nm) is added after "Ultra-violet rays" in the first column.

Furthermore, the Community questions the deletion of a required minimum contact times as regards iodophore-disinfection of eyed eggs in the third column.

Disinfection

See Table 1.

Table 1. *Disinfection and method of use*

Processes	Indications	Method of use *	Comments
Physical			
Desiccation, light	Fish pathogens on earthen bottoms	Dry for 3 months at an average temperature of 18°C	Drying period can be reduced by the use of a chemical disinfectant

Dry heat	Fish pathogens on concrete, stone, iron, ceramic surfaces	Flame-blower, blow-lamp	
Damp heat	Fish pathogens in transportation vehicle tanks	Steam at 100°C or more for 5 minutes	

Table 1 (continued). *Disinfection and method of use*

Processes	**Indications**	**Method of use ***	**Comments**
8.2. Physical			
Ultra-violet rays	Viruses and bacteria	10 mJ/cm^2	Minimum lethal dose
Ultra-violet rays	[*Myxosporidian* spores in water] *Myxobolus cerebralis*	35 mJ/cm^2	In order to inactivate all sporoplasm cells in the triactinomyxon stage a dose of 1300 mJ/cm^2 must be used
Ultra-violet rays	Infectious pancreatic necrosis (IPN) and nodavirus (VNN/VER[1]) in water	125–200 mJ/cm^2	
8.3. Chemical			
Quartenary ammonia	Virus, bacteria, hands	1 mg/litre for 1 minute	IPN virus resistant
Quartenary ammonia	Gill bacteria, plastic surfaces	2 mg/litre for 15 minutes	
Calcium[a] oxide	Fish pathogens on dried earth-base	0.5 kg/m^2 for 4 weeks	Replace in water and empty disinfected pools keeping the effluents at pH <8.5
Calcium[a] (hypochlorite)	Bacteria and viruses on all clean surfaces and in water	30 mg available chlorine/litre left to inactivate for several days	Can be neutralised with sodium thiosulfate. See special recommendations
Calcium[a] cyanamide	Spores on earthen bottoms	3000 kg/ha on dry surfaces; leave in contact for 1 month	
Formalin	Fish pathogens in sealed premises	Released from formogenic substances, generally trioxymethylene. Comply with instructions	Nodavirus resistant
Iodine (iodophors)	Bacteria, viruses		See special recommendations
Iodine (iodophors)	Hands, smooth surfaces	>200 mg iodine/litre a few seconds	

[1] Viral nervous necrosis/Viral encephalopathy and retinopathy

Iodine (iodophors)	Eyed eggs	[100 mg iodine/litre for 10 minutes] 100 mg iodine/litre for not more than 30 minutes	
Iodine (iodophors)	Gametes during fertilisation	25 mg iodine/litre for several hours	
Iodine (iodophors)	Nets, boots and clothing	200 mg iodine/litre	

Table 1 (continued). *Disinfection and method of use*

Processes	Indications	Method of use *	Comments
8.4. Chemical			
Ozone	Sterilisation of water, fish pathogens,	0.2–1 mg/litre for 3 minutes	Costly
Ozone in seawater	Egg disinfection	0.2–1 mg/litre TRO[2] for 0.5–3 minutes	
Ozone in seawater	Surfaces, equipment	0.5–1 mg/litre TRO for 30–60 minutes	
Sodium[a] (hydroxide)	Fish pathogens on resistant surfaces with cracks	Mixture: Sodium hydroxide, 100 g Teepol®, 10 g Calcium hydroxide, 500 g Water, 10 litres Spray, 1 litre/10 m^2 Leave for 48 hours	The most active disinfectant $Ca(OH)_2$ stains the surfaces treated; Teepol® is a tensio-active agent. Turn water on, checking pH
Sodium[a] (hypochlorite)	Bacteria and viruses on all clean surfaces and in water	30 mg available chlorine/litre. Leave to inactivate for a few days or neutralise with Na thiosulfate after 3 hours	
Sodium[a] (hypochlorite)	Nets, boots and clothing	200 mg available chlorine/litre for several minutes	
Sodium[a] (hypochlorite)	Hands	Rinse with clean water or neutralise with thiosulfate	

a Dangerous – See precautions indicated in general recommendations

* The concentrations indicated are those for the active substance. NB: The chemicals must be approved for the prescribed use and used according to the manufacturer's specifications.

Article 5.2.2.3.

Neutralisation of halogens

2 Total residual oxidant

Chlorine and iodine are highly toxic for *aquatic animals* and, in order to prevent serious accidents that could result from a manipulation error, it is recommended to neutralise these products with sodium thiosulfate – five moles of thiosulfate neutralise four moles of chlorine. The molecular proportions are the same for iodine.

Accordingly, in order to inactivate chlorine, the amount of thiosulfate should be 2.85 times the amount of chlorine (in grams):

Number of grams of thiosulfate = 2.85 × number of grams of chlorine.

For iodine, the amount of thiosulfate should be 0.78 times the amount of iodine in grams:

Number of grams of thiosulfate = 0.78 × number of grams of iodine.

It is also possible to prepare a thiosulfate solution at 1% by weight, in which case the neutralising volumes will be as follows (in ml):

1. for chlorine:

   28.5 × [number of litres of the disinfecting solution × concentration mg/litre] / 100

2. for iodine:

   it is necessary to multiply by 7.8 instead of by 28.5.

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Community comments:

The Community supports the amendments proposed by the FDC presented in Appendix VIII.

SECTION 2.1.

DISEASES NOTIFIABLE TO THE OIE (OF FISH)

CHAPTER 2.1.X.

DISEASE NAME

. . .

Article 2.1.X.7.

[*Importing countries* that are officially declared DISEASE NAME free should only accept for importation live *fish* or *sexual products* of *fish* from *exporting countries* declared DISEASE NAME free, or from clearly defined DISEASE NAME free zones in countries not declared DISEASE NAME free.

Importing countries not regarded as DISEASE NAME free, but that have officially recognised DISEASE NAME free zones, should only import live *fish* and *sexual products* of *fish* into such zones from other countries or zones that are officially declared DISEASE NAME free.

For *aquaculture establishments* officially declared DISEASE NAME free that exist in infected zones, the *Competent Authority* of the country concerned should allow importation of live *fish* or *sexual products* of *fish* only from officially declared DISEASE NAME free countries, zones or *aquaculture establishments*.]

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SECTION 3.1.

DISEASES NOTIFIABLE TO THE OIE (OF MOLLUSCS)

CHAPTER 3.1.X.

DISEASE NAME

...

Article 3.1.X.7.

[*Importing countries* that are officially declared DISEASE NAME free should only accept for importation live *molluscs* from *exporting countries* declared DISEASE NAME free, or from clearly defined DISEASE NAME free zones in countries not declared DISEASE NAME free.

Importing countries not regarded as DISEASE NAME free, but that have officially recognised DISEASE NAME free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared DISEASE NAME free.

For *aquaculture establishments* officially declared DISEASE NAME free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared DISEASE NAME free countries, zones or *aquaculture establishments*.]

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SECTION 4.1.

DISEASES NOTIFIABLE TO THE OIE (OF CRUSTACEANS)

CHAPTER 4.1.X.

DISEASE NAME

...

Article 4.1.X.7.

[*Importing countries* that are officially declared DISEASE NAME free should only accept for importation live *crustaceans* belonging to the susceptible host species listed in Article 4.1.1.1 from *exporting countries* declared DISEASE NAME free, or from clearly defined DISEASE NAME free zones in countries not declared DISEASE NAME free.

Importing countries not regarded as DISEASE NAME free, but that have officially recognised DISEASE NAME free zones, should only import live *crustaceans* belonging to the susceptible host species listed in Article 4.1.1.1 into such zones from other countries or zones that are officially declared DISEASE NAME free.

For *aquaculture establishments* officially declared DISEASE NAME free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of live *crustaceans* belonging to the susceptible host species listed in Article 4.1.1.1 or fertilised eggs/nauplii from officially declared DISEASE NAME free countries, zones or *aquaculture establishments*.]

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Community comments:

The Community supports the preparation of this Appendix, provided that the specific comment given below is taken into account.

As regards the proposed new wording of Article 3.1.5.1, the Community proposes that the new text should read as follows: "species known to be susceptible for *Perkinsus olseni/atlanticus* are abalones and clam species, among which clinical signs and disease have been observed only in *Haliotis rub*er, *H. cyclobates*, *H. scalaris* and *H. laevigata*, *Ruditapes philippinarum* and R. *decussatus*. Other species may become infected under certain circumstances"

Mollusc diseases: new categories of host species

In the *Aquatic Animal Health Code* (AAHC) and the *Diagnostic Manual for Aquatic Animal Diseases* (the *Manual*) susceptible species for *Perkinsus olseni/atlanticus* are: *Haliotis ruber, H. cyclobates, H. scalaris, H. laevigata, Ruditapes philippinarum* and *R. decussatus*, although current evidence suggests that *P. olseni/atlanticus* can cause mortality in species other than those listed. While Ray's fluid thioglycollate medium (RFTM) culture technique is more reliable than histology for detecting infection, it gives no information on whether the host is simply a carrier of the infection, or whether it is diseased. Using histology instead of RFTM, *P. olseni* was found to cause disease in other species including pearl oysters (2, 3). Currently, it appears that many families and species of molluscs may carry schizonts of the parasite that, in some individuals and for unknown reasons, become activated, culminating in systemic disease. Most hosts are probably susceptible to infection under certain circumstances. Therefore to name, in the AAHC, only a few species as being susceptible to disease may be misleading and the following change of the wording to Article 3.1.5.1. is proposed:

> "… susceptible host species for *Perkinsus olseni/atlanticus* are abalones and clam species, among which clinical signs and disease are observed only in *Haliotis ruber, H. cyclobates, H. scalaris and H. laevigata, Ruditapes philippinarum* and *R. decussatus*. Many other species may become diseased under certain circumstances."

However, in the case of *Perkinsus olseni/atlanticus* more than 50 mollusc species would have to be listed as carriers, which is neither practicable nor fully exhaustive. Changing Articles 3.1.5.6. and 3.1.5.8. by deleting the reference to "perkinsosis susceptible host species" could resolve the situation. This would emphasise the potential role of molluscs species as vectors and carriers.

From a more general point of view, it is proposed to modify Articles 3.1.X.6. and 3.1.X.8. in a similar way for the same reasons in all the mollusc disease chapters in the AAHC.

It has also been established that *Haplosporidium nelsoni* infects, but does not cause disease in, *Crassostrea gigas* (1, 4), whereas it causes serious disease in *C. virginica*. The FDC discussed two consequences of this situation, which are 1: the difference in risks associated with movements and transfers of the two susceptible host species, and 2: the difference in surveillance programmes that may be implemented when clinical disease may be absent and prevalence of infection is extremely low. Taking into account this situation, the Commission proposes the following change of wording to Article 3.1.2.1.:

"… susceptible host species for *Haplosporidium nelsoni* are*: Crassostrea virginica* and *C. gigas,* among which clinical signs and disease are observed only in *Crassostrea virginica*".

1. FRIEDMAN C.S., CLONEY D.F., MANZER D. & HEDRICK R.P. (1991). Haplosporidiosis of the Pacific oyster, *Crassostrea gigas*. *J. Invertebr. Pathol*., **58**, 367–372.

2. HINE P.M. & THORNE T. (2000). A survey of some parasites and diseases of several species of bivalve mollusc in northern Western Australia. *Dis. Aquat. Org*., **40**, 67–78.

3. NORTON J.H., SHEPHERD M.A., PERKINS F.P. & PRIOR H.C. (1993). Perkinsus-like infection in farmed golden-lipped pearl oyster *Pinctada maxima* from the Torres Strait, Australia. *J. Invertebr. Pathol*., **62**, 105–106.

4. RENAULT T., STOKES N.A., CHOLLET B., COCHENNEC N., BERTHE F., GERARD A. & BURRESON E.M. (2000). Haplosporidiosis in the Pacific oyster *Crassostrea gigas* from the French Atlantic coast. *Dis. Aquat. Org.,* **42**, 207–214.

SECTION 3.1.

Community comments:

The Community supports the preparation of this Appendix, provided that the comments given below, and the specific comments included in the text are taken into account.

The Community supports the proposals in Articles 3.1.x.2, 3.1.x.3, and 3.1.x.4 but would like see that the requirements in Articles 4.1.3.2 point 3, and 4.1.3.4 point 4 (see Appendix XII) are introduced in this Appendix.

Furthermore, the Community would propose to introduce the requirement laid down in Article 4.1.3..4 point 3, (see Appendix XII) into Articles 3.1.x.4 of this Appendix.

In general, the Community supports the proposals in Article 3.1.x.7. Yet it would propose to include a requirement for proper treatment of the water in the storage tank, referred to in the third paragraph, point 2 of these articles, when the tank is emptied, or a proper disinfection equipment, to secure a safe outlet water if the tank is not a closed system.

The specific comments given in Chapter 3.1.1 below, Articles 3.1.1.x applies also to the corresponding articles of the other chapters in this Appendix.

DISEASES NOTIFIABLE TO THE OIE

CHAPTER 3.1.1.

[BONAMIOSIS] HAEMOCYTOSIS OF FLAT OYSTERS

(*Bonamia ostreae* [*B. exitiosus, Mikrocytos roughleyi*])

Article 3.1.1.1.

Community comments:

In general, the Community supports the proposals in Article 3.1.1.1. However, it does not support a definition of susceptible hosts for Bonamia ostreae, including probably all Ostrea species. The Community therefore proposes the following wording in the second paragraph of Article 3.1.1.:

"For the purposes of this *Code,* known susceptible host species for *Bonamia ostreae* are: *Ostrea edulis, O. angasi, O. denselammellosa, O. puelchana, Ostreola conchaphila* (*= O. lurida*) and *O.chilensis* (*= Tiostrea lutaria*), in which clinical signs and disease have been reported in all species."

The present chapter refers only to [bonamiosis] haemocytosis of flat oysters when caused by [the *disease agents* listed below as the susceptible host species indicated for each pathogen] *Bonamia ostreae*.

For the purposes of this *Code,* susceptible host species for *Bonamia ostreae* are probably all *Ostrea* species including: *Ostrea edulis, O. angasi, O. denselammellosa, O. puelchana, Ostreola conchaphila* (= *O. lurida*) and *O.* [*Tiostrea*] *chilensis* (= *Tiostrea lutaria*), in which clinical signs and disease have been reported [susceptible host species for *Bonamia exitiosus* are: *Tiostrea chilensis* and *Ostrea angasi,* and the susceptible host species for *Mikrocytos roughleyi* is: *Saccostrea commercialis*].

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

Article 3.1.1.2.

[Bonamiosis] Haemocytosis of flat oysters free country

A country may be considered free from [bonamiosis] haemocytosis of flat oysters when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.1.1] *Bonamia ostreae* has occurred within its *territory* for at least the previous two years;

1. no [*disease agent* listed in Article 3.1.1.1] *Bonamia ostreae* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.1.3.

Community comments:
In general, the Community supports the proposals in Article 3.1.1.3. However, since Article 3.1.1.3. deals with free zones, the reference to territory in point 1, may be changed to zone.

Point 1 of Article 3.1.1.3 should thereby read: " no *outbreak* caused by *Bonamia ostreae* has occurred within the *zone* for at least the previous two years"

[Bonamiosis] Haemocytosis of flat oysters free zone

A zone may be considered free from [bonamiosis] haemocytosis of flat oysters when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.1.1] *Bonamia ostreae* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.1.1] *Bonamia ostreae* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.1.4.

Community comments:

The first paragraph of Article 3.1.1.4 may read:

"Status of haemocytosis of flat oyster free aquaculture establishment may be achieved regardless of the status of the zone or country, provided that:

1. no *outbreak* caused by *Bonamia ostreae* has occurred in the establishment for at least the previous two years;"

The former points 1 and 2 becomes points 2 and 3 respectively

[Bonamiosis] Haemocytosis of flat oysters aquaculture establishment

A [bonamiosis] haemocytosis of flat oysters free *aquaculture establishment* may be located within a [bonamiosis] haemocytosis of flat oysters free country or zone or within a [bonamiosis] haemocytosis of flat oysters infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.1.1] *Bonamia ostreae*, and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.1.1] *Bonamia ostreae* that may be present.

Article 3.1.1.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [bonamiosis] haemocytosis of flat oysters free status if no [*disease agent* listed in Article 3.1.1.1] *Bonamia ostreae* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.1.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [bonamiosis] haemocytosis of flat oysters free.

If the place of harvest of the consignment is not a country officially declared [bonamiosis] haemocytosis of flat oysters free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [bonamiosis] haemocytosis of flat oysters free, or

2. an *aquaculture establishment* officially declared [bonamiosis] haemocytosis of flat oysters free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.1.7.

Importing countries that are officially declared bonamiosis free should only accept for importation live *molluscs* from *exporting countries* declared bonamiosis free, or from clearly defined bonamiosis free zones in countries not declared bonamiosis free.

Importing countries not regarded as bonamiosis free, but that have officially recognised bonamiosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared bonamiosis free.

For *aquaculture establishments* officially declared bonamiosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared bonamiosis free countries, zones or *aquaculture establishments*.]

Article 3.1.1.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as bonamiosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [bonamiosis] haemocytosis of flat oysters.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.1.8.

[Certificates are optional for *molluscs* not listed as natural or experimental bonamiosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Bonamia ostrea*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.2.

[BONAMIOSIS] HAEMOCYTOSIS OF DREDGE OYSTERS (*Bonamia exitiosus* [*B. ostreae, Mikrocytos roughleyi*])

Article 3.1.2.1.

The present chapter refers only to [bonamiosis] haemocytosis of dredge oysters when caused by [the *disease agents* listed below as the susceptible host species indicated for each pathogen] *Bonamia exitiosus*.

For the purposes of this *Code,* susceptible host species for *Bonamia exitiosus* are probably all *Ostrea* species including: *Ostrea* [*Tiostrea*] *chilensis* (= *Tiostrea lutaria*) and *Ostrea angasi,* in which clinical signs and disease have been reported [susceptible host species for *Bonamia ostrea* are: *Ostrea edulis, O. angasi, O. denselammellosa, O. puelchana, Ostreola conchaphila* (= *O. lurida*) and *Tiostrea chilensis* (= *T. lutaria*) and the susceptible host species for *Mikrocytos roughleyi* is: *Saccostrea commercialis*].

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

Article 3.1.2.2.

[Bonamiosis] Haemocytosis of dredge oysters free country

A country may be considered free from [bonamiosis] haemocytosis of dredge oysters when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.2.1] *Bonamia exitiosus* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.2.1] *Bonamia exitiosus* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.2.3.

[Bonamiosis] Haemocytosis of dredge oysters free zone

A zone may be considered free from [bonamiosis] haemocytosis of dredge oysters when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.2.1] *Bonamia exitiosus* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.2.1] *Bonamia exitiosus* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.2.4.

[Bonamiosis] Haemocytosis of dredge oysters aquaculture establishment

A [bonamiosis] haemocytosis of dredge oysters free *aquaculture establishment* may be located within a [bonamiosis] haemocytosis of dredge oysters free country or zone or within a [bonamiosis] haemocytosis of dredge oysters infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.2.1] *Bonamia exitiosus*, and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.2.1] *Bonamia exitiosus* that may be present.

Article 3.1.2.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [bonamiosis] haemocytosis of dredge oysters free status if no [*disease agent* listed in Article 3.1.2.1] *Bonamia exitiosus* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.2.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [bonamiosis] haemocytosis of dredge oysters free.

If the place of harvest of the consignment is not a country officially declared [bonamiosis] haemocytosis of dredge oysters free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [bonamiosis] haemocytosis of dredge oysters free, or

2. an *aquaculture establishment* officially declared [bonamiosis] haemocytosis of dredge oysters free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.2.7.

Importing countries that are officially declared bonamiosis free should only accept for importation live *molluscs* from *exporting countries* declared bonamiosis free, or from clearly defined bonamiosis free zones in countries not declared bonamiosis free.

Importing countries not regarded as bonamiosis free, but that have officially recognised bonamiosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared bonamiosis free.

For *aquaculture establishments* officially declared bonamiosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared bonamiosis free countries, zones or *aquaculture establishments*.]

Article 3.1.2.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as bonamiosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [bonamiosis] haemocytosis of dredge oysters.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.2.8.

[Certificates are optional for *molluscs* not listed as natural or experimental bonamiosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Bonamia exitiosus*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.3.

[BONAMIOSIS] WINTER MORTALITY
(*Mikrocytos roughleyi* [*Bonamia ostreae, B. exitiosus*])

Article 3.1.3.1.

The present chapter refers only to [bonamiosis] winter mortality when caused by [the *disease agents* listed below as the susceptible host species indicated for each pathogen] *Mikrocytos roughleyi*.

For the purposes of this *Code,* susceptible host species for *Mikrocytos roughleyi* is: *Saccostrea commercialis* (≡ *S. glomerata*) [susceptible host species for *Bonamia exitiosus* are: *Tiostrea chilensis* and *Ostrea angasi,* susceptible host species for *Bonamia ostreae* are *Ostrea edulis, O. angasi, O. denselammellosa, O. puelchana, Ostreola conchaphila* (= *O. lurida*) and *Tiostrea chilensis* (= *T. lutaria*)].

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

Article 3.1.3.2.

[Bonamiosis] Winter mortality free country

A country may be considered free from [bonamiosis] winter mortality when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.3.1] *Mikrocytos roughleyi* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.3.1] *Mikrocytos roughleyi* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.3.3.

[Bonamiosis] Winter mortality free zone

A zone may be considered free from [bonamiosis] winter mortality when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.3.1] *Mikrocytos roughleyi* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.3.1] *Mikrocytos roughleyi* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.3.4.

[Bonamiosis] Winter mortality aquaculture establishment

A [bonamiosis] winter mortality free *aquaculture establishment* may be located within a [bonamiosis] winter mortality free country or zone or within a [bonamiosis] winter mortality infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.3.1] *Mikrocytos roughleyi*, and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.3.1] *Mikrocytos roughleyi* that may be present.

Article 3.1.3.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [bonamiosis] winter mortality free status if no [*disease agent* listed in Article 3.1.3.1] *Mikrocytos roughleyi* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual.*

Article 3.1.3.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [bonamiosis] winter mortality free.

If the place of harvest of the consignment is not a country officially declared [bonamiosis] winter mortality free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [bonamiosis] winter mortality free, or

2. an *aquaculture establishment* officially declared [bonamiosis] winter mortality free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.3.7.

Importing countries that are officially declared bonamiosis free should only accept for importation live *molluscs* from *exporting countries* declared bonamiosis free, or from clearly defined bonamiosis free zones in countries not declared bonamiosis free.

Importing countries not regarded as bonamiosis free, but that have officially recognised bonamiosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared bonamiosis free.

For *aquaculture establishments* officially declared bonamiosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared bonamiosis free countries, zones or *aquaculture establishments*.]

Article 3.1.3.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as bonamiosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [bonamiosis] winter mortality.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.3.8.

[Certificates are optional for *molluscs* not listed as natural or experimental bonamiosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Mikrocytos roughleyi*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.4.

MSX DISEASE
(*Haplosporidium nelsoni*)

Article 3.1.4.1.

The present chapter refers only to MSX disease when caused by *Haplosporidium nelsoni*.

For the purposes of this *Code,* susceptible host species for *Haplosporidium nelsoni* are: *Crassostrea virginica* and *C. gigas,* among which clinical signs and disease are observed only in *C. virginica.*

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

Article 3.1.4.2.

MSX disease free country

A country may be considered free from MSX disease when:

1. no *outbreak* caused by *Haplosporidium nelsoni* has occurred within its *territory* for at least the previous two years;

2. no *Haplosporidium nelsoni* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.4.3.

MSX disease free zone

A zone may be considered free from MSX disease when:

1. no *outbreak* caused by *Haplosporidium nelsoni* has occurred within its territory for at least the previous two years;

2. no *Haplosporidium nelsoni* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.4.4.

MSX disease free aquaculture establishment

an MSX disease free *aquaculture establishment* may be located within an MSX disease free country or zone or within an MSX disease infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of *Haplosporidium nelsoni*, and

2. it is supplied with water by a means that ensures removal or destruction of any *Haplosporidium nelsoni* that may be present.

Article 3.1.4.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to MSX disease free status if no *Haplosporidium nelsoni* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.4.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared MSX disease free.

If the place of harvest of the consignment is not a country officially declared MSX disease free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared MSX disease free, or

2. an *aquaculture establishment* officially declared MSX disease free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code.*

[Article 3.1.2.7.

Importing countries that are officially declared MSX disease free should only accept for importation live *molluscs* from *exporting countries* declared MSX disease free, or from clearly defined MSX disease free zones in countries not declared MSX disease free.

Importing countries not regarded as MSX disease free, but that have officially recognised MSX disease free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared MSX disease free.

For *aquaculture establishments* officially declared MSX disease free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared MSX disease free countries, zones or *aquaculture establishments*.]

Article 3.1.4.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as MSX disease susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from MSX disease.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.4.8.

[Certificates are optional for *molluscs* not listed as natural or experimental MSX disease susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Haplosporidium nelsoni*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.5.

[MARTEILIOSIS] ABER DISEASE
(*Marteilia refringens* [*M. sydneyi*])

Article 3.1.5.1.

The present chapter refers only to [marteiliosis] Aber disease when caused by [the *disease agents* listed below in the susceptible host species indicated for each pathogen] *Marteilia refringens*.

For the purposes of this *Code,* susceptible host species for *Marteilia refringens* are: *Ostrea edulis, O. angasi* and *Ostrea* [*Tiostrea*] *chilensis* [and susceptible host species for *Marteilia sydneyi* is: *Saccostrea* (= *Crassostrea*) *commercialis*.]

However, the role of other bivalve species as potential vectors is still unclear. The taxonomy of the genus is uncertain and the identification of other *Marteilia* species is difficult.

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

Article 3.1.5.2.

[Marteiliosis] Aber disease free country

A country may be considered free from [marteiliosis] Aber disease when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.5.1] *Marteilia refringens* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.5.1] *Marteilia refringens* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.5.3.

[Marteiliosis] Aber disease free zone

A zone may be considered free from [marteiliosis] Aber disease when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.5.1] *Marteilia refringens* has occurred within its territory for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.5.1] *Marteilia refringens* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.5.4.

[Marteiliosis] Aber disease free aquaculture establishment

An [marteiliosis] Aber disease free *aquaculture establishment* may be located within an [marteiliosis] Aber disease free country or zone or within an [marteiliosis] Aber disease infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.5.1] *Marteilia refringens*, and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.5.1] *Marteilia refringens* that may be present.

Article 3.1.5.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [marteiliosis] Aber disease free status if no [*disease agent* listed in Article 3.1.5.1] *Marteilia refringens* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.5.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [marteiliosis] Aber disease free.

If the place of harvest of the consignment is not a country officially declared [marteiliosis] Aber disease free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [marteiliosis] Aber disease free, or

2. an *aquaculture establishment* officially declared [marteiliosis] Aber disease free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.3.7.

Importing countries that are officially declared marteiliosis free should only accept for importation live *molluscs* from *exporting countries* declared marteiliosis free, or from clearly defined marteiliosis free zones in countries not declared marteiliosis free.

Importing countries not regarded as marteiliosis free, but that have officially recognised marteiliosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared marteiliosis free.

For *aquaculture establishments* officially declared marteiliosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared marteiliosis free countries, zones or *aquaculture establishments*.]

Article 3.1.5.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as marteiliosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [marteiliosis] Aber disease.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.5.8.

[Certificates are optional for *molluscs* not listed as natural or experimental marteiliosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Marteilia refringens*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.6.

QX DISEASE [MARTEILIOSIS]
(*Marteilia sydneyi* [*M. refringens*])

Article 3.1.6.1.

The present chapter refers only to [marteiliosis] QX disease when caused by [the *disease agents* listed below in the susceptible host species indicated for each pathogen] *Marteilia sydneyi*.

For the purposes of this *Code,* susceptible host species *Marteilia sydneyi* is: *Saccostrea* [(= *Crassostrea*)] *commercialis (= glomerata)* [and for susceptible host species for *Marteilia refringens* are: *Ostrea edulis, O. angasi* and *Tiostrea chilensis*].

[However, the role of other bivalve species as potential vectors is still unclear.] The taxonomy of the genus is uncertain and the identification of other *Marteilia* species is difficult.

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

Article 3.1.6.2.

[Marteiliosis] QX disease free country

A country may be considered free from [marteiliosis] QX disease when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.6.1] *Marteilia sydneyi* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.6.1] *Marteilia sydneyi* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.6.3.

[Marteiliosis] QX disease free zone

A zone may be considered free from [marteiliosis] QX disease when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.6.1] *Marteilia sydneyi* has occurred within its territory for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.6.1] *Marteilia sydneyi* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.6.4.

[Marteiliosis] QX disease free aquaculture establishment

A [marteiliosis] QX disease free *aquaculture establishment* may be located within a [marteiliosis] QX disease free country or zone or within a [marteiliosis] QX disease infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.6.1] *Marteilia sydneyi*, and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.6.1] *Marteilia sydneyi* that may be present.

Article 3.1.6.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [marteiliosis] QX disease free status if no [*disease agent* listed in Article 3.1.6.1] *Marteilia sydneyi* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.6.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [marteiliosis] QX disease free.

If the place of harvest of the consignment is not a country officially declared [marteiliosis] QX disease free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [marteiliosis] QX disease free, or

2. an *aquaculture establishment* officially declared [marteiliosis] QX disease free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.3.7.

Importing countries that are officially declared marteiliosis free should only accept for importation live *molluscs* from *exporting countries* declared marteiliosis free, or from clearly defined marteiliosis free zones in countries not declared marteiliosis free.

Importing countries not regarded as marteiliosis free, but that have officially recognised marteiliosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared marteiliosis free.

For *aquaculture establishments* officially declared marteiliosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared marteiliosis free countries, zones or *aquaculture establishments*.]

Article 3.1.6.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as marteiliosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [marteiliosis] QX disease.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.6.8.

[Certificates are optional for *molluscs* not listed as natural or experimental marteiliosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Marteilia sydneyi*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.7.

DENMAN ISLAND DISEASE [MIKROCYTOSIS]
(*Mikrocytos mackini*)

Article 3.1.7.1.

Community comment:
The Community proposes that the second paragraph should read as follows

" For the purposes of this *Code,* susceptible host species for *Mikrocytos mackini* are: *Crassostrea gigas, C. virginica, Ostrea edulis* and *O. conchaphila*, among which clinical signs and disease are less frequently seen in *Crassostrea gigas*."

The present chapter refers only to [mikrocytosis] Denman Island disease when caused by *Mikrocytos mackini*.

For the purposes of this *Code,* susceptible host species for *Mikrocytos mackini* are: *Crassostrea gigas, C. virginica, Ostrea edulis* and *O. conchaphila*. *Crassostrea gigas* seems to be more resistant to the disease than the other species.

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

Article 3.1.7.2.

[Mikrocytosis] Denman Island disease free country

A country may be considered free from [mikrocytosis] Denman Island disease when:

1. no *outbreak* caused by *Mikrocytos mackini* has occurred within its *territory* for at least the previous two years;

2. no *Mikrocytos mackini* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.7.3.

[Mikrocytosis] Denman Island disease free zone

A zone may be considered free from [mikrocytosis] Denman Island disease when:

1. no *Mikrocytos mackini* has occurred within its territory for at least the previous two years;

2. no *Mikrocytos mackini* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.7.4.

[Mikrocytosis] Denman Island disease free aquaculture establishment

A [mikrocytosis] Denman Island disease free *aquaculture establishment* may be located within a [mikrocytosis] Denman Island disease free country or zone or within a [mikrocytosis] Denman Island disease infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of *Mikrocytos mackini*, and

2. it is supplied with water by a means that ensures removal or destruction of any *Mikrocytos mackini* that may be present.

Article 3.1.7.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [mikrocytosis] Denman Island disease free status if no *Mikrocytos mackini* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.7.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [mikrocytosis] Denman Island disease free.

If the place of harvest of the consignment is not a country officially declared [mikrocytosis] Denman Island disease free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [mikrocytosis] Denman Island disease free, or

2. an *aquaculture establishment* officially declared [mikrocytosis] Denman Island disease free.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.4.7.

Importing countries that are officially declared mikrocytosis free should only accept for importation live *molluscs* from *exporting countries* declared mikrocytosis free, or from clearly defined mikrocytosis free zones in countries not declared mikrocytosis free.

Importing countries not regarded as mikrocytosis free, but that have officially recognised mikrocytosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared mikrocytosis free.

For *aquaculture establishments* officially declared mikrocytosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared mikrocytosis free countries, zones or *aquaculture establishments*.]

Article 3.1.7.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as mikrocytosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [mikrocytosis] Denman Island disease.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.7.8.

[Certificates are optional for *molluscs* not listed as natural or experimental mikrocytosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Mikrocytos mackini*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.8.

DERMO INFECTION [PERKINSOSIS]
(*Perkinsus marinus*)

Article 3.1.8.1.

The present chapter refers only to [perkinsosis] Dermo infection when caused by [the *disease agents* listed below in the susceptible host species indicated for each pathogen] *Perkinsus marinus*.

For the purposes of this *Code,* susceptible host species for *Perkinsus marinus* are: *Crassostrea virginica* and *C. gigas,* among which clinical signs and disease are mainly observed in *C. virginica*. [and susceptible host species for *Perkinsus olseni/atlanticus* are: *Haliotis ruber, H. cyclobates, H. scalaris, H. laevigata, Ruditapes philippinarum* and *R. decussatus*.]

[Some 50 other species of *molluscs* may harbour *Perkinsus* species that are apparently non-pathogenic.]

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

Article 3.1.8.2.

[Perkinsosis] Dermo infection free country

A country may be considered free from [perkinsosis] Dermo infection when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.8.1] *Perkinsus marinus* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.8.1] *Perkinsus marinus* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.8.3.

[Perkinsosis] Dermo infection free zone

A zone may be considered free from [perkinsosis] Dermo infection when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.8.1] *Perkinsus marinus* has occurred within its territory for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.8.1] *Perkinsus marinus* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.8.4.

[Perkinsosis] Dermo infection free aquaculture establishment

A [perkinsosis] Dermo infection free *aquaculture establishment* may be located within a [perkinsosis] Dermo infection free country or zone or within a [perkinsosis] Dermo infection infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.8.1 *Perkinsus marinus*], and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.8.1] *Perkinsus marinus* that may be present.

Article 3.1.8.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [perkinsosis] Dermo infection free status if no [*disease agent* listed in Article 3.1.8.1] *Perkinsus marinus* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.8.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [perkinsosis] Dermo infection free.

If the place of harvest of the consignment is not a country officially declared [perkinsosis] Dermo infection free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [perkinsosis] Dermo infection free, or

2. an *aquaculture establishment* officially declared [perkinsosis] Dermo infection free.

The *certificate* shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.5.7.

Importing countries that are officially declared perkinsosis free should only accept for importation live *molluscs* from *exporting countries* declared perkinsosis free, or from clearly defined perkinsosis free zones in countries not declared perkinsosis free.

Importing countries not regarded as perkinsosis free, but that have officially recognised perkinsosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared perkinsosis free.

For *aquaculture establishments* officially declared perkinsosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared perkinsosis free countries, zones or *aquaculture establishments*.]

Article 3.1.8.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as perkinsosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [perkinsosis] Dermo infection.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.8.9.

[Certificates are optional for *molluscs* not listed as natural or experimental perkinsosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Perkinsus marinus*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

CHAPTER 3.1.9.

PERKINSUS OLSENI/ATLANTICUS INFECTION [PERKINSOSIS]

([*Perkinsus marinus*,] *Perkinsus olseni/atlanticus*)

Article 3.1.9.1.

The present chapter refers only to [perkinsosis] *Perkinsus olseni/atlanticus* infection when caused by [the *disease agents* listed below in the susceptible host species indicated for each pathogen] *Perkinsus olseni/atlanticus*.

For the purposes of this *Code,* susceptible host species for [*Perkinsus marinus* are: *Crassostrea virginica* and *C. gigas,* and susceptible host species for] *Perkinsus olseni/atlanticus* are: abalones and clam species, among which clinical signs and disease are mainly observed in: *Haliotis ruber, H. cyclobates, H. scalaris, H. laevigata, Ruditapes philippinarum* and *R. decussatus*. Many other species may become diseased under certain circumstances.

[Some 50 other species of *molluscs* may harbour *Perkinsus* species that are apparently non-pathogenic.]

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

Article 3.1.9.2.

[Perkinsosis] *Perkinsus olseni/atlanticus* infection free country

A country may be considered free from [perkinsosis] *Perkinsus olseni/atlanticus* infection when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus* has occurred within its *territory* for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual*.

Article 3.1.9.3.

[Perkinsosis] *Perkinsus olseni/atlanticus* infection free zone

A zone may be considered free from [perkinsosis] *Perkinsus olseni/atlanticus* infection when:

1. no *outbreak* caused by [the *disease agents* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus* has occurred within its territory for at least the previous two years;

2. no [*disease agent* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus* has been detected in any *mollusc* tested during operation of an official mollusc health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual* (where a zone common to several countries is involved, these countries should implement harmonised and co-ordinated national disease *surveillance* programmes).

Article 3.1.9.4.

[Perkinsosis] *Perkinsus olseni/atlanticus* infection free aquaculture establishment

A [perkinsosis] *Perkinsus olseni/atlanticus* infection free *aquaculture establishment* may be located within a [perkinsosis] *Perkinsus olseni/atlanticus* infection free country or zone or within a [perkinsosis] *Perkinsus olseni/atlanticus* infection infected zone provided that:

1. it has been tested in an official mollusc health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of [any of the *disease agents* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus*, and

2. it is supplied with water by a means that ensures removal or destruction of any [of the *disease agents* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus* that may be present.

Article 3.1.9.5.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to [perkinsosis] *Perkinsus olseni/atlanticus* infection free status if no [*disease agent* listed in Article 3.1.9.1] *Perkinsus olseni/atlanticus* has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

Article 3.1.9.6.

When importing live *molluscs* of all age groups [of any susceptible host species] for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This certificate must certify, on the basis of an official mollusc health *surveillance* scheme comprising inspection and laboratory tests on susceptible host species conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared [perkinsosis] *Perkinsus olseni/atlanticus* infection free.

If the place of harvest of the consignment is not a country officially declared [perkinsosis] *Perkinsus olseni/atlanticus* infection free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared [perkinsosis] *Perkinsus olseni/atlanticus* infection free, or

2. an *aquaculture establishment* officially declared [perkinsosis] *Perkinsus olseni/atlanticus* infection free.

The *certificate* shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Code*.

[Article 3.1.5.7.

Importing countries that are officially declared perkinsosis free should only accept for importation live *molluscs* from *exporting countries* declared perkinsosis free, or from clearly defined perkinsosis free zones in countries not declared perkinsosis free.

Importing countries not regarded as perkinsosis free, but that have officially recognised perkinsosis free zones, should only import *molluscs* into such zones from other countries or zones that are officially declared perkinsosis free.

For *aquaculture establishments* officially declared perkinsosis free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of *molluscs* from officially declared perkinsosis free countries, zones or *aquaculture establishments*.]

Article 3.1.9.7.

Competent Authorities of *importing countries* should require:

for *molluscs* of commercial size destined for human consumption

the presentation of an *international aquatic animal health certificate* attesting that the *molluscs* [listed as perkinsosis susceptible host species] have as their place of harvest a country, a zone or an *aquaculture establishment* free from [perkinsosis] *Perkinsus olseni/atlanticus* infection.

The certificate shall be in accordance with Model Certificate No. 3.

This certificate may not be required for *molluscs* [listed as susceptible host species] originating from an infected zone if they are destined:

1. directly for human consumption without any re-immersion, or

2. for storage, during a short period before consumption, in a tank located in an infected zone. The tank should be isolated from the local environment (e.g. in quarantine) to avoid the potential introduction of different strains of the pathogen.

Article 3.1.9.9.

[Certificates are optional for *molluscs* not listed as natural or experimental perkinsosis susceptible host species] This certificate may not be required for mollusc species that have been demonstrated not to be vectors of *Perkinsus olseni/atlanticus*, even if the *molluscs* originate from an infected country, zone or *aquaculture establishment*.

Appendix XI

Community comments:

The Community supports the preparation of this Appendix

LIST OF DISEASES NOTIFIABLE TO THE OIE AND OTHER SIGNIFICANT DISEASES

Article 1.1.2.1.

Diseases notifiable to the OIE

. . .

2. Diseases of molluscs

[Bonamiosis] Haemocytosis of flat oysters (*Bonamia ostreae* [, *Bonamia exitiosus, Mikrocytos roughleyi*)]

[Bonamiosis] Haemocytosis of dredge oysters ([*Bonamia ostreae,*] *Bonamia exitiosus* [, *Mikrocytos roughleyi*])

[Bonamiosis] Winter mortality ([*Bonamia ostreae, Bonamia exitiosus,*]) *Mikrocytos roughleyi*)

[Mikrocytosis] Denman Island disease (*Mikrocytos mackini*)

MSX disease *(Haplosporidium nelsoni)*

[Marteiliosis] Aber disease (*Marteilia refringens* [*, M. sydneyi*])

[Marteiliosis] QX disease ([*Marteilia refringens,*] *Marteilia sydneyi*)

[Perkinsosis] Dermo disease (*Perkinsus marinus* [*, P. olseni/atlanticus*])

[Perkinsosis] *Perkinsus olseni/atlanticus* infection ([*Perkinsus marinus,*] (*Perkinsus olseni/atlanticus*)

. . .

Article 1.1.2.2.

Other significant diseases

. . .

2. Diseases of molluscs

SSO disease *(Haplosporidium costale)*

Withering syndrome of abalones (*Candidatus* Xenohaliotis californiensis)

. . .

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[ ] deleted

Appendix XII

Community comments:

The Community supports the preparation of this Appendix, provided that the specific comments included in the text are taken into account.

In general, the Community sees the need for harmonisation of the wording in Chapter 4.1.3 and the wording of Chapters 3.1.1 3.1.9. The Community also proposes to introduce some of the recommendation laid down in this Appendix into the relevant chapters in Appendix X (see comments to Appendix X).

Furthermore, the Community would like to draw the attention to the fact that article 4.1.3.7 is proposed deleted. It seems therefor necessary to re-numerate the following articles, as well as to check the references made to article 4.1.3.7 in the other articles of this chapter.

CHAPTER 4.1.3.

YELLOWHEAD DISEASE

Article 4.1.3.1.

For the purposes of this *Code*, susceptible host species for yellowhead disease are: Black tiger shrimp (*Penaeus monodon*), Pacific white shrimp (*P. vannamei*), Pacific blue shrimp (*P. stylirostris*), Gulf white shrimp (*P. setiferus*), Gulf brown shrimp (*P. aztecus*), Gulf pink shrimp (*P. duorarum*), and Kuruma prawn (*P. japonicus*).

For the purpose of this *Code*, the causative agents (*disease agents*) of yellowhead disease are yellowhead virus and related strains of the virus (e.g. gill-associated virus).

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

Article 4.1.3.2.

Yellowhead disease free country

A country may be considered free from yellowhead disease when:

1. no recorded *outbreak* of yellowhead disease has occurred within its *territory* for at least the previous two years;

2. no *disease agent* listed in Article 4.1.3.1 has been detected in any *crustacean* belonging to the susceptible host species listed in Article 4.1.3.1 tested during operation of an official crustacean health *surveillance* scheme for a period of at least two years using the procedures described in the *Manual;*

3. it is observing the conditions referred to in Articles 4.1.3.6, 4.1.3.7 and 4.1.3.8.

Article 4.1.3.3.

Community comments:

The Community questions the possibility of establishing a free zone, without having the requirement for no outbreaks during the last two years as presented in Appendix X.

Yellowhead disease free zone

A yellowhead disease free zone may be established within the *territory* of one or more countries if within the zone:

1. *aquaculture establishments* and wild populations containing *crustaceans* belonging to the susceptible host species listed in Article 4.1.3.1 have been tested in an official crustacean health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual;*

2. no *disease agent* listed in Article 4.1.3.1 has been detected during this two-year period.

Such yellowhead disease free zones must comprise the entire water supply in an area complying with the definition of *zone/zoning* laid down in Chapter 1.1.1 Definitions in this *Code*.

Such zones must be clearly delineated on a map of the *territory* of the country concerned by the *Competent Authority* and the conditions referred to in Articles 4.1.3.6, 4.1.3.7 and 4.1.3.8 must be observed.

Article 4.1.3.4.

Yellowhead disease free aquaculture establishment

A yellowhead disease free *aquaculture establishment* may be located not only within a yellowhead disease free country or zone but also within a yellowhead disease infected zone provided that:

1. it has been tested in an official crustacean health *surveillance* scheme for at least the previous two years using the procedures described in the *Manual,* without detection of the *disease agents* listed in Article 4.1.3.1);

2. it is supplied by water disinfected with approved technical devices proven to inactivate the *disease agents* listed in Article 4.1.3.1);

3. there is a natural or artificial barrier that prevents contamination of the *aquaculture establishment* or its water supply;

4. it is observing the conditions referred to in Articles 4.1.3.6, 4.1.3.7 and 4.1.3.8.

Article 4.1.3.5.

Community comments:

The Community do not support the proposal in the second paragraph, giving an establishment that have undergone thorough stamping out policy under the supervision of the Competent Authority, the possibility of restoration of free status in less than two years. If this was proposal should be acceptable, the stamping out procedure must be followed by a fallowing period. There should also be a requirement that the fish that are introduced at the establishment must come from an approved zone or farm. The text should be changed accordingly.

Restoration of free status

A country, a zone or an *aquaculture establishment* may be restored to yellowhead disease free status if it has been subjected to a *stamping-out policy* or effective disease eradication measures and if no *disease agent* listed in Article 4.1.3.1 has been detected for the last two years of a *surveillance* scheme using the procedures described in the *Manual*.

A newly constructed *aquaculture establishment,* or one that has undergone a thorough *stamping-out policy* under supervision of the *Competent Authority,* may achieve yellowhead disease free status in under two years if it otherwise meets all the requirements for a yellowhead disease free *aquaculture establishment*.

Article 4.1.3.6.

When importing live *crustaceans* (fertilised eggs/nauplii, postlarvae, juveniles and/or broodstock) of any *susceptible species,* the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country.*

This certificate must certify, on the basis of an official crustacean health *surveillance* scheme comprising inspection and laboratory tests conducted according to the procedures described in the *Manual,* whether or not the place of harvest of the consignment is a country officially declared yellowhead disease free.

If the place of harvest of the consignment is not a country officially declared yellowhead disease free, the certificate must state whether the place of harvest of the consignment is:

1. a zone officially declared yellowhead disease free, or
2. an *aquaculture establishment* officially declared yellowhead disease free.

The certificate shall be in accordance with Model Certificate No. 4 given in Part 6 of this *Code.*

[Article 4.1.3.7.

Importing countries that are officially declared yellowhead disease free should only accept for importation live *crustaceans* belonging to the susceptible host species listed in Article 4.1.3.1 from *exporting countries* declared yellowhead disease free, or from clearly defined yellowhead disease free zones in countries not declared yellowhead disease free.

Importing countries not regarded as yellowhead disease free, but that have officially recognised yellowhead disease free zones, should only import live *crustaceans* belonging to the susceptible host species listed in Article 4.1.3.1 into such zones from other countries or zones that are officially declared yellowhead disease free.

For *aquaculture establishments* officially declared yellowhead disease free that exist in infected zones, the *Competent Authority* of the country concerned should only allow importation of live *crustaceans* belonging to the susceptible host species listed in Article 4.1.3.1 or fertilised eggs/nauplii from officially declared yellowhead disease free countries, zones, or *aquaculture establishments*.]

Article 4.1.3.8.

The *Competent Authority* of a country importing dead *crustaceans* belonging to the susceptible host species listed in Article 4.1.3.1 should require that the consignment be accompanied by an *international aquatic animal health certificate,* conforming to the Model Certificate No. 5, issued by the *Competent Authority* in the exporting country.

This certificate should declare the health status of the place of harvest of the consignment in respect of yellowhead disease and the other crustacean diseases listed in this *Code*.

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[ ] deleted

Community comments:

The Community strongly supports that criteria for listing of diseases are introduced into the AAHC and agrees in general to the criteria proposed this Appendix XIII, yet it would like the following comments to be taken into consideration.

Table I: C 8 Explanatory note: This requirement is impossible to fulfil when it comes to emerging diseases (see explanatory note to B 5).

Table II: A 1; The Community consider the criteria for urgent notification both in case for a situation where a Member Country never has experienced the disease before, regardless of there is an ongoing surveillance program for the disease in question. However, the text may be re-written in order to make this more clear.

I. Proposed criteria for listing an aquatic animal disease (June 2002)

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
		A. Consequences	
1.		Where it occurs, the disease has been shown to cause significant production losses due to morbidity[3] or mortality at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will always lead to losses in susceptible[4] species, and that morbidity or mortality are related primarily to the agent and not management or environmental factors.
2.	Or	The disease has been shown to, or is strongly suspected to, negatively affect wild aquatic animal populations that are shown to be an asset worth protecting.	See above
3.	Or	The agent is of public health concern.	
		B. Spread	
4.		Infectious aetiology of the disease is proven.	
5.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
6.	And	Potential for international spread, including via live animals, their products and inanimate objects.	Under international trading practices, the entry and establishment of the disease is a likely risk.

[3] 'morbidity' includes, for example, loss of production due to spawning failure

[4] 'susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
7.	And	Several countries/zones are free of the disease based on the recommendations of the *International Aquatic Animal Health Code* and *Diagnostic Manual for Aquatic Animal Diseases*.	Free countries/zones could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of broodstock from widespread diseases, or the protection of the last remaining free zones from a widespread disease.
C. Diagnosis			
8.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available, or has undergone a formal standardisation and validation process using routine field samples (see OIE *Diagnostic Manual for Aquatic Animal Diseases*).

II. Proposed criteria for <u>urgent</u> notification of aquatic animal diseases (June 2002)

A. Listed diseases	
1.	First occurrence or re-occurrence of a disease in a country or zone of a country, if the country or zone of the country was previously considered to be free of that particular disease
2.	Occurrence in a new host species
3.	New pathogen strain or new disease manifestation
4.	Potential for international spread of the disease
5.	Zoonotic potential
B. Non-listed diseases	
1.	Emerging disease/pathogenic agent if there are findings that are of epidemiological significance to other countries

Appendix XIV

GUIDELINES FOR APPLICANTS FOR DESIGNATION

AS OIE REFERENCE LABORATORY

1. Name of expert (a brief and informal curriculum vitae should be included).

2. Name and address of laboratory (telephone and fax numbers, e-mail address, etc.).

3. Name of Director.

4. Number of staff available to carry out the specific OIE Reference Laboratory duties.

5. Experience in diagnostic testing for the disease using validated and calibrated techniques with capacity to process significant number of analyses (provide approximate number of tests performed annually for each technique).

6. Data and administration system to enable traceability of results.

7. Additional expertise, e.g. in disease agent characterisation techniques, molecular techniques, monoclonal antibody techniques.

8. Experience in standardisation of diagnostic tests.

9. Reagent production capability (provide details of current stock of reagents for the disease).

10. Capability for timely international shipment in accordance with the requirements for postage and packaging of biological materials described in chapter 1.5.6. of the OIE *International Aquatic Animal Health Code*.

11. Current and completed research and methods development projects on the disease, including a list of relevant publications.

12. Training and consultation experience for the disease in the past two years (courses provided, number of people trained, examples of international consultation).

13. Contribute to the preparation or reviewing of reference documents (chapters for the *Diagnostic Manual for Aquatic Animal Diseases*, fish disease cards, etc.).

14. Production of an annual report of activities to be sent the OIE Central Bureau.

AMPHIBIAN TRADE: DISEASE THREATS TO AMPHIBIANS AND FISH?

Dr Andrew A. Cunningham, Head of Wildlife Epidemiology, ZSL Institute of Zoology, Regent's Park, London NW1 4RY, United Kingdom

9. INTRODUCTION

Over recent years, the numbers of reports of infectious diseases of amphibians have increased markedly, as, in general, have the scales of morbidity and mortality caused by these diseases. Of the many amphibian diseases known, two in particular (ranavirus disease and the fungal disease, chytridiomycosis) stand out in importance, because of their global distribution, their high mortality rates and, hence, their impact on amphibians. International concerns have been relatively slow to register the importance of these phenomena, but public concerns have generally been very high and increasingly louder warning bells are being rung in the scientific press.

10. RANAVIRUS DISEASES

One of these warning bells has concerned an epizootic of ranavirus disease, which probably kills tens of thousands of frogs in Great Britain annually. This disease was first noticed in the early 1990s, following increasingly large numbers of unsolicited reports from members of the public of mass mortality incidents of frogs. A combination of field work, post-mortem investigations, transmission experiments and laboratory analyses led to the detection of a ranavirus as the cause of a previously unreported, fatal, epizootic of common frogs (*Rana temporaria*) in Great Britain. Follow-up questionnaires and field investigations indicate a negative effect on, including local extinction of, frog populations at affected breeding ponds, which can endure for several years subsequent to the initial disease outbreak. Other species, namely the common toad (*Bufo bufo*) and pet tortoises (*Testudo* sp.), are also killed by this ranavirus.

Although ranaviruses have been isolated from amphibians for many decades, in recent years there has been a dramatic increase in the number and size of epizootics, with very high mortality rates in wild amphibian populations. Apart from the situation in Great Britain, perhaps the most notable of these have been repeated fatal epizootics in tiger salamanders (*Ambystoma tigrinum*) in Canada (1997) and in the United States of America (USA) (Arizona, 1995; North Dakota, 1998; Maine, 1998; and Utah, 1998). The outbreak in Arizona in 1995 decimated a large population of the Sonoran tiger salamander (*A. tigrinum stebbinsi*), an endangered subspecies.

Chytridiomycosis

The phenomenon of a global decline in amphibian populations has been recognised since the late 1980s. In Australia, for example, marked declines (with local extinctions) in amphibian populations have been monitored as spreading in a wave-like manner, from an initial focus in the southern New South Wales area, travelling northwards at approximately 100 km per year. By 1993, the wave of declines had spread throughout Eastern Australia. At the same time, a similar wave of amphibian declines and local extinctions travelled southwards through Central America, from northern Costa Rica in 1988 to western Panama by 1996. In 2000, this wave had reached Ecuador, and in 2001 declines started to be reported from Colombia. Concurrent with these waves of decline and local extinctions, were the global extinctions of the golden toad (*Bufo periglenes*) in Costa Rica and of up to seven species of rain forest frog (including the only two known species of gastric-brooding frog) in Australia.

In 1998, a paper was published in which a novel chytrid fungus was reported as causing the declines in amphibians in the rain forests of Australia and Central America. It was by combining the efforts of researchers in these two continents, through the auspices of the Pathology Working Group of the International Union for

Conservation of Nature and Natural Resources (IUCN)'s Declining Amphibian Populations Task Force, that the chytrid discovery was made. Morphological and, latterly, genetic analyses of the causative agent has shown the cause to be the same organism, a new genus of chytrid – and the only chytrid known to infect vertebrates – which has since been named *Batrachochytrium dendrobatidis*. Retrospective studies have now shown that this disease caused marked amphibian declines, and local extinctions, in the mid-western and western USA, which occurred in the 1970s. More recently, chytridiomycosis has been found as the cause of current marked declines of *Bufo borreas* in Colorado, USA, *Rana* spp. in Arizona, USA, the endemic Archey's frog in New Zealand and the midwife toad in Spain. The last adds a fourth continent to the list of infected regions of the world. It is difficult to predict the effect of the loss of multi-species assemblages, in often otherwise pristine habitat, on the ecosystems concerned and this is an area that is in urgent need of study.

Amphibian trade

There is a global trade in amphibians and their products for the purpose of: the pet industry, the food industry, the supply of biological materials and for other commodities, such as scientific or educational materials.

Knowing that this trade occurs is one thing, establishing the size of this trade is quite another. In the United Kingdom (UK), for example, Her Majesty's Customs & Excise code and record the import and export of both live and dead amphibians (including products). These are, however, coded along with other commodities. For example, live amphibians are coded along with "Live Animals NES: Other Live Animals NES", while dead amphibians are coded along with "Animal PDT and dead animals unfit for human consumption NES". This makes it impossible to extract information on amphibian imports/exports alone. In addition, it is very likely that many amphibian consignments are not declared to, or recorded by, customs officials. This is particularly likely as there is no regulation of amphibian movements, unless the species involved are protected, such as being listed under CITES[5] (see below).

Of the approximately 5500 species of amphibians only 111 (approx. 2%) are CITES-listed. Although international trade figures are available from many countries, including the UK, for CITES-listed species, the numbers are extremely small compared with the figures for trade in non-CITES listed amphibians. Figures from the UK Government's Department for the Environment Food and Rural Affairs (DEFRA) indicate a negligible export market and a small, but growing, import market. According to these figures, over the past five years, an average of approximately 500 CITES-listed amphibians hasbeen imported into the UK annually. The trend is upwards.

Another aspect of the amphibian trade the UK authorities keep records for, is the trade in frogs' legs for human consumption. Figures for recent years available from HM Customs & Excise are as follows:

	IMPORTS		**EXPORTS**	
YEAR	**Quantity**	**Value (GBP)**	**Quantity**	**Value (GBP)**
1999	28,583	102,659	697	4751
2000	127,293	196,876	4559	13,871
2001	50,483	147,919	2103	5612

Approximately 90% of these were recorded as being imported from the European Union (EU), with 10% coming from "Asia and Oceania". In fact, it is likely that most of the former were re-exports, having originated from a third country – most probably from Asia. In some Asian countries, such as Thailand and Indonesia, frog farming for the food market is a large and growing industry, with the EU as a major importer of these products. One newspaper reported the importation of seven tons of frogs' legs into France from Indonesia alone for a single 2-day festival in a single town in France.

It might be assumed that a general lack of figures is because international trade in amphibians is small and irrelevant. Figures from the USA, however, tend to dispute this. In the five-year period, 1996-2001, 26.5 million

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5 Convention on International Trade in Endangered Species of Wild Fauna and Flora

live amphibians were imported into the USA and 1.9 million live amphibians were exported from the USA. This is five times greater than the import trade in reptiles. Of the imported amphibians, 74% had been wild-caught, 23% captive-bred and 3% came from an unknown source. Of the exported animals, 72% were wild-caught or from an unknown source, while 28% were recorded as having been captive-bred. Most were re-exports, having been imported into the USA from a third country. Over 6 million amphibians imported into the USA were *Rana catesbeiana*, an endemic US species that is now farmed intensively in many South American countries to supply the US restaurant trade. Approximately 0.1% of the imported amphibians were of CITES-listed species.

The situation regarding world trade in amphibians is summed up by TRAFFIC, the wildlife trade monitoring programmes of the World Wildlife Fund (WWF) and the IUCN, which states on its Web site that: "The worldwide trade in live reptiles and amphibians is huge." It also, quite correctly states: "Unlike the trade in live birds and mammals, the live reptile and amphibian trade is largely unregulated, with comparatively few species listed on CITES."

Is trade a factor in the recent epizootics in wild amphibian populations?

Work on the ranavirus epizootic in Great Britain, including molecular and other laboratory, comparisons, indicates that all the British isolates fall within a clade of amphibian ranaviruses from North America and are more distantly related to ranaviruses from South America, Australia and continental Europe. The epidemiological and virological findings, therefore, suggest that the frog epizootic in Great Britain is caused by a virus that has been recently introduced from North America. There has been speculation that the importation of bullfrogs and goldfish from North America for the UK pet trade is a possible route of introduction of a North American ranavirus into Great Britain. The trans-Atlantic trade in these species increased markedly in the 1980s, and often in the UK, pet bullfrogs and goldfish are housed in outdoor garden ponds, which also are the primary breeding habitat for the common frog in the UK.

Similarly, molecular and DNA sequencing work on *Batrachochytrium dendrobatidis* by several independent groups has shown the causative agents in North America, South America and Australia to be indistinguishable from each other. This suggests a point source with global incursions and some authors believe the likeliest route of introduction was via the anthropogenic movement of infected materials, possibly amphibians or fomites (inanimate objects), but possibly also fish (it is currently not known if fish are capable of acting as vectors). Studies in New Zealand are more demonstrative, with an apparent close spatial and temporal association between outbreaks of chytridiomycosis in wild amphibians with the release of Australian frogs from the pet trade.

Are fish at risk?

Although goldfish have been implicated as possible vectors for the introduction of ranaviruses into Great Britain, it is possible that, conversely, ranavirus diseases of amphibians pose a threat to fish health. In addition to the common frog, the UK ranavirus has caused natural mortality in common toads and tortoises (*Testudo* sp.) thereby crossing into a second animal Class. The Australian amphibian ranavirus, BIV, has been used to infect fish (barramundi *Lates calcarifer*) experimentally, with a high degree of mortality. In the USA, an amphibian ranavirus (RCV) has been found naturally to infect and kill both red-legged frogs (*Rana aurora*) and fish (threespine stickleback *Gasterostelus aculeatus*). The extent to which amphibian ranaviruses will naturally cross Class barriers is very poorly understood. In Great Britain, however, there was a very highly significant association between the occurrence of an outbreak of ranaviral disease of frogs in a pond and the concurrent deaths of fish.

11. FDC WORKPLAN FOR 2002 – 2003

Update *International Aquatic Animal Health Code*

- Re-draft *Code* chapter on Evaluation of Competent Authorities on the basis of the new chapter in the *International Animal Health Code (AHC)* on Evaluation of Veterinary Services
- Re-draft *Code* chapter 5.2.3 on disinfection of mollusc farms and circulate to FDC Members before next meeting
- Re-draft *Code* chapter 5.2.4. on disinfection of crustacean farms and circulate to FDC Members before next meeting
- Draft new *Code* chapter on destruction of carcasses in disease outbreaks and circulate to FDC Members before next meeting
- Draft new *Code* chapter on aquatic animal disease listing and notification

Update *Diagnostic Manual for Aquatic Animal Diseases*

- Finalise disease chapters at the January 2003 meeting for the fourth edition of the *Manual*
- Develop a new surveillance and sampling for surveillance chapter for the fourth edition *Diagnostic Manual*
- Develop a new template for disease chapters for future editions of the *Diagnostic Manual*

11.1.1.1. Meetings

- Representation at the APEC (Asia Pacific Economic Cooperation) Second Training/Workshop entitled Capacity and Awareness Building on Import Risk Analysis (IRA) for Aquatic Animals, to be held in Sinaloa, Mexico, 12–17 August 2002
- Representation at the Fourth International Symposium on Aquatic Animal Health to be held in New Orleans, USA, 2–5 September 2002
- Representation at FAO/DFO Canada/OIE Expert Consultation on Surveillance and Zonation for Responsible Movement for Live Aquatic Animals: A Framework for Reducing the Risk of Transboundary Spread of Aquatic Animal Diseases, Rome, 14–18 October 2002
- Representation at the Fifth Symposium on Diseases in Asian Aquaculture, to be held on the Gold Coast, Australia, 24–28 November 2002
- Provision of training at Phase 2 of the Training Programme on Mollusc Disease Diagnosis for Asian Countries, to be held on the Gold Coast, Australia, 2–6 December 2002
- Fish Diseases Commission meeting to be held in Paris, OIE headquarters, 6–14 January 2003

11.2. Other issues

- Evaluate the responses to the questionnaire sent to all OIE Delegates on the responsible body, legislation, policy, import statistics, etc., regarding amphibians

- Propose an expert on aquatic animal welfare issues to be nominated to the OIE Working Group on Animal Welfare

- Consider the advice from the Ad hoc Group on Risk Analysis for Aquatic Animal Health and agree tasks for the Commission for action to fulfil the recommendations of the OIE International Conference on Risk Analysis in Aquatic Animal Health, which was held in February 2000

- Propose to the President of the Regional Commission for Asia, the Far East and Oceania to include an aquatic animal health topic at the Regional Commission Conference to be held in New Caledonia in 2003

ANNEX **Part** **3**

Comments from Member States on the OIE draft diagnostic manual